Proceedings Of The First

International Conference of Medical Device Regulatory Authorities (ICMDRA)

June 2-6, 1986

World Health Organization
Pan American Health Organization
Food & Drug Administration

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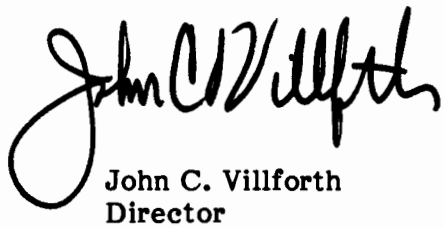
FOREWORD

The objective of the first International Conference of Medical Device Regulatory Authorities (ICMDRA) was the promotion of information exchange in the medical device and health technology area. The conference was held June 2-6, 1986, in Washington, D.C., under the sponsorship of the World Health Organization (WHO), the Pan American Health Organization (PAHO), and the U.S. Federal Food and Drug Administration (FDA). It was the intent of the sponsors to provide an opportunity for health authorities from interested countries to:

- exchange information and improve communication;
- exchange information on the availability and use of devices;
- consider future activities to promote communication and cooperation; and
- exchange information on mechanisms for the involvement of health care professionals and their associations in the appropriate use and maintenance of devices.

One hundred twenty-five participants from fifty-two countries took advantage of that opportunity. This document is the record of their communications.

These proceedings have been translated and edited in a joint effort by PAHO and FDA. Publication is undertaken by the Center for Devices and Radiological Health, FDA, as a continuation of FDA support for the ICMDRA.



John C. Villforth
Director
Center for Devices and
Radiological Health

A MESSAGE FROM DR. H. MAHLER, DIRECTOR GENERAL, WHO

New technologies have far-reaching consequences for health care, and the issues involved in the regulation of medical devices, ranging from simple articles such as thermometers to computerized axial tomography, are particularly complex. These devices represent an important investment and, at a time of rationalization of domestic resources, all countries would clearly benefit from easy access to information on their safety and efficacy, premarket evaluation, postmarket surveillance, life expectancy of equipment, and operating and replacement costs.

This International Conference of Medical Device Regulatory Authorities is a significant first step towards the promotion of exchange of information, and closer communication and cooperation among countries. The magnitude of the task before you is reflected in the agenda with time allotted for consideration of global and national perspectives. A unique opportunity is offered for representatives from both developed and developing countries to gain knowledge and experience that will enable them to formulate or adapt guidelines and criteria for a national medical device policy. Above all, I sincerely hope that it will create a favorable climate for international cooperation in this important and rapidly changing area of health technology.

INTRODUCTION

HEALTH TECHNOLOGY INNOVATION, AN INTERNATIONAL DILEMMA

Innovation in medical device technology has complicated and profoundly affected modern health care. The rapid proliferation of new and exciting medical device technologies, holding the promise of great potential health benefit, confronts health authorities with a bewildering array of choices as they evaluate health priorities and allocate scarce resources. The burden of decision is rendered more difficult by the number and complexity of the questions that must be considered and factored into the decision-making process:

- Are the new, attractive, and promising technologies safe? Are they effective?
- How will these new technologies impact on health care?
- What mechanisms will be used to track experience with new medical device technologies, during the pre- and postmarketing periods?
- What specific burdens will these technologies impose on health care delivery systems?
- Will essential technical support for complex technologies be available?

As health authorities ponder these and other difficult questions, they seek assistance and welcome constructive guidance. Many new medical devices incorporate state-of-the-art technology. They are complex, costly, and technically demanding. Their effective utilization, maintenance, and repair requires sophisticated medical and sophisticated engineering talent. The latter is often scarce or absent in developing countries. Yet these countries face great pressures for the procurement, integration, and assimilation of sophisticated medical device technology into their national health care delivery systems. National health authorities need data bases which can be used as an information resource; they need to know, and exchange information with, their counterparts in other national programs; they need to know about programs with substantial experience in health technology management, that can serve as a resource and provide technical information, assistance, and training; and they need to know whether there is international health agency support available as they face issues created by rapid innovation and pressure for massive proliferation of health technology.

Although health technology management problems may vary qualitatively, they equally confront public health officials of both developed and developing countries. They are a heavy burden on national resources. There is a clear need for expanded inter-national leadership, coordination, cooperation, and communication. International collaboration and effective information exchange may speed the introduction of new medical devices into the marketplace, and assure their effective utilization for the improvement of public health. International collaboration and information exchange may be particularly helpful to developing countries in helping them to use scarce economic resources effectively. Although approaches to risk-benefit and cost-benefit analysis may vary from country to country, standardization of evaluation criteria and systematic and timely exchange of information may contribute to improvement of health care irrespective of differences in local conditions.

The World Health Organization (WHO) occupies a unique position as the premier international public health agency. It is the natural focus for international collaboration and coordination of medical device activities. WHO has recognized the need for assistance and has established global and regional foci of significant activity in the medical device/health technology area: global - within the Division of Diagnostic,

Therapeutic, and Rehabilitative Technology, WHO, Geneva; and regional - within the WHO Regional Office for Europe, and the Pan American Health Organization. These important centers of WHO activity in the medical device/health technology area have coordinated and encouraged activities that have expanded information exchange, interaction, and collaboration among increasing numbers of member states.

International and national initiatives of note include the following:

- The Tripartite Subcommittee on Medical Devices, involving Canada, the United Kingdom and the United States, Washington, Ottawa, London, 1984-1986

- Conferencia Internacional Sobre Evolucion Tecnologica en Salud. Brazilia, November 14-18, 1983,

- Seminario Internacional Sobre Desarrollo Tecnologico en Salud. Brazilia, October, 15-20, 1984.

- Seminario Ibero-Americano de Tecnologia Medica, Madrid, 1985.

The environment of increased need, with past precedents for effective international leadership and successful international collaboration encouraged and supported by WHO, have fostered an international desire for the expansion of the leadership role of WHO in this rapidly developing and complex area of public health.

INTERNATIONAL CONFERENCE OF MEDICAL DEVICE REGULATORY AUTHORITIES (ICMDRA) - HISTORICAL NOTES

In 1983 discussions took place between Dr. B. Sankaran, Director, Division of Diagnostic, Therapeutic, and Rehabilitative Technology, World Health Organization, Geneva, and Mr. J. C. Villforth, Director of the Food and Drug Administration Center for Devices and Radiological Health (CDRH). These discussions examined problems facing public health authorities responsible for the management of medical device programs, the need for international cooperation and information exchange, and the need for international leadership to provide assistance, information, and a forum for international discussion of problems created by the rapid innovation and proliferation of medical device technologies.

The WHO/CDRH discussions were successful, and on March 5, 1984, Dr. Sankaran agreed, in a meeting with Dr. M. L. Shore (CDRH), held in Geneva, to consider the formal proposal of an International Conference on Medical Devices to be cosponsored by WHO and FDA/CDRH. On April 2, 1984, Mr. Villforth formally proposed, in a letter to Dr. Sankaran, the cosponsorship by WHO and CDRH/FDA of an International Conference on Medical Devices.

A follow-up meeting took place at CDRH, Rockville, on April 12, 1984. This was attended by representatives of WHO/HQ, the Pan American Health Organization(PAHO) and CDRH/FDA. At this meeting it was provisionally decided that an international conference be held in Washington. PAHO provisionally offered to make its facilities available for the proposed Conference. It was suggested that, in addition to WHO/HQ and PAHO, the European Office of WHO be involved in the planning and implementation of the proposed Conference. The possibility of shared funding among the sponsoring organizations was discussed.

An International Steering Committee was formed to guide activities related to the implementation of the International Conference. The Steering Committee met several times in Washington and Geneva, and was intimately involved in the development of the agenda for the Conference and the selection of experts to address and serve the Conference in various capacities, including Chairs and Rapporteurs.

The World Health Organization played a vital role in the planning and implementation of this important effort. It was envisioned that this may in fact be the first of a number of Conferences that may take place in the future under similar auspices, and that may provide an important international forum for exchange of information and for cooperation, in the interest of improved international public health.

Identified areas that could benefit from expanded international dialogue included:

1. evaluation of scientific criteria for determining the safety and effectiveness of medical devices;

2. evaluation of scientific criteria for determining the acceptability of evidence used to establish the safety and effectiveness of medical devices;

3. evaluation of protocols for post-marketing surveillance of new medical devices and technologies, and for the examination of approaches to alert health authorities should foreseen or unforseen adverse reactions occur;

4. examination of approaches for evaluating the health impact of new medical devices and technologies;

5. examination of criteria for reuse of medical devices;

6. identification of educational and training needs for proper use and avoidance of overuse of medical devices;

7. evaluation of approaches that promote technology transfer from technologically advanced countries to less developed countries; and

8. examination of approaches and implementation of mechanisms for effective and timely international information transfer.

The first International Conference of Medical Device Regulatory Authorities is a global manifestation of the international leadership of WHO in the complex health care technology area.

The International Conference of Medical Device Regulatory Authorities, cosponsored by the World Health Organization, the Pan American Health Organization, and the Food and Drug Administration was held in Washington, D.C., June 2-6, 1986.

ICMDRA PROCEEDINGS - ORGANIZATION

The proceedings which follow include the collection of the presented papers and reports of the discussions in committee and in plenary session (Parts I, II, and III), and three appendices.

PREFACE - Statement from the Director General of the World Health Organization.

INTRODUCTION - Historical setting in which the ICMDRA evolved with the current sponsorship, international involvement and international support; description of the organization of the proceedings; the list of sponsors and sources of financial and logistic support for the Conference, and a statement of acknowledgement.

PART I. Objectives of the Conference - provides the charge to the Conference. It includes:

A. Statements of substance and welcome from the Director of the Pan American Health Organization, and the Commissioner of the Food and Drug Administration

B. WHO and FDA perspectives on medical devices, presented by the by the two Co-Chairmen of ICMDRA

PART II. Technical Presentations - contains the papers presented during the course of the Conference in the following order:

A. Global Overview of Medical Devices: Problems, Issues, and Trends - which contains the presentations made during Session II

B. Round Table Review of Problems, Issues, and Trends - contains the report of discussions by the four groups during Session III

C. Public Health Management of Medical Devices - including the papers presented during Session IV

E. Medical Devices and Government Policy - including the presentations made in Session V

F. Information Exchange - including the presentations made during Session VI

D. Public Health Management of Medical Devices: The FDA Experience - containing the presentations made during Session VIII

PART III. Analysis and Conclusions:

A. Reports of the Working Groups of the Conference presented in Session IX

B. Summary of the general discussion following Working Group reports in Session IX

C. Summary Points of the Conference, presented in Session IX by the Conference Co-Chairmen

APPENDICES

A. List of Participants

B. Agenda of the Conference

C. Alphabetic Index of Presentations by Authors

SPONSORS AND SUPPORTERS OF ICMDRA

Although the original and primary sponsors of ICMDRA were the World Health Organization, the Pan American Health Organization, and the Food and Drug Administration, this conference has had many de facto sponsors. The support of these sponsors was indispensable and is hereby acknowledged.

The Conference received financial and logistic support from:

The World Health Organization
The Pan American Health Organization
The Food and Drug Administration
The Environmental Health Directorate, Health and Welfare of Canada
The W.H.O. Regional Office for Europe
The W.H.O. Regional Office for Africa
The W.H.O. Regional Office for the Eastern Mediterranean
The W.H.O. Regional Office for South East Asia
The W.H.O. Regional Office for the Western Pacific, and
The Ministries of Health of the Members States of the W.H.O.

ACKNOWLEDGEMENT

The conference owes a special debt of gratitude to Dr. B. Sankaran and Mr. J. C. Villforth. Their vision, energy, and persistence made this conference possible.

This conference is indebted for the involvement, encouragement, and the enthusiastic moral and financial support provided by Dr. H. Mahler, Director General of WHO; Dr. F. Young, Commissioner of FDA; and Dr. C. Guerra de Macedo, Director of the Pan American Health Organization.

Planning for this Conference was effected through the International Steering Committee whose membership included: Mr. J. C. Villforth, Chairman; Dr. M. L. Shore, Executive Secretary; Dr. A. K. Das Gupta; Dr. G. Coe; Mr. G. Higson; Dr. R. Knauss; Dr. S. L. Nightingale; Dr. J. Pena-Mohr; Mr. R. Rogers; Dr. B. Sankaran; Dr. J. Vang; and Dr. C. Vieira.

Last and most important, the conference owes its success to the commitment and hard work of the Chairs, Co-chairs, Rapporteurs, Speakers, and Participants of Plenary Sessions, Round Tables, and Working Groups.

The local arrangements committee was chaired by Mrs. Bobbi Dresser, and consisted of Dr. G. Coe, Mr. L. Gonzales, Dr. J. Pena, and Dr. M. L. Shore.

We want to express our appreciation to the support staff of PAHO: Ms. Elia Cadena, and Mrs. Betty Rodriguez, as well as the conference staff headed by Mr. Luis Gonzalez; to the support staff from the Center for Devices and Radiological Health: Mrs. Yolanda Colina, Mrs. Rena Sodie, Mrs. Lorna Wells, Mrs. Betty Kramer, Mrs. Betty Roberts, and Mrs. Joy Stanley.

The editors are particularly grateful for the help of the CDRH Editorial Staff headed by Mrs. Betty Fachine, and specifically to Mr. Maurice Herbert and Mrs. Alice H. Rohan, for their invaluable assistance in the editing, formatting, and typesetting of this proceedings.

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As regulatory authorities from developed and developing countries, we face difficult problems and challenges as we strive to manage medical device technology to obtain the greatest benefit at minimum and acceptable risk to public health. The problems we face beg for international leadership and coordination of international effort. They mandate improvement of our ability to communicate with one another. Their effective management will require increased international cooperation, collaboration, and shared resources.

The first International Conference of Medical Device Regulatory Authorities is a significant attempt to identify and open channels for effective communication and encourage international cooperation and collaboration under the leadership of the World Health Organization.

Having come this far, we face the future with optimism.

M. L. Shore and A. Solari, Editors

CONTENTS

I. OPENING SESSION

A. INTRODUCTION AND WELCOME

Dr. S. L. Nightingale presided over the Opening Session of the Conference Following his opening and welcoming remarks, Dr. Nightingale introduced the speakers of the opening session: Dr. Carlyle Guerra de Macedo, Director of PAHO; Dr. Frank E. Young, Commissioner of the Food and Drug Administration; and Dr. Balu Sankaran. Dr. Sankaran read a special message from Dr. Halfdan T. Mahler, Director General of WHO. Dr. Mahler's message is the preface of this proceedings.

CHAIRMAN'S REMARKS

S. L. Nightingale

Good Morning. I am Dr. Stuart Nightingale, Associate Commissioner for Health Affairs at FDA. One of the responsibilities of my office is the coordination of international activities. I would like to welcome each of you to the first International Conference of Medical Device Regulatory Authorities. I am delighted to see approximately 120 participants from 52 countries who have come together to exchange information on a number of important topics related to the management and regulation of medical device technology.

I was very pleased and honored to be asked to chair the opening session of this historic conference. This conference brings together, under the co-sponsorship of WHO, PAHO, and FDA, leaders in the field of medical device regulation and registration at a time when a wide variety of important issues in this field have surfaced in many countries. The agenda identifies these issues and provides the distinguished participants with numerous opportunities to discuss them, in a setting that will be conducive to open and frank discussion. This is in the spirit of the series of meetings of regulatory authorities cosponsored by WHO and individual countries in the drug and veterinary medicine area, that have become regular international events. In my brief comments this morning, there are a number of important points I want to make that may help to place this conference in perspective. These comments are in addition to Dr. Shore's excellent letter to conference participants that lists the conference objectives and the abstracts of the working groups, highlighting carefully selected discussion points.

This cosponsored WHO/PAHO-FDA conference is in the tradition of several others of this type that began at the start of this decade and have bloomed into regular (biennial) meetings co-sponsored by WHO and a rotating national host country regulatory authority. The first, the pharmaceuticals conference in 1980--the International Conference of Drug Regulatory Authorities (ICDRA)--is now a well-known and very useful group. The fourth ICDRA will be meeting in July in Tokyo. The International Consultation on Veterinary Products Registration began with technical consultations and is also now well established on a 2-year cycle of meetings.

As some of you know, FDA cohosted the first ICDRA in 1980 and the first International Technical Consultation on Veterinary Drug Registration in 1983. I participated in the planning for both of those previous meetings and, after having worked with the international steering committee for this meeting, I can safely say that no group worked harder than this one to assure a well-organized and successful meeting. It was a pleasure to work with such dedicated individuals. The membership of the

steering committee was both unique and valuable, drawing from WHO headquarters and regional offices, as well as governments.

While the International Conference of Medical Device Regulatory Authorities follows in the tradition of the earlier meetings there are some significant characteristics that make this conference, its agenda, and its participants rather unique.

First, medical device regulation or registration in many countries is not yet a reality. The very convening of this meeting, with its identification of those working in the field, or related or surrogate areas worldwide, has been a giant step towards identifying contacts and counterparts in many nations. As with the other conferences, discussions here will serve to strengthen and provide a framework and network for any future network of communications. As a parenthetical statement, some people said that the most important event in the first drug conference was the development of a list of attendees with telephone and telex numbers.

Second, in the drugs area there already was a pharmaceutical unit at WHO performing a variety of so-called normative functions. That unit served as a focus for the internationl exchange of information. More importantly, because of long traditions at the government level, the parameters of information to be exchanged were generally agreed upon among countries at that time. Because device regulation varies so widely, and because so little contact has taken place among member countries, there is a great deal that needs to be done in the early stages of preparation for any kind of broad international device communication program. In certain areas, such as technology assessment, there already is significant facilitative groundwork that has been laid.

Third, not only is governmental handling of device regulation and registration varied and complex, but issues such as use by practitioners and maintenance of equipment loom quite large, much larger than they do in areas such as drugs. This makes the need for user information and education especially critical.

I would like to note here that WHO, understanding the complexities and the importance of the issues, must be given a great deal of credit for embarking with member countries on this enterprise. Dr. Balu Sankaran personally deserves the credit for gaining the approval of WHO headquarters to proceed with this conference. Obviously, the endorsement and support of WHO and PAHO, as well as other regional offices, were essential to the convening of this conference. Indeed, I would also like to single out the support of Dr. Macedo and his staff for making this conference possible and particularly for providing us with these magnificent facilities. All are to be commended for securing such a high level of government and international organization participation and support.

The steering committee has planned a program that is focused on information exchange, a very appropriate theme for this first device conference. Toward this end, as the host country, we have made arrangements on Wednesday afternoon for conference participants to visit FDA's Center for Devices and Radiological Health offices and laboratories. This will provide an opportunity for you to meet some of our scientists and hear about our activities and approaches to device regulation. I urge all of you to take advantage of this visit and to sign up as soon as possible so that transportation arrangements can be finalized. We have also planned a Thursday evening session which will present detailed information on FDA's experience in the medical device area.

The information exchange theme should carry throughout each conference session and all participants should do their part to promote this objective.

Finally, I would like to thank the steering committee for offering me the opportunity to chair this important session which initiates the first International Conference of Medical Device Regulatory Authorities, a conference that, because of the organizations represented and the individuals present, may blaze the trail to the worldwide safe and effective use of medical devices.

IA2. THE CHALLENGE OF MEDICAL DEVICE TECHNOLOGICAL DEVELOPMENT

C. Guerra de Macedo

The presence of delegates from dozens of countries from around the world at this Conference demonstrates the importance that the challenges in technological development are acquiring in the health area. Medical devices, as one of the products of modern technology, are the focal point of the debate that begins today.

The Pan American Health Organization is very pleased to serve as a forum for this debate, which should produce collaborative actions among the countries on an international scale. On behalf of Dr. Halfdan Mahler, Director-General of the World Health Organization, and on my own behalf, I would like to welcome the delegates from the member countries.

The history of health technology development in Latin America and the Caribbean has differed substantially from that in the industrialized countries. In the latter, the decline in the incidence of communicable diseases, and in mortality therefrom, began to be felt at the beginning of this century, and with the advent of medical technology in the post-war period, infectious and parasitic diseases ceased to constitute priority health problems.

Owing to various factors of social, economic, and political nature in the developing countries, large population groups are completely or partially excluded from the benefits of health technology, such as hygiene, sanitation, nutrition, and health education; and their access to preventive, diagnostic, and therapeutic technology is seriously restricted. Growing populations, the urbanization process, and the effects of the economic crisis are aggravating this situation.

However, the bold and creative advance of technology toward new frontiers has not allowed us to stop and consider the effects that it is producing nor to anticipate the impact that its application will have in the future. Decisions to incorporate modern medical technology are accompanied by a large number of investment decisions that irreversibly commit and impose a structure on available long-term resources. If at least a part of the considerable effort being focused by industrialized countries on state-of-the-art products were being used to find solutions within the vast realm of the pressing social and health needs of the people on this planet, we could be more optimistic about the role of technology in "Third World" societies.

This criticism becomes more acute when we see that technology is not always translated into effective results; rather, it frequently introduces new risks, spurs a rise in health care costs, and, through its synergistic effect, promotes high levels of specialization. The fundamental reservation, however, becomes more clearly evident when we analyze the social distribution of benefits.

PAHO-sponsored research has begun to show a high concentration of investments in diagnostic technology, with no certainty that this provides more effective diagnostic or therapeutic benefit. In some countries, more than 95 percent of investments are centralized in the capital city, where less than 45 percent of the population lives.

Even more serious are the distortion in investments at the tertiary level and the imbalance in the sector's institutional makeup and the technical organization of systems. This means that, in most of the countries of Latin America, priority is given to intensive coverage of small parts of the population, which, because they have the highest levels of income (those who can pay), are also the groups who are least at risk.

The indiscriminate incorporation of technology is contributing to a polarization of health practice and services. While on the one hand the elite have access to hospitals with services equivalent to those in developed countries, public hospitals and services frequently lack the most essential critical supplies and are not able to modernize their technological infrastructure. The shortage of parts and deficiencies in maintenance have paralyzed most of the installations of medical equipment, reaching a level of 96 percent in extreme cases; on the average, it is more than 40 percent.

The growing foreign debt is affecting imports, which have fallen by more than 50 percent in several countries in recent years. Latin America and the Caribbean import from various countries the equivalent of nearly US$ 1.5 billion each year in medical devices. This figure represents 35 percent of the world market, which totals more than US$ 48 billion. This is already more than half the amount spent on drugs. If we add to this figure investments in physical plants and installations and locally-acquired equipment and materials, we begin to have an idea of the impact of medical devices on the health economy.

Except for Brazil, Argentina, and Mexico, the countries of this region do not have an active industry that produces medical devices. More than 400 industries in Brazil have expanded their role in the market, in contrast to a decline in industrial exports from Argentina. It is regrettable, however, that the most advanced sector of this industry does not have significant research and development activities for the products that are best suited to the health needs that are of highest priority from the social standpoint.

The governments are becoming aware that the incorporation of technology is not only an issue in the technical sphere but also a priority topic for public policy in health. This international conference, which was preceded by the Ibero-American Seminar on Sanitary Products, held in Madrid, Spain, at the end of 1985, under the auspices of the Ministry of Health, the United Nations Center for Transnational Corporations (UNCTC), the Institute of Ibero-American Cooperation (ICI), and PAHO/WHO, should serve as a forum in which to debate problems, specify technical and public policy challenges, and design concerted plans of action for the better utilization of existing technological capacity and its potential in behalf of the health of these peoples.

This is a task to be shared among countries, in which both industrialized and developing countries can cooperate; the health sector and other sectors can integrate their policies; and the public and private sectors can demonstrate the merit of innovative and collaborative associations.

The exchange of technological information can serve as the cornerstone for cooperation, beginning with the formulation and application of national technological policies and extending to international cooperation. The complexity of the challenge in this strategic area of health development requires innovation not only in the area of more effective medical devices, but also, and preferably, in the social monitoring of technology through policies that would direct and redistribute their benefits to the entire population.

The challenges that I have posed here will be supplemented, sharpened, and prioritized at this Conference through the efforts of the participants. The expectation, however, is much greater. This Conference should fulfill the mission of developing strategies for the international exchange of information that will encourage and facilitate the development of effective national health technology management policies.

This international Conference, sponsored by WHO, PAHO, and the Food and Drug Administration of the United States of America, must generate proposals for concrete action on behalf of the large population groups who still have limited access to the patrimony of health technology that has been accumulated by mankind.

I offer you my best wishes for a stimulating debate and hope that this week, besides being productive, will provide an opportunity for all of us to share in the brotherhood that unites us based on the mission of ensuring that health is within everyone's reach.

IA3. EFFECTIVE INTERNATIONAL COMMUNICATION: AN IMPORTANT KEY TO THE SUCCESSFUL MANAGEMENT OF HEALTH TECHNOLOGY

F. E. Young

It is an honor to welcome you here today. It gives me great pleasure to see distinguished colleagues with whom I have worked at other international conferences and in other fields of international health.

Nothing is more difficult and bewildering to the physician, to the public health official, and to the patient, than medical technology. As Dr. Nightingale has mentioned, I have had the privilege and responsibility of bringing complicated technologies into use in my own hospital in Rochester, New York, a hospital that served approximately 1 to 2 million people, in a complicated referral system. Developing and coordinating the combination of primary health care in the more rural hospitals, and the referral patterns of the highly urban sophisticated hospital, and ensuring that the resources were appropriately used was an overwhelming task.

I look forward to our individual and collective success in dealing with the difficult tasks that we face at this conference. Particularly important in our efforts, I believe, is the sharing of information. Just as the biomedical scientists need to attend meetings to share scientific breakthroughs, public health officials need to come together to share ideas. We must learn from each other. We all have a great deal to give, and a great deal to receive.

Our efforts, just as the efforts of our scientific colleagues, are designed to improve the status of public health. To be charged with the custodianship of that responsibility is grave. I was delighted to note that so many in the audience are physicians, and will contribute to the promotion of medical advances in the most responsible fashion.

I have had an opportunity to work with Drs. Sankaran, Coe, Pena, and Knauss, from WHO Headquarters and PAHO, as well as with people from FDA such as Drs. Nightingale and Moy, and Messrs. Harty, and Batts from his office, and most importantly, John, your fine people in the Center for Devices and Radiological Health, where the idea for this conference had its genesis.

The goal of the conference is the promotion of effective national and international communication. There are four derivative subpoints that I would like to emphasize. First and foremost, I believe that we must get together and understand each other and learn about each others' problems. I profited greatly by being present in Nairobi and working at the Essential Drugs Conference. The concept of getting to know other people, seeing problems through other people's eyes, and maintaining regular contact, is important. Second, we are in an area of information overload. We need to know what to tell each other. It is critical that we work together these few days to find out what kind of information we need to exchange. What really makes a difference? Third, we need to determine how best to communicate with each other. Each of us has a different set of cultural signals. In the last 2 years I have had to learn the culture of the Food and Drug Administration and to learn that the words that I would have used in a medical center have a slightly different meaning when they are used at FDA. I would dare to venture that each of us, in our own countries, have little twists on the same word. We need to know how best to communicate those words and in what format. Finally, we need to determine when to communicate. If there is a device that is unsafe and/or is not effective, we need to share that information. Similarly, if there is a breakthrough

in a diagnostic test, which would advance public health, as Dr. Macedo said, we need to communicate that information rapidly.

In a single unifying principle, our goal at this conference is to exchange information and lay the foundation for what will come in the future. To the degree that we learn to communicate with each other, we will judge the conference to be a success.

I hope that there will be a forthright sharing of the successes and the problems we all face in assuring that our efforts to improve public health through the use of medical devices are effective. As I said earlier there is no more bewildering point for the physician, the nurse, and the paramedical person than the appropriate use of devices. In such simple things as the anesthesiology machines, more deaths are related to improper use of the device than to failure of the device itself. So education becomes an important point to consider.

When I became Commissioner, Secretary Heckler charged me with developing an action plan for the FDA to meet the challenges of the 21st century. One of the major components of that plan was device approval and regulation by FDA. It was a fortunate coincidence that at the time Mr. Villforth was conducting an intensive Criticism Task Force effort focusing on a critical evaluation of the device approval process. We would be happy to share with you what we have done in our action plan and make copies available to you. The plan is designed to be implemented, and not stuck on a shelf. We would be happy to share our plan and receive your comments.

Medical devices are the junction not only of technology, but also of social problems in each of our nations. Improving the product approval process was one of our major goals, and you will see that emphasized, but Mr. Villforth also focused considerable attention on education. I think that education is an important effort. As we share information, it would be important to determine what other nations have done to educate physicians and patients on the appropriate use of devices.

Finally, as we work, we will experience the collective joys of new technology, its frustrations, its promise, its successes, and its failures. We must focus national effort on the use of resources in the most prudent fashion. Resources are scarce, yet this is a time of innovation of technology that is really remarkable, and demands attention. I am confident that our efforts during the next few days will be a giant step forward in the discussion of the correct and appropriate use of devices to lessen the suffering associated with illness throughout the world.

Let us communicate freely and strive vigorously and successfully so that each of us can be worthy to serve the populations of the world that we represent.

IB1. WHO PERSPECTIVE ON MEDICAL DEVICES

B. Sankaran

It gives me great pleasure to address you all on this bright Monday morning. I sincerely hope that this week's discussions will result in a solid foundation for the advancement of knowledge and information on medical devices that we can carry back to our various climes.

The World Health Organization is an international health cooperative and responds to the requirements of member countries based on decisions and resolutions adopted by its supreme governing bodies, the Executive Board and World Health Assembly.

In the field of medical devices we do not as yet have an identified program, but that does not mean that we have not been interested. As early as the first World Health Assembly, Resolution WHA 1.60 recommended setting up a bureau to give advice on:

1. the procurement of essential drugs;
2. biological products; and
3. other medical supplies.

SPECIAL CONSIDERATION BEING GIVEN IN CASE OF EMERGENCY

Since then, on a number of occasions the Organization has responded to requests from member countries by not only establishing an office of emergency relief operations, but also by strengthening the supplies department, and becoming actively involved in supplying and maintaining needed equipment in the African continent. Many other areas of the world will, I am sure, be highlighted in the regional presentations.

As you are probably aware, we have six regions in the structural management of the Organization. They are the: African region, with its headquarters in Brazzaville; American region or the Pan-American Health Organization, with its headquarters in this building in Washington, D.C.; the Eastern Mediterranean region, with its headquarters in Alexandria, Egypt; the European region, with its headquarters in Copenhagen, Denmark; the South-East Asian region in New Delhi, India; and the Western Pacific region in Manila, the Philippines.

Some of the program areas, both at headquarters and in the regions, involved in medical devices are:

1. Expanded Program on Immunization, which has critically assessed the capacity and criteria for syringes and sterilizers.

2. Health Care Technology Assessment, which has looked into the proper presentation and adaptation of technology to the needs of developing countries, particularly during the last 4 years. These activities will be detailed in the respective WHO regional office presentations.

3. Health Laboratory Technology, which is an area in which standardization of clinical chemistry, laboratory diagnostic equipment, and diagnostic reagents has been undertaken in close collaboration with the International Federation of Clinical Chemistry and the International Union of Microbiologists.

4. In the Radiation Medicine Program, the basic radiological system has been critically assessed through field studies in many collaborating centers of both developing and developed countries. In developing countries, primarily in collaboration with the International Society of Radiology, there has been an assessment of the role of new imaging techniques: computerized axial tomography, scanning ultrasound, and magnetic resonance imaging.

5. Appropriate Technology for Health, which is a global program, is collaborating with INSERM in Paris, in carefully examining the use of the insulin pump in the home management of diabetes mellitus.

6. Collaborating centers in Lyon, France, Nicosia, Cyprus, and Lome, Togo, which are training technically-qualified people to repair and maintain equipment

7. Development of a list of minimum equipment that would be necessary and desirable to keep a district hospital functioning effectively with adequate surgical, medical, obstetrical and gynecological, pediatric, anesthetic, laboratory, and radiological services.

In addition, interest in medical devices has been exhibited in the International Classification of Procedures in Medicine, in which the following have been outlined:

1. Medical diagnostic procedures,
2. Laboratory procedures,
3. Preventive procedures,
4. Surgical procedures,
5. Other therapeutic procedures,
6. Ancillary procedures, and
7. Radiology and certain other applications of physics in medicine.

As a further elaboration of this Classification, complications peculiar to certain specific procedures have been introduced in the Standard Nomenclature of Diseases and in the International Classification of Diseases. These include mechanical and other complications connected with:

1. Cardiac devices - implant and graft;
2. Other vascular devices - implant and graft;
3. Neurological system stimulation devices;
4. Genito-urinary devices;
5. Intrauterine contraceptive devices;
6. Internal orthopedic devices - implant and graft;
7. Other prosthetic devices such as for orbit of the eye; and
8. Nonabsorbable surgical materials, including sutures.

Another area in which the Organization has shown interest has been in the field of rehabilitation devices. I would be treading on the regional presentations if I tried to expand on medical device regulations in various countries, so I will leave it to the regional and country representatives who are more conversant with them.

As an orthopedic surgeon, I would like to end this presentation on a somber note. Because of financial stringency, exchange conservation, and the volume of devices imported, many countries have started manufacturing their own devices using imported or locally available stainless steel or other substitutes. With a large amount of implantable

material, such as ceramics, titanium, and ultracarbon, now becoming more readily available and with knowledge and techniques becoming more difficult to replicate and almost impossible to import, I would like to add a note of caution.

In a doctoral thesis, on corrosion of implants, based on work performed between the years 1975-76 in a country that I know well, corrosion was demonstrated in implants that required removal. Metallic implant material was found in the soft tissue near the screw head at the site of implantation, and the contribution of corrosion to the development of fatigue fractures of implants was demonstrated. Additionally, corrosion resulting from the fusion of dissimilar metals was demonstrated at the site of fusion within the implant

These are complications well known to and studied by many orthopedic surgeons throughout the world. These have been largely stemmed by intense collaboration between metalurgists, researchers, manufacturers, local authorities, and national professional organizations.

I believe that during the process of evolution of a specialty such as medical devices, it is important that national authorities rationalize and present standards based on international experience, expertise, and published literature. The formulation of standards alone does not lend itself to universal acceptability. Ways and means of implementing them should be carefully studied so that the user does not suffer. The necessity for a clearinghouse, a testing laboratory, a standards reference laboratory, a reporting system, and the institution of good manufacturing practices has to be taken into account. This is what we hope to be doing during the next 5 days. If at the end of this time we are not wiser, we shall certainly be better informed.

IB2. FDA PERSPECTIVE ON MEDICAL DEVICES

J. C. Villforth

As public health officials, we often deal with national and international public health problems, and are frequently struck by the realization that we live in a very small world.

In May 1986, that realization was reinforced when we were exposed to the difficult international situation stemming from the unfortunate nuclear accident in the Ukraine. The accident confronted us with many complications. We were concerned for the health and safety of the citizens of our own countries, we were concerned for the population in the Ukraine, and we were apprehensive about the heavy international news media coverage of this event. For the first 30 days following the incident, there were daily articles and reports in the American news media and in news media around the world, covering some aspect of the incident and the attempts to bring it under control.

Shortly after the incident, it became evident that the direct radiation from the cloud of radioactive material, as it passed over the northern hemisphere, was not the only source of possible radiation exposure. Concern developed over the potential radioactivity of foodstuffs that might be imported from contaminated areas. The lack of international safety standards which could be used with assurance became painfully evident. The permissible radiation levels of one country might not necessarily be consistent with those of another country. This event reinforced the need for international collaboration and information exchange. An acute need existed for a mechanism to facilitate the prompt, collective, and competent management of incidents .

It was fortunate that the World Health Organization, primarily as a result of the foresight of the World Health Assembly, had established radiological communication leadership at the European Office of WHO in Copenhagen. Without the radiation measurements that you and many of your colleagues made, without the transmission of this data to Copenhagen, and without the ability of the WHO staff in Copenhagen to manage, collate, and re-disseminate the combined information to the rest of the world, the collective ability to assess the magnitude of the problem and take appropriate action would have been seriously impaired.

This incident illuminated the need for: international public health collaboration, rapid data collection, and dissemination of information, and consistent international standards.

The need was also evident to assure access, by the public, to information of high quality and accuracy, to avoid misunderstanding and counterproductive public pressure. In the Ukranian incident, the media was responsible in its reporting, and public reaction was mature.

There is a rough analogy in the medical device area. I do not mean to imply that the magnitude, the seriousness, and the newspaper notoriety of the Ukranian reactor incident and that which we face in the medical device area are of equal dimension. However, there is no question that problems associated with medical devices, whether they involve defective anesthesia equipment, defective heart valves, or problems with intrauterine devices, have given much notoriety to medical devices.

Information available from our medical device reporting networks, in operation slightly more than a year, suggest that, in the United States, there might be approximately 500 deaths per year out of approximately 5000 serious injuries attributed to the use of medical devices. In our country this generates not only public concern, but also congressional pressure to investigate, explore, and find ways of improving the regulations to assure safety and effectiveness of medical devices.

The issue of national standards, international standards, and international normalization becomes important when export and import of medical devices are considered. A mechanism is required to assure that our respective countries will neither export nor import defective products to or from other countries.

Incidentally, the medical device law in the United States prohibits the export of devices that do not meet requirements for entry into interstate commerce in the United States. Our Center for Devices and Radiological Health (CDRH), FDA, enforces this law. We do not allow the export of non-approved devices unless the recipient country, aware of the deficiency, specifically requests us to allow such export to their country.

There is a need to establish mechanisms to assure that information on medical device problems is rapidly disseminated to all users throughout the world. International cooperation, coordination, and information exchange in the medical device area is just as important as it was in the case of the recent nuclear power plant accident.

Medical devices, unlike drugs or foods, have some peculiarities of their own. The definition of medical devices varies from country to country. We think of the implantable prosthetic devices that Dr. Sankaran described as a typical example of the medical device. In fact the spectrum of medical devices is enormous. It spans the range from the most complex diagnostic and therapeutic apparatus involving sophisticated high technology, complex electronics, computer technology, exotic chemistries and materials, to the simplest mechanical devices and laboratory and diagnostic apparatus.

In vitro diagnostics are of particular interest as medical devices. They are undergoing rapid development and are widely used in homes. Electronics, microprocessors, computers, and software complicate the picture, with issues that range from reliability, safety and effectiveness, to the fundamental definition of a medical device.

The disciplines involved in the field of medical devices include: medicine, biology, epidemiology, computer science and all the elements of physics and engineering, as well as such hybrid fields as biomaterials science, biotoxicology, and biotechnology, and biocompatibility. Dr. Sankaran pointed out the importance of certain aspects of metallurgy. Ceramics are becoming popular and find increasing use in medical devices. The ceramic engineer plays an increasing role as does the polymer chemist and the polymer engineer in the development of medical device technologies. Biomaterials are also being incorporated into devices. We are increasingly concerned with the impact of bioenvironments on the strength of metals and other materials, their effect on ceramics, and their effect on polymers. Underlying these are the crucial issues of biocompatibility and biotoxicology. All of these complications demand a high degree of sophistication and scientific competence on the part of the public health regulator. Only a sophisticated multidisciplinary team approach can deal with this level of intricacy.

Another complexity of medical devices is related to their accelerating rate of technological development and technology diffusion. This places a very heavy burden on regulatory authorities struggling to keep abreast of developments in medical device

technology. The shock-wave lithotripter, which a year ago did not exist in this country, is now widely accepted as a means of destroying certain types of kidney stones without the need for surgery. Slightly more than a year ago the cochlear implant was first approved in this country. It is now having a big impact on those who are totally deaf, providing a sensation that assists them in lip-reading. Intraocular lenses have been around for some time and are increasingly accepted. The new neodynium-YAG laser has replaced conventional surgery for lens replacement capsulotomy. Newer technologies involving the excimer laser are on the horizon, providing an additional mechanism of photochemical action for use in delicate surgery on the eye and other tissues. Fiber optics as a means of visualizing internal body structures and collecting important diagnostic information may affect future in vitro diagnostic product technologies. Artificial intelligence will help the clinician in the diagnosis of disease and the determination of the course of the patients' well-being.

The complexity and rapidly changing field of medical devices will provide increased pressure on us as public health officials to stay on top of the technology and to make maximum use of the limited resources that we have.

In our Center we celebrated the 10th Anniversary of the Medical Device Amendments at of the end of last month. The Medical Device Amendments were a milestone for the Food and Drug Administration because they launched our public health regulatory program in medical devices. These amendments provided for a classification of all medical devices into Class I, Class II, and Class III, based on the amount of risk they posed, from lowest to highest. The law provided a mechanism for categorizing new products and products that were substantially equivalent to preamendment devices.

The amendments required manufacturers to test or investigate the products that were not substantially equivalent to ones on the market in 1976, when the Medical Device Amendments came into being. Magnetic resonance imaging devices, surgical YAG lasers, lithotripters, and cochlear implants are examples of post-1976 new technologies. The Medical Device Amendments provided for the orderly engineering as well as clinical testing of these products so that their safety and effectiveness could be evaluated. These findings would then serve as the basis for Agency decision as to whether they could be put into commercial distribution in this country.

The manufacturers, under the Medical Device Amendments, were required to comply with certain requirements, such as registration and labeling of their products. They were subjected to inspections of their facilities to assure that they complied with the requirements of Good Manufacturing Practices. Provisions were made for recalls and followup inspections for those products and facilities that did not comply with the medical device regulations.

As part of our efforts to regulate medical devices, CDRH maintains data bases, such as the medical device reporting requirements (MDR), which allow us to stay abreast of information on deaths and serious injuries related to medical device use, and malfunctions of medical devices that have a potential of causing death or serious injury. This information helps us set priorities for action on medical devices. It has become clear to us, with the spectrum of devices, and their complexity, that we must use some system to prioritize our programmatic and regulatory actions. We are presently setting up a priority mechanism that will draw from our experience and, we would hope, the collective international experience.

An important provision of the Medical Device Amendments requires that some products falling into certain categories have performance standards. Although we have

done very little to establish mandatory performance standards within FDA for medical devices, we have worked very aggressively with the voluntary standards community and have participated in more than 200 standard-setting functions, both national and international. Still, we must do more of this to be able to extend our resources. We must collaborate more with our colleagues around the world in the international standards-setting scene.

Separate from the specific mandates of the law, as Dr. Young pointed out, there is the element of educational activity. Apart from the problems of the mechanical failure of a device per se, there are failures that may be the result of user error. Whether the user be the clinician, the technologist, or the nurse anesthetist in the illustration he used, or whether the user be the consumer for some home use type of diagnostic product or a tampon, we must develop educational programs to inform and educate the professional user and the public about these kinds of problems to improve the situation. We must work with the clinicians, we must work with the consumers, and we must work with the technologists to bring this about. We realize that we cannot do it at the Federal level by ourselves; we must start to develop ideas and concepts that can be multiplied and expanded by professional organizations, consumer groups, and international organizations to extend the limited resources that we have available to get the job done. The multiplier effect will supplement our resources and amplify our activities in the U.S. and, we hope, throughout the world.

It is very appropriate that the emphasis of this conference be on international information exchange because the very same concepts of networking of information and exchange of information that we are trying to develop in our own country are applicable around the world. We need your help and ideas, we need to do this collectively. We hope that optimized information exchange will help us to achieve the maximum use of resources at the minimum cost to industry and at maximum public health benefit for the people who pay for our services.

We look forward to collaboration with our friends in the World Health Organization and the Pan American Health Organization and with all of you in the international public health community. We look forward with optimism to the increased international collaboration, cooperation, and information exchange that will hopefully be promoted by this conference.

II. TECHNICAL PRESENTATIONS

A1. GLOBAL OVERVIEW ON MEDICAL DEVICES PROBLEMS, ISSUES, AND TRENDS

IIA1. INTRODUCTION

After the Opening Session and the presentations on Perspectives on Medical Devices by the two Co-Chairmen of the Conference, Session II began. Its objective was the presentation of a global overview of problems, issues, and trends related to medical devices in six geographical areas: Africa, Europe, the Middle East, America, the Far East, and the Western Pacific.

Session II was chaired by Dr. R. Caram, who, in his opening remarks, pointed out the objectives of the overview and the opportunity it provided to begin effective exchange of information on the central topic of the Conference. Following his introductory remarks, Dr. Caram introduced each of the speakers.

IIA2. REPORT FROM AFRICA

P. Msaki

INTRODUCTION

Production of medical equipment has, up to now, been designed to meet the need of industrialized countries with sound economies. Thus, the existing manufacturing practices are more or less geared to meet the requirements of a rapidly changing technology taking place in these countries without taking into consideration the hardships these practices are causing to less developed countries that are among the best buyers. The following presents some of the difficulties that the national health services in developing countries encounter in the procurement of medical equipment.

MAJOR PROBLEMS

As a result of advances in technology, medical device manufacturers now produce equipment that is more sophisticated and costly. Some of the features added to new equipment, to satisfy the demand of advanced countries, are neither essential or desirable for developing countries in Africa. Thus, in terms of cost and benefit, developing countries pay higher prices than necessary for modern equipment; that is not utilized to full capacity. The necessity of simplicity in medical devices for developing countries, which have limitations in times of skilled manpower and maintenance facilities, should not be equated with a desire for low-quality equipment.

Repairs, by replacement, of equipment components that fail can be complicated. Because most repair components in developing countries are ordered from industrialized countries as the need for them arises, the time interval between order and delivery becomes a significant issue. This interval is unimportant to advanced countries because it is relatively short and also because in these countries there may be several similar pieces of equipment in one single department. In the developing countries of Africa, because of long distances between suppliers and consumers, shortage of foreign exchange, and the formalities that must be satisfied before the limited foreign exchange which is available can be used, the delivery of spares takes a relatively long time, ranging from months to years. The long waiting period inevitably leads to heavy losses of essential and scarce public services, which developing countries cannot afford. For the sake of comparison, in terms of cost and benefit, this partial utilization of medical equipment makes medical facilities more expensive for developing than for advanced countries.

Although the significance of some medical equipment diminishes with time, and at some stage old equipment is completely replaced by newer forms of equipment, the need in developing nations for simple and inexpensive equipment partially contributes to the great desire they express in prolonging the use of old equipment. However, this desire is frustrated because production of spare components is generally stopped when the equipment ceases to be manufactured in advanced countries.

The price of some equipment can be prohibitive to most developing countries. As a result, procurement of expensive equipment is mostly through loans from the World Bank or from rich countries. Some of these loans, however, are sometimes tied to very unfavorable ("take or leave it") conditions. For example, in the past, loans have been given on condition that a given country purchase specific items from a given firm. It takes the country only a short time to realize that the loan was, in fact, spent on the wrong equipment. There are various factors that contribute to these expensive mistakes, including the lack of evaluation facilities. The amount of medical equipment lying idle in developing countries is not only shocking, but it is also undeniable evidence of the number of mistakes which have been made in medical device procurement.

Medical device regulations in Africa exist in a few countries, such as Algeria, Burundi, Burkina Faso, Cape Verde, Gabon, Kenya, Nigeria, and Zambia. The advantages these countries have over those with no medical device regulations are marginal. This is mainly because the existing medical equipment evaluation facilities needed to implement the regulations are inadequate (in some cases non-existent) as a result of shortage of skilled persons to carry out the task and lack of information needed for evaluation. For example advertisements of medical equipment are rare in a number of countries in Africa where procurement of equipment is done by the Ministry of Health with the help of foreign experts. The disadvantages of purchase of medical equipment with limited information and using foreign experts are numerous. Developing countries may be vulnerable to commercial tricks and propaganda used by equipment vendors from industrialized countries. Foreign experts, on a number of occasions, have given flawed evaluations in favor of countries of origin or specific firms based on personal interest. It is, therefore, not surprising that for a long time, Africa has been the unsuspecting recipient of substandard equipment sold to satisfy the profit motive of multinational companies. This may partly account for the large number of idle pieces of equipment found in Africa and for the familiar expression "Africa is a dumping ground."

We have now reached a point of choice between acquiring medical equipment through loans or the termination of essential medical services. Judging from past experiences, the latter alternative is becoming more attractive with each passing day. A number of organizations such as WHO, IAEA, SIDA, DANIDA, FINIDA, etc. are quite aware of the desperate situations currently existing in the developing countries of Africa. These organizations and some rich countries have provided valuable assistance, some in the form of donated medical equipment and training facilities in the medical field. In a number of cases, donations in the form of reconditioned equipment have been useful. The department of radiotherapy in Kenya, for instance, was initiated by the gift of an old cobalt unit donated by Sweden in the late 1960s. Through the effort of Professor Walstam, who ensures quick delivery of spare parts for repair from Sweden, the equipment has been maintained in good working condition for more than 15 years, with a current workload of more than 40 patients per day. The neighboring countries with no radiotherapy facilities have also benefited from this valuable donation.

CONCLUSION

We cannot do good work in developing countries without good equipment. Simple equipment appropriate for intended functions will be appreciated in Africa where shortages of skilled manpower and funds are critical. We need more information to be able to assess medical equipment, and the opportunity to have a say on the type of equipment we want. We need more help from international health organizations. We request that these organizations consider incorporating some solutions to the problems outlined above into existing assistance programs for developing countries.

IIA3. REPORT FROM EUROPE

J. Vang

Europe is a region which stretches from the arctic Greenland to Israel and the Middle East, from the Islands of the Azores in the Atlantic to the Chinese border in the East: 33 countries, heterogeneous in climate and population, in economy and cultural traditions, with different health care systems, different ways of dealing with health care technology, and with different outlooks as producers, exporters, and importers of health care devices.

The concern of governments in Europe may be viewed from two different perspectives: one, the protection and promotion of national health device industries, especially export-oriented industries; the other, protection of the public by not accepting unsafe and inefficacious health devices and by acting against inappropriate use of accepted devices.

Of course, the relative emphasis on these two objectives will vary among countries, depending upon whether they are producers and exporters or merely importers of health care devices. The realization of the objectives will to a large extent depend upon regulatory efforts, and the degree to which these are sensible and appropriate.

There is today an increase in regulatory activity in Europe in the field of medical devices. In fact, if you ask industry, it will tell you that it is flooded by an avalanche of regulations or quasi-regulatory activity. Such a complaint is, however, not quite fair because the European dilemma results more from segmentation and sequestration due to different political, economical, historical and cultural traditions, than from over-regulation.

Going from east to west in Europe, you will find nationalized/socialized health care systems working towards nationalized/socialized industries using standards and inspections to control safety and efficacy of health care devices. Within these systems you also may find varying degrees of centralization and decentralization in the decision process. In the Scandinavian countries, the United Kingdom, Ireland, and Italy, you will find socialized/nationalized health care systems working towards a device marketplace, again with varying degrees of centralization of the approval and buying processes. This gives decentralized buyers different options among approved alternatives—but often with a national monopoly of the approval process itself. You will find countries such as the Netherlands, Belgium, Luxembourg, and France with an insurance-driven health care system and a liberal device market, and countries such as the Federal Republic of Germany, Greece, and Turkey with strong market forces in play, not only within the device trade but also within the health service systems. Thus, the interplay between buyers/users and sellers/producers of health care devices in Europe is quite varied, often complex, sometimes entangled and obscure.

The market point of view is a major concern in Western European countries. These countries, small as they are, have considerable variations in regulations according to economic and cultural traditions. Therefore, they have trade barriers and sequestration of the market, which from an industrial/commercial point of view, reduces their ability to compete with the United States and the Asian industry. The EEC which we shall hear about later, is 12 countries' answer to that problem, but demolishing trade barriers does not comply with national diversity in health device regulations conditioned by national circumstances and policies, so harmonization of regulations has become the key word in

that part of Europe. But until this happens, there will be a conflict of interest between ministries of health and those of industry and commerce.

The regulatory dilemma of devices in Europe is not derived from conflict between industry/commerce and health care, but is rather the classical conflict between the common good and that of the individual.

Society wishes to protect the innovator and the first investor both in order to protect industrial development and to encourage the development of better health technologies in the interests of health and improved treatment of diseases. Again society does also wish to protect the imitator to ensure competition and competitive pricing in the interest of export and in the interest of the user and the patient. These two objectives, both beneficial to the public, are, however, mutually conflicting, and regulation will have to balance interests.

Protection of the individual patient is a different issue. Any patient exposed to medical devices should feel confident that the technology is safe and efficacious. This must be dealt with both at the level of the producer and the level of the user. Some countries, as mentioned, do this through standards and inspection, others through good manufacturing practice (GMP), premarketing approval, and postmarketing surveillance. The producers' interests in regulations through GMP or premarketing approval increase considerably if producer liability also is involved. In the field of medical devices, however, most accidents or incidents are related to inappropriate use rather than to a production error. User liability is therefore a more visible field although producer liability plays a central role in some instances, as for example the discussion of the reuse of disposables. The appropriate use of devices, although somewhat related to design, is mainly dependent on user education and probably even more on the quality of the clinical decision process. This however is not the topic of this discussion.

The liability issue is to a certain degree linked to the question of insurance. Traditionally we insure ourselves against events which we do not expect to happen, but if they do (say your house burns down), we are at least able to foresee the cost of the event. In the use of medical technology, unlikely risks have been turned into predictable risks, and the forseeable cost of the risk has become incalculable and unpredictable. No one with a limited budget and profit interest would undertake that kind of insurance. The problem of the "no-fault" event, in which neither the producer nor the user can be held responsible, calls for a "deep pocket" from which funds can be retrieved to compensate those who suffer from the event. In Europe, Sweden has solved this problem through a national "patient insurance" system that, as a spin-off, also acts as an excellent postmarket surveillance system for safety and effectiveness.

National products and imports may not necessarily be treated the same way within countries and among different countries because of different vested interests. Besides laws, standards and regulations, GMP's, etc., there are trade barriers, economic and regulatory, all of which influence the options and availability of devices in a given country. So, as mentioned before, segmentation characterizes Europe.

What is then the role of the World Health Organization European program? The last thing we need in Europe is another regulatory agency, and the thing we want the least is a new battlefield. We believe that the producers of health devices and the producers of health care services, independent of economic systems, are partners in the struggle towards better health and disease prevention, and treatment. We may sometimes differ in views about the size of the market, but never in the objectives: safe and efficacious equipment that can be used effectively. WHO has many tasks to perform together with

the member states, their health ministries, their research institutes, their health industries and their health services.

Some of the issues in which the World Health Organization Regional Office for Europe tries to be particularly helpful are listed below.

WHO EUROPEAN PROGRAM
(DEVICES)

Objectives: Sharing of Knowledge
Transfer of Information
Data Collection
Clearinghouse Function

Issues: Nomenclature
Computer Coding
International Dictionary
Center and Clearinghouse for Information
Classification
Harmonization

These issues deal with the sharing of knowledge, transfer of information, data collection, and the clearinghouse function. As instances of more specific problems, I may mention that we have no common nomenclature, we need a common computer-coding and an international dictionary, we need a center and clearinghouse for information, we need to deal with classification issues, harmonization to test protocols, and comparison of products and performance.

The World Health Organization Regional Office for Europe is now in the process of establishing access to data bases as well as creating new ones. The information service, to be named "CITECH" (Centre for Information on Technology for Health) is envisaged to function in collaboration with ECRI, the International Working Group for Medical Device Testing, and European Hospital Institutes. It will hopefully be operational during 1987. An international dictionary also is under development and several projects of collaboration have been initiated. We hope to reach out to producers of health care devices in a fruitful collaboration in this international undertaking, which we feel is of immense importance, not only for the appropriate use of appropriate technologies and the establishment of balance and harmony between care and technology, but also as a part of the efforts towards health for all.

IIA4. REPORT FROM THE EASTERN MEDITERRANEAN

M. L. Swicord

The Eastern Mediterranean Region (EMRO) consists of 22 widely diverse member states that are diverse both economically and culturally. Table 1 presents economic data reported by the World Bank for five member states within the region, with comparative data from the United States. It will be noted that there are marked differences in gross national product per capita. Also listed is the percentage of GNP expended on public health. This figure highlights the disparity of actual funds spent per capita. Of the 22 member states, records in our possession indicate that only three, the Syrian Arab Republic, Tunisia, and Morocco, have addressed issues relating to medical devices through legislation.

Table 1. Health Expenditure in Representative EMRO Countries
World Bank Report 1982 and 1983

Country	Percent of GNP of Public Health Expenditure	GNP per Capita (1981)
Saudi Arabia	2.1	$ 12,600
Kuwait	1.6	$ 20,900
Egypt	2.2	$ 650
Iran	1.5	$ 2,160 (1977)
Iraq	0.6	$ 1,550
U.S.A.	3.3	$ 12,820

IMPORTATION AND PRODUCTION OF MODERN EQUIPMENT

The majority of medical equipment utilized in various countries within the region is imported, although some production of a limited number of products does take place. For example, the five countries listed in Table 1 import more than 90 per cent of their medical equipment, and the region imports in excess of $150 million worth of medical equipment from one major exporting country. Saudi Arabia imports more than 60 percent of that total, which includes 48 different classes of products ranging from first aid kits to x-ray equipment.

Prospects for local production vary. Currently, local production is negligible in most countries in the region where domestic markets are comparatively small, and scarce labor resources are committed to other types of manufacturing operations. Egypt may be an exception where there are plans to locally design and assemble more sophisticated medical equipment. To date, however, production has been limited to supplies of non-chemical consumables and custom-built items such as prostheses used in rehabilitation.

Despite the fact that local production of medical equipment is limited, there is a strongly felt need for it in countries within the region. The major reason for local involvement would be to produce simpler and cheaper equipment that may be more

appropriate to local needs, particularly because many users in the region feel that imported equipment is often over-engineered.

APPROPRIATE TECHNOLOGY

Simple equipment can be rendered useless when local needs and customs are not considered in technology transfer. For example, in Iraq, scissors imported from the West for use in cutting plasters were found to be useless because the plaster casts used in Iraqi hospitals were harder than those used in Europe. Purchase decisions are often made by people who do not have the necessary knowledge of local conditions.

In order to be economical and effective, technology must be:

1. scientifically sound,
2. acceptable by the population, and
3. affordable.

Dr. A. Gaber, a member of the Faculty of Engineering at Cairo University, has furnished some detailed examples of successful and less successful transfers of medical equipment and systems to Egypt, a successful example being the Diagnostic Ultrasound Center, established at Cairo University Hospital with the assistance of the U.S. National Science Foundation and the Alliance for Engineering in Medicine and Biology. This project, operating since 1976, was established as a nucleus for the development and diffusion of such services. Many factors contributed towards the success of this transfer:

1. Excellent cooperation between "donors" and the "receiver."

2. Sound planning at all stages, e.g., equipment specification, procurement, relations with manufacturers, and supporting services.

3. Adequate training of sufficient numbers of all types of staff: medical, operating, and maintenance.

4. Good routine management, with regular coordinating meetings between all involved groups, progress evaluation, and education workshops.

5. Adequate budgetary allocations, covering staff incentives and technical support needed.

6. Ample provision of maintenance facilities and commitment to this work.

An example of a relatively unsuccessful transfer of medical technology to Egypt concerns Neonatal Intensive Care Centres. These were established in eight Egyptian university hospitals with assistance from the U.S. Department of Health, Education, and Welfare (now the Department of Health and Human Services). All three units opened have experienced great difficulties at various stages of development. In one hospital none of the more than 20 incubators functioned satisfactorily. Reasons cited were:

1. Poor initial specification of equipment to be procured. Many incubators were supplied with the wrong main voltage characteristics.

2. Faulty installation and commissioning by the manufacturers' agents. In many cases the operating temperatures of the incubators could not be set above 90 °F.

3. Inadequate provisions for preventive maintenance or repairs. No available in-house staff had the technical competence for this job, and there was inadequate distribution of spare parts ordered with the initial purchase. No technical service manuals were provided.

4. Lack of any engineering "voice" in the management of the technology.

5. Inadequate training of nurses. Only the senior staff had received useful training, and they were not involved in the day-to-day control and operation of equipment.

6. Poor relationships between hospitals, manufacturers, and their agents.

These examples serve to demonstrate that effective medical equipment and systems require sound planning and initial specification, adequate training, and good day-to-day management and maintenance.

EXAMPLE OF WHO-SPONSORED TECHNOLOGY ADVANCEMENT

WHO has played a role in appropriate technology development; the Basic Radiological System is an example.

Radiological services, especially diagnostic radiology, are certainly among the least developed branches of health care systems in the Region. Lack of equipment and shortage of trained staff are among the crucial handicaps impeding progress. Such constraints are mainly derived from economic factors, such as the high cost involved in providing and maintaining sophisticated equipment, assuming that proper maintenance facilities are available, which is often not the case.

Having recognized these facts, the meeting of Subcommittee A of the 31st Session of the Regional Committee for the Eastern Mediterranean adopted a resolution (EM/RC31A/R.10) recommending the use of the Basic Radiological System (BRS) concept for providing better coverage of populations at all levels of health delivery systems. This system was developed under WHO sponsorship. It is a simplified machine that is easy to operate and repair. Simplification of design has increased its reliability and reduced its cost, making it more appropriate for use in developing countries.

The Regional Office has collaborated with member states in promoting the establishment of BRS within the framework of health care systems and a number of machines haave been installed throughout the region.

To facilitate the use of BRS machines by general practitioners and radiographers, there has been wide distribution of three manuals:

1. operation of the BRS machines,
2. interpretation of images, and
3. darkroom technique.

These manuals are also being translated into Arabic.

SERVICING AND MAINTENANCE

The problem most frequently discussed in connection with transfer of medical equipment and systems is not the appropriateness of the technology, but its servicing and maintenance. This is widely recognized as one of the most important problems facing health programs everywhere. Servicing and maintenance are considered crucial in the analysis of technology absorption, because 20 to 60 percent of existing medical equipment in the region may be out of order at any given time.

With the very rapid expansion in recent years of the health services of member states, rich and poor alike, there has been a large accumulation of all forms of equipment used. This equipment, purchased from widely different sources and, in itself, of a wide range of sophistication and complexity, must be properly repaired and maintained. Yet in almost all countries there is little tradition of providing either the financial or human resources necessary for this work. As a result, medical equipment that is even minimally damaged may be out of service for extended periods, or even permanently.

EMRO believes that the major reasons for these problems are:

1. lack of understanding of the need to plan and budget for maintenance and repair;

2. inadequate administrative mechanisms to ensure prompt and regular delivery of spare parts and expendable supplies;

3. failure of maintenance and repair services to reach peripheral areas; and

4. competition between the various suppliers and agencies that sometimes sell equipment without guarantee of spares or service.

For these reasons, maintenance and repair of medical equipment is one of the priority areas in EMRO's collaborative program with member states. The regional office is assisting member states in all aspects of wise purchase and use of capital equipment. Thus, in addition to providing advice on purchase, the Office is strongly supporting countries' efforts to become self-sufficient in maintenance and repair of medical and hospital equipment. For example, activities in this area have been focused on:

1. Developing the Regional Training Centre for Maintenance and Repair of Medical Equipment at the Higher Technical Institute, Nicosia, Cyprus,and a second training center at the Technical Health Institute, Damascus.

2. Providing services of consultant engineers to organize national workshops and national programs on the maintenance and repair of medical equipment.

3. Collaborating with national institutions that are capable of undertaking training in the field of maintenance and repair of medical equipment.

Local national efforts have also addressed this problem. For example, the Department of Medical Equipment at Abbassia, Cairo, was established by the Ministry of Health with assistance from the Great Britain Overseas Development Administration and the Department of Clinical Physics and Bioengineering in Glasgow. The latter project, successfully progressing since 1978, was designed primarily to provide manpower development facilities and to build a service organization for using medical equipment maintenance engineers and technicians.

WHO/EMRO continues to collaborate with member states in order to achieve the ultimate aim of self-sufficiency in developing maintenance and repair of medical equipment services. For example, collaborative programs have been established with Afghanistan, Iraq, Democratic Yemen, Yemen, Cyprus, Somalia, Sudan, and Tunisia. Appropriately trained technicians of all categories constitute a sine qua non for attaining this goal but the task ahead will not be easy. It requires:

1. identifying training needs for each category of essential technicians;

2. developing relevant training programs for each of the above categories;

3. cooperation in the spirit of Technical Cooperation among Developing Countries (TCDC), among the training institutions of different countries and mobilization of resources for implementing their programs; and last but not least,

4. increasing the planning and management capability of countries to ensure that the personnel trained will have the tools needed to perform their task and that the tools will be rationally utilized.

Cooperation between countries is essential in order to achieve appropriate health care for all. Economic cooperation between the more economically fortunate countries of the region and their less well endowed sister countries has always been a special feature of cooperation for health in the region. It has supplemented WHO resources in providing cooperation for high priority health areas and has, in effect, meant that these more fortunate countries have relinquished their share of the WHO Regular Budget in favor of others. They have also provided additional funds through WHO and other agencies for the implementation of health programs in other countries.

IIA5. REPORT FROM THE AMERICAS

J. Peña Mohr

INTRODUCTION

In my presentation I will cover three topics. The first is science and technology in Latin America. I will examine how some countries of the region have dealt with these two important areas. Second, I will explore some points, themes, and problems in the field of technology, specifically dealing with medical devices, which are emerging as topics of national policy debate in many countries. Third, I will comment on some ideas flowing out of the public policy debate on medical devices that is taking place both within individual countries and in forums of international cooperation.

Concern with science and technology, and more specifically with the formulation of public policies in this essential area of economic and social development, increased considerably in the 1960s in Latin America and the Caribbean. Several countries set up special committees to promote scientific and technological policies. Some countries had agencies of this type as early as 1950, such as the National Institute for Scientific Research in Mexico (*1*).

Most of these efforts were focused on the science and technology necessary for economic development, with emphasis on agriculture and industry. Technology for the social sectors was relatively excluded from this process throughout the 1960s and 1970s.

In the late 1970s, the World Health Organization and the Pan American Health Organization began focusing on the social applications of technology, being primarily concerned with appropriate technology for primary health care.

At the beginning of this decade, the health sector became more responsive and began to recognize the problems of technology and public policy topics and gave them higher priority in programming and policy agendas. This increase in the priority of this field is due in part to a recognition of the impact of technology in skyrocketing health care costs and to the criticism regarding the effectiveness of high-cost technology that is rapidly spreading across the region.

The growing foreign debt of Latin American countries and the subsequent crisis in the balance of payments of most of them have made it necessary to implement a policy to restrict imports and curtail costs. It is necessary, then, to acknowledge the seriousness of converging challenges in the scope of action of the health sector and to rebuild strategies that maintain the objective of social justice that is implicit in the goal of Health for All and also considerably improve the effectiveness and efficiency of the sector.

At international and national forums, representatives and health ministers from several countries have expressed their concern with the existing situation and have placed their hope in joint regional actions for scientific and technological development.

HEALTH TECHNOLOGY DEVELOPMENT

Health technology includes all forms of knowledge that can be used to solve or reduce a group or an individual health problem. It includes, accordingly, not only devices, medical procedures, equipment, surgery, drugs, diagnostic examinations, and medical information systems, but also the so-called "nonmedical technology," such as technologies of hygiene, nutrition, health education, and health services coordination.

The development of medical technology emerged in the 17th century as a consequence of the discoveries and inventions in the area of physics and the biological sciences (*2*).

It was not until after the Second World War that the explosive process of innovation and dissemination of modern medical technology was triggered, accompanied by growth in the number and variety of medical procedures.

Socioeconomic development in the industrialized countries coupled with the impact of the health movement in the 19th century, which incorporated "nonmedical" technologies such as nutrition, hygiene, education, and the coordination of services--which were disseminated to most of the population--began to produce improvements in health indicators. The effect of this mass dissemination of "nonmedical" technology was first felt early in the 20th century as shown by the drop in the incidence of and mortality from such diseases as tuberculosis, typhoid, and pneumonia (*3,4*).

Life expectancy in these countries had already reached 70 years for men and 64 for women. The advent of medical technology in the post-war period dealt the final blow to infectious and parasitic diseases and birth-related complications, leaving chronic and degenerative diseases as the principal health problems.

The story in Latin America and the Caribbean has been substantially different. Owing to socioeconomic factors, the countries have not been able to disseminate "nonmedical" technology on a mass scale, as shown by the low coverage of immunization programs. In countries where this has been achieved, as for example in Costa Rica, Cuba, and Chile (*5*), the experience of the developed countries has been reconfirmed.

Medical technology has begun to spread rapidly throughout Latin America. The population groups with standards of living similar to those of the developed countries create a demand for the same modern, and usually high-cost, technology that is marketed in the northern hemisphere.

In addition to the political and economic power mobilized by this demand of the elite in developing countries, there is international pressure to sell modern equipment through grants, loans, and trade arrangements. This technology is concentrated in large urban centers at hospitals that have the same services as their equivalents in developed countries. Thus, technology, as well as the form of practice, is becoming transnational. The result of this anomalous and artificial process is an imbalance in the allocation of limited technological resources in relation to the heterogeneous health needs and problems.

Based on a synergistic interaction, this distortion and imbalance affects and is accentuated by the equally anomalous distribution of the work force. In terms of planning and public policy, the situation could not be worse (*5*).

SUPPLY AND UTILIZATION OF TECHNOLOGY

Biologicals, drugs, and medical devices constitute incorporated technologies, or technological products as they are also called, that are implemented in health practice and services. These technological products, of varying levels of complexity and sophistication (*6-9*), which represent a very broad repertory of solutions, incorporate flexible technological functions.

The proliferation of products and presentations has increased. Argentina had 17,000 registered drugs in 1974; Brazil had 14,000, and Colombia had 15,000 (*10*). The FDA in the United States has registered some 40,000 medical devices.

The drug industry hit a level of world sales of US$ 84 billion in 1980; Latin America and the Caribbean consumed US$ 3.3 billion that same year (*10*). The medical devices industry is next in importance with world sales of approximately US$ 48 billion in 1986. This industry is in a stage of full expansion with a growth rate of 8 percent per annum for the period 1981-86 (*11*).

Many of these products are manufactured industrially and are the fruit of research and development activities carried out by industry, universities, and specialized institutes. Research and development is concentrated in the developed countries. Companies make large investments in order to launch new products, particularly more sophisticated ones. Consequently, production is concentrated not only in the industrialized countries, but it is further concentrated in transnational companies that extend their production and marketing network to Latin America and the Caribbean.

In Brazil, where local production supplies more than 70 percent of the market, approximately 400 companies make medical devices and approximately 50 percent of them are subsidiaries of the ETN. These companies are mainly located in the more advanced sectors: the entire area of pacemakers is in the hands of the ETN along with 80 percent of monitoring equipment, 70 percent of dialyzers, 60 percent of syringes and needles, and 50 percent of the x-ray equipment market (*11*).

Exports of medical devices from Brazil have been rising since 1979 when they totalled US$ 14 million. They reached US$ 26 million in 1980 and US$ 38 million in 1983. Medical device exports from Argentina fell from US$ 1.1 million in 1979 to US$ 0.8 million, US$ 0.5 million, US$ 0.6 million, and US$ 0.1 million in 1980, 1981, 1982, and 1983, respectively (*12*).

Except for Brazil, Argentina, and Mexico, and to a lesser extent other countries that have a production infrastructure for drugs and medical devices, the countries of the region depend on imports. The level of imported raw materials, drugs, and medical devices is considerable; but it was not until recently that information has become available for some countries.

Levels of medical equipment imports in Argentina have shown major fluctuations that can be attributed to changes in economic policy. Imports in this country totalled US$ 38.9 million in 1979 and rose to US$ 78.1 and US$ 98.9 million in 1980 and 1981, respectively, falling to US$ 53.1 and US$ 36.4 million in 1982 and 1983. Eighty-two percent of these imports are medical instruments and apparatus and x-ray equipment from the United States, Europe, and Japan (*12*).

The marketing of drugs, medical devices, and scientific literature is carried out by the private sector. Some countries have set up a central office for purchase and distri-

bution. Drug promotion strategies have been especially aggressive in Latin America and the Caribbean (*13*).

Technology is also brought in through international loans and investment proposals. Health services incorporate technology by acquiring it on the local or international markets. Dissemination is influenced strongly by market forces, which lead, in the face of weak planning processes, to distortions in the distribution of technology (concentration at tertiary levels) and to geographical and institutional imbalances.

Forty-one percent of the technologies studied in Mexico (*14*) are concentrated proportionally higher in the private sector than in the public sector, based on the number of beds. In Uruguay (*15*), technology is concentrated in the private subsector (65.6 percent) and, within this subsector, in the strictly private sector (52.2 percent), which serves 1.9 percent of the population. The same study pointed out that 96.9 percent of the technology is concentrated in Montevideo which has 44.5 percent of the country's population. These preliminary studies describe a situation whose trends diverge considerably from the guidelines contained in health strategies, policies, and plans.

The conditions for the implementation of technology and the maintenance of equipment, facilities, and buildings is another area of concern. With respect to maintenance, a study carried out in 1981 showed that 96 percent of the equipment imported in recent years was not functioning (*16*). The most serious problem, however, is the weakness of the processes for evaluating technology and the use of evaluative information in decision-making (*17*). Experience in the evaluation of technology in Latin America (*18*) is based on clinical testing of drugs and, in general, has a weak methodological design.

In the last decade, Latin America and the Caribbean have expanded their installed capacity at hospitals, health centers, and health posts; at the same time, intensive care units and highly specialized centers have begun to proliferate. Evaluation of the quality of care in terms of results and its association to the composition of technological functions is becoming an area of growing concern (*19–21*).

The public social security systems of private prepayment are encountering problems in redefining which services to cover and which technology to pay. Problems in redesigning the reimbursement system (how much to pay) for the technologies are also encountered; the varied gamut of new technologies and the growing expectations of the population and the suppliers make it difficult to rationalize the public social security systems for which costs increase daily.

The effects of technology on individual health, the impact on overall health conditions and, in a broader context, on the medical practice, and the operation of national development and services is a topic that should receive higher priority on the research agenda. Concern with evaluation of the effectiveness of programs and projects is growing and should result in innovative proposals in the future.

CHALLENGES AND STRATEGIES FOR REGIONAL COOPERATION AND INTEGRATION

Regional cooperation in the health field has a long tradition. In the 1970s, the countries formulated a 10-year health plan with the fundamental purpose of extending health service coverage. To this end, various investment proposals were implemented with domestic and international financing.

The extensive service network that forms the current infrastructure is feeling the effects of new forces created by the critical economic situation. The health policies and plans of the past are losing their validity and effectiveness in this new, more encompassing context of global crisis.

The health sector today is feeling the impact of financial policies aimed at reducing public spending, against which it has little arguing power, in order to be spared from budget cuts. Health has only received marginal consideration in the area of economic development and planning. This exclusion from national policy decisions on development is also seen at the regional level.

The lack of regional projection has been particularly notable in the forums for debate and decisions on cooperation in economic integration, in which health technology issues have not been included on priority agendas. Only recently has PAHO, as a specialized agency, begun to fill this gap through its initiative in Central America and projects in the field of health technology, which have an important intersectoral component.

The need to formulate explicit regulatory and redistributive policies for health technology has already become evident in regard to drugs. This concern is gradually spreading to the area of medical devices, as seen at the Ibero-American Meeting on Sanitary Products, held in 1985 in Madrid, Spain, and at the International Conference of Medical Device Regulatory Authorities, in which we are currently engaged.

Technological problems go beyond national boundaries. There are many intercountry activities in the area of technology. The region has an opportunity to formulate proposals for collaborative policies based on extensive projects and, at the same time, promote projects for economic integration.

It is necessary to compile a portfolio of research and development proposals that are of high priority for the region with a view to concentrating the efforts of scientific institutions, industry, and governments in order to support them. Pharmacology, biotechnology, and microelectronics are only a few of the fields that should be explored.

The transfer of technology between countries and the joint acquisition of technology is another avenue of possibilities. Trade agreements and purchasing systems could be supported and modernized. Exchange of information on markets, suppliers, products, and prices is essential.

The drug industry has been studied and information is now available on its characteristics, production, marketing, and technological level. There is nonetheless a need to continuously monitor this sector in order to identify opportunities for investment proposals and the transfer of technology. The need to strengthen research and development of essential products of suitable quality, effectiveness, and cost is fundamental.

The production of medical devices is concentrated in three countries in Latin America and little is known about this industrial sector. The possibility of using strategies for collaboration between the public and private sectors to support the development of widely used basic devices so as to be able to advance to projects of greater technological intensity should be explored and supported.

The countries of the region are faced with the task of evaluating the technology that they import and the technology that they produce. It would be difficult to carry out such a task in isolation; hence, thought should be given to a collaborative system on the regional and global scale.

Regional articulation of the purchasing power of the countries through the exchange of information and mechanisms for joint purchasing is urgently needed. A network of this nature could play an important role in controlling the market, strengthening the capacity for joint negotiation, and promoting the trade of technological products within the region.

During the past decade some major investment proposals were implemented. To support these processes, data is needed on available technology, technical specifications, prices, and operating and maintenance conditions.

Waste caused by improper use and overuse of technology is considerable. Part of the high level of unnecessary hospitalization resulting from prolonged stays can be attributed to delays in diagnostic examinations, particularly in radiology. The introduction of basic radiological systems, and equivalent solutions in laboratories and dentistry create opportunities for rationalizing investments with effective, lower-cost solutions (*22,23*).

The greatest challenge facing the region is the redistribution of technology in accordance with the epidemiological profile of the population so as to concentrate resources to benefit the large population groups most at risk. The countries of Latin America and the Caribbean have had little success in formulating and implementing redistributive policies (*24*).

In response to these challenges, the region, as it has done in other critical fields of development, must formulate national and regional strategies. In this matter, it will first be necessary to support a research process so as to compile a body of knowledge to serve as a basis for decision-making (*25*). Simultaneously, efforts should be made to promote the establishment of a technological information network. This information is abundant and varied. Some of this information is protected by the international patent system; other information, however, is accessible and useable.

Advances in the establishment of regional currencies, an exchange system, and systems for joint purchasing should encourage broader coordination through regional conventions and agreements.

It is urgent that discussions begin on indicators of technological development (*26, 27*) for the purpose of enhancing data collection systems.

Latin America and the Caribbean have been gaining valuable experience in the development of channels for regional cooperation. Since the Second World War, several mechanisms for regional and subregional integration have arisen, with special concern for economic aspects, e.g. the Latin American Free Trade Association (LAFTA), the Central American Common Market, the Andean Group, the Free Trade Area of the Caribbean (today CARICOM), and the Latin American Economic System (LAES).

Concern has arisen in some of these cooperation efforts regarding technology in the developing areas. The actions of the Andean Group were the first to serve as a basis for more in-depth studies on the management of technological knowledge and its implications for developing countries. This task culminated in the United Nations Conference on Science and Technology for Development, held in Vienna, Austria, in 1979, at which Latin American delegations played a significant role.

In the future, it will be necessary to establish an active relationship with agencies for cooperation and economic integration such as LAES, LAFTA, the Andean Group, SIECA, CARICOM, the IDB, CAF, and others in order to extend action to the field of social sciences and technology, particularly in the area of health. This cooperation, articulated in the Pan American context in which PAHO, the OAS, and the IDB play a fundamental role, should be integrated into broader efforts at the international level in order to ensure that technology is used to serve the large population groups that are presently excluded from its benefits.

SUMMARY

Concern with science and technology increased considerably in the 1960s in Latin America and the Caribbean. Several countries set up scientific and technological committees. Efforts were focused on science and technology for economic development.

At the beginning of this decade, the health sector became more responsive and began to recognize the problems of technology and public policy topics as a field for priority action. The growing debt and the subsequent crisis in the balance of payments is making it necessary to implement policies to limit imports and curtail costs.

The history of technological development in Latin America and the Caribbean has been substantially different from that of the developed countries. Owing to socioeconomic factors, the countries have not been able to disseminate "nonmedical" technology on a mass scale.

Latin America and the Caribbean consume US$ 3.3 billion in drugs and import US$ 1.5 billion in medical devices annually. Only Brazil, Argentina, and Mexico produce equipment and materials.

Technology is concentrated mostly in the private sector, in capital cities, at the tertiary level, and in the area of diagnosis. This technology is spreading rapidly through investment proposals and other channels.

The challenges faced by the countries of the region are based on the need to continue to extend coverage and redistribute access. In addition to these requirements, there are other restrictions created by the economic crisis.

The countries need to formulate explicit regulatory and redistributive strategies. The region has an opportunity to formulate proposals for collaborative policies based on extensive projects for economic integration. Based on these projects, it will be possible to arrange international financial and technical collaboration.

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IIA6. REPORT FROM SOUTH EAST ASIA

U. M. Rafei

INTRODUCTION

The South-East Asia Region is comprised of 11 countries that are at different stages of development with regard to their health activities and health infrastructure. At one end, countries like India, Indonesia, and Thailand have developed an elaborate health infrastructure and have succeeded in providing the impetus for technical development in the fields of health and health related activities. On the other hand countries like Bhutan, Nepal, or Maldives are in the initial stages of development or utilization of health technologies and must develop and strengthen their infrastructure for absorbing health technologies.

The ministries of health in all countries of the South-East Asia Region have the regulatory responsibility for health development and have enacted different regulations that cover control of quality, efficacy and safety of pharmaceuticals and medicinal products. Thus, India, Indonesia, and Thailand have enacted comprehensive regulations and also developed an infrastructure for implementation of various provisions of a Drug Act. On the other hand, countries such as Bangladesh, Burma, Nepal, and Sri Lanka have a comprehensive Drug Act but have as yet to develop an efficient infrastructure to implement the provisions of this act. In Burma the government has yet to establish a proper regulatory authority.

The regulatory agencies often have been headed by a director-general or drug controller for food and drug control within the ministries of health, assisted by several directorates in charge of specific activities. These regulatory agencies are assigned the task of implementing the provisions of a drug and cosmetic act through rulemaking and instituting training programs for their officials and scientists. The objective of all these activities is to ensure standardization, efficacy, and safety of drugs and medicinal products. WHO has collaborated over the last few years in developing and strengthening the drug regulatory agencies in most of these countries. WHO's main thrust is to strengthen health legislation and update health laws so as to be in tune with the objectives of HFA 2000 with an emphasis on Primary Health Care.

Only a few countries in our region have initiated activites that enlarged the scope of their Drug Act to include medical devices. Such activities have been initiated in India, Indonesia, Sri Lanka, and Thailand. However, most of these are still in an early stage of implementation.

PROCUREMENT, PRODUCTION, DISTRIBUTION OF MEDICAL DEVICES

In response to rapid advances in health technology, most developing countries have initiated action to absorb new technologies through adoption/adaptation. Many medical devices have been used in different branches of medicine either inside or outside the body. Most such devices are at present being imported from developed countries. Only a few countries, such as India and Indonesia, have been able to devote necessary resources or develop facilities for the local manufacture of medical devices within the public or private sector.

Simple medical devices used in disease diagnosis, orthopedics, dentistry, blood-banking, cardiovascular surgery, etc. are either already being manufactured in the public or private sectors in these countries or activities have been initiated for the development of technology for their manufacture. India and Indonesia also have taken steps for acquiring technologies or are developing the means for the manufacture of sophisticated medical devices used inside the body, such as heart valves.

Whether procured or locally manufactured, medical devices are at present not under regulatory control with regards to their standardization, specifications, and quality assurance. The subsidiaries of parent companies, operating under license in developing countries and manufacturing medical devices, have adopted specifications obtained from their parent companies. However, in many cases they have not been able to maintain quality of their products. Mechanisms and procedures for registration, licensing, and operations of such subsidiary companies differ from country to country. The licensing of such companies is done by ministries of commerce or industry, while their products are used in the health programs, with the result that there is hardly any maintenance of standards in this regard as there is no effective coordination between the concerned ministries.

The ministry of health must play a very pivotal role in the choice of technologies for adoption/adaptation, maintenance of the quality of medical devices, ensuring their safety and efficacy and above all making such devices available at prices that can be borne by the health care programs. It should be emphasised here that more than 80 percent of the population of such developing countries as Bangladesh, Bhutan, Nepal, and Sri Lanka must depend upon public sector organizations for medical relief. It is therefore important that the medical devices be provided through public hospitals and institutions at economical prices.

In some countries such as India, there is a statutory organization, such as the Indian Standards Institute, that formulates standards and specifications for some of the devices. Such specifications are mostly based on the products marketed by the companies from developed countries. However, through optimum utilization of national expertise and after taking into account the industrial development in different sectors, the Indian Standards Institute has evolved its own standards. However, very few countries in the region have evolved their own standards or specifications for medical devices.

INFORMATION SOURCES

Most hospitals, health institutions, health personnel, and patients obtain information about medical devices from local manufacturers or traders/agents of companies operating from developed countries. As yet there has been no development of a centralized mechanism or system for providing appropriate information on medical devices to the user with respect to appropriateness, safety, efficacy, utility, and durability. Failure of medical devices is only rarely reported, if at all. That information is often relayed back to the manufacturer or its agent, and not widely disseminated or made available to other professionals or to the consumer.

There is no comprehensive system by the centralized regulatory authorities for collecting information either from the patient or health institution. Occasionally, failure of a medical device comes to light through the media, such as press or television reports that a hazardous episode has occured as a result of the use of a substandard medical device. Such episodes generally occur in orthopedic or ophthalmic fields.

Certain devices such as the intrauterine device for family planning are being used in the national program in several countries of the region. The program is monitored either on a pilot or continuing basis and therefore under such circumstances, it is possible to obtain information on the failure of the device. There is a need to assist countries in the collection, collation, analysis, and dissemination of appropriate information not only to the medical profession but also through the media to the community. This would help in creating community awareness and in a way accelerate the process for establishing a regulatory authority for medical devices.

INFORMATION SYSTEM

General information systems on health and health-related activities in most developing countries are still in the early stages of development. Although some countries have established health information bureaus for collection, collation, and dissemination of valid information on health matters, others have yet to develop and strengthen a full-fledged information system.

In the absence of a sound infrastructure for information collection, one cannot expect there would be a centralized source that could provide valid information on medical devices. Such information is made available on request by the manufacturers or through their catalogs, brochures, and technical data sheets, and through medical journals. A few countries have developed some centralized information systems through their ministries of commerce or industry, as in Burma and India. However at present there is no agency that can serve as a clearinghouse for information on medical devices and render appropriate advice to both the government and medical profession.

Several scientific institutes and research organizations also act as a source of information on medical devices. In India there are several institutions, such as the Indian Institute of Technology, research institutes under the Indian Council for Scientific and Industrial Research, etc., that render technical advice on medical devices on reference.

Establishment of a regional mechanism/center to act as a clearinghouse for information on some commonly-used medical devices is an urgent need. A small beginning has been made by ESCAP by establishing a center on technology transfer and information at Bangalore, India.

POSTMARKETING SURVEILLANCE

Postmarketing surveillance is still in rudimentary stages in most countries of this region. Only a few countries, such as India, Indonesia, and Thailand, have initiated a program for postmarket surveillance, particularly for adverse reactions following the use of drugs and medicinal products.

In order to be able to estimate the failure rate of medical devices commonly used in medical practice, it would be necessary to establish mechanisms for postmarketing surveillance of such devices in a systematic manner. At present, surveillance of this type is being done mostly by the representatives of private manufacturers in order to obtain feedback on the performance of their device. The representatives are therefore maintaining a liaison with the users in order to collect information on the efficiency and safety of their products. This enables them to create some data bases on their product and take effective measures to improve the quality. However, such data is not made available to health authorities.

MAINTENANCE AND REPAIRS

Most developing countries have not yet formulated policies or approaches for procurement of devices or equipment that take into account real health needs. WHO has been providing inputs from time to time to establish systems for preventive maintenance and establish training facilities for maintenance and repair of equipment. Because efficient functioning of any medical device, whether inside or outside the body, depends upon the development of adequate maintenance and repair systems, this aspect assumes a great deal of importance, particularly in developing countries in which the infrastructure is weak. Major problems that we see in this area are:

1. Grossly inadequate trained manpower;
2. shortage of management skills; and
3. indifferent or callous attitude of suppliers of devices after they have succeeded in selling them to the customers.

This picture is further complicated because most governments have not taken steps to standardize equipment. Most countries buy equipment or devices from different manufacturers. There is no adequate inventory of spare parts. There is also a scarcity of foreign exchange. It is therefore no surprise that most equipment and many devices remain unused for the greater portion of their lifetime.

Some countries in our region have become alert to these serious problems and are developing systems for maintenance and repair. Thus, India has established an institute for maintenance and repair that imparts training in this field not only to their own nationals but also to those from other countries of this region. WHO/SEAR in collaboration with this institute has trained several nationals from Sri Lanka, Bhutan, Nepal, and Bangladesh. This organization, called Central Scientific Institute Organisation (CSIO), has several field stations in different parts of the country that liaise with medical institutions and research organizations and assist them in establishing systems for maintenance and repair. They also undertake training programs.

Because this is an important requirement for the effective use of medical devices, international agencies may need to give priority in their programs to strengthening and developing the capability of the countries to institute programs of maintenance and repair systems, with special emphasis on commonly-used medical devices.

INTERSECTORAL COORDINATION

To assist countries in becoming self-reliant in the field of medical devices, with respect to procurement, manufacture and to ensure safety and effectiveness, it is necessary to establish intersectoral coordination between different ministries concerned with import, licensing, manufacture, distribution, and sale of medical devices.

Ministries of health will need to play a nodal role. In view of the fact that such devices are meant to be used in health programs, the ministry of health will have to be responsible for the efficacy and safety of these devices. Other ministries such as commerce, industry, science, and technology, will be required to play their respective roles in order to ensure that the choice of medical devices is based on such considerations as appropriateness in technology, available technical expertise in the country and manpower training, development of infrastructure, and acceptance by the community. The ministry of health will need to devise specifications, institute mechanisms for standardization, enact legislation to ensure safety and efficacy of the product, build

an infrastructure for implementation of various provisions of legislation, and take all steps necessary to ensure that the medical devices are safe, effective and also available in required quantities at all times in the health programs. This program can be developed in phases for regulated devices. It may be necessary to be more stringent with regard to quality control specifications and standardization for devices to be introduced into the body. Countries may have to seek collaboration with international agencies in order to initiate these activities because most countries in our region at present do not have such expertise.

PRIORITY AREAS

Priority areas in our region with regard to development of programs for regulation of medical devices could be summarized as follows.

Manpower development: There is a need to train nationals to serve as regulatory officials for medical devices. Countries also need international consultants to assist them in establishing standards and specifications for medical devices.

Legislative development: There is a need to develop legislation for regulating the procurement, manufacture, and sale of medical devices.

Development of infrastructure to implement regulatory control: This includes training nationals in both technical and administrative aspects in order to implement effectively the provisions of the medical device act.

Because the medical device act may not be able to encompass all the different devices at one time, it may be necessary to prioritize areas that would be covered in a phased manner by the act. Some priority areas for the use of medical devices are as follows.

Most countries in our region are using blood and blood components extensively. In order to ensure safety, blood must be collected in disposable plastic bottles. It may be necessary to formulate specifications for the use of such disposable plastic materials for blood collection and infusion and also for diagnostic kits and microbiological reagents that are being increasingly used in our health programs.

Prevention and treatment of injuries and accidents form an important program in all the countries of this region. WHO has been actively collaborating with countries in accident prevention. Different medical devices used in orthopedic or ophthalmic medicine would need standardization and specifications as a priority.

Some centers in India and Indonesia are doing organ transplants and cardiac valve transplants. India also has already developed the technology necessary to manufacture heart valves. These would have to be evaluated and their standards and specifications would have to be formulated.

There is an increasing use of devices in the ophthalmic field. Several centers have started up particularly in our region for manufacture of contact lenses. There is also an increasing use of lens implants after cataract surgery and an increasing demand for their manufacture in such countries as India.

CONCLUSION

WHO has been collaborating with most countries in reviewing public health laws, updating them, and making them relevant to countries' needs in the context of new shifts in WHO and national policies and programs to achieve health for all by the year 2000. In this context, one of the most important tasks is to promote appropriate technology. It is therefore necessary to make every effort to develop an expertise in the country that will enable the country to adapt or adopt technology that is most appropriate for its own people. Countries must develop in a phased manner a program for the control of these devices with a view to improving their effectiveness and safety. It also may be necessary to assist some countries in developing their capabilities to produce some of their own widely-used medical devices in order to attain self-sufficiency. WHO should also aim at regional self-reliance by establishing centers that could assist countries in making decisions with regard to the adoption of appropriate technologies and also provide technical information on medical devices.

IIA7. REPORT FROM THE WESTERN PACIFIC REGION

B. Sankaran

The Western Pacific Regional Office has expressed regret at not being officially represented at the Conference. But, with the participation of nationals from several countries within the Region, their particular concerns will not be overlooked. Some of the statements in this paper refer to certain countries whose representatives may wish to make further comment.

The countries within the Western Pacific Region vary from the small island territories to the most populated country in the world, and from the highly industrialized economies, such as Japan and Australia, to developing countries whose per capita income would be considered low by world standards. There are also countries which, in the recent past, have achieved spectacular advances both in industrialization and in health benefits to the population: the Republic of Korea, Malaysia, Singapore.

Medical traditions and medical practice vary widely in the Western Pacific. Western medical practice, with its high reliance on modern technology and instrumentation is the most widely utilized. Although there is a lack of specific information on medical devices, according to available records, only four countries (Australia, Japan, New Zealand, and Singapore) have comprehensive legislation on this subject.

An example of such legislation is that established by the Government of Australia. The stated reason for such legislation is "to ensure that medical devices used by Australian patients are safe and effective." To this end, the Health Ministry will:

1. establish a register of medical devices sold in Australia;
2. collate and disseminate information on problems relating to them;
3. evaluate the safety and effectiveness of high-risk items prior to marketing; and
4. establish a facility to develop standards and to test certain types of devices.

The government has become aware through community concerns and through representations from professional organizations that more needs to be done to ensure that medical devices are safe and effective.

It seems that sharing of information that is derived from such a program would be most helpful, particularly to developing countries.

Most countries in the region import a considerable amount of medical equipment as indicated in Attachment 1. These imports vary in cost from a few thousand dollars to approximately $300 million; 11 of these countries import more than $1 million from one major exporting country. Some of these countries are also important manufacturers of medical equipment and devices, principally in the private sector.

The following are the highlights of the legislation in Australia, Japan, New Zealand, and Singapore, where device regulations exist.

AUSTRALIA

The first legislation enacted by Australia addressing medical devices was the Therapeutic Goods Act of 1966. Subsequently, the Medical Device Act was passed on August 21, 1984.

The Therapeutic Goods Act of 1966 includes, by definition, orthotics and prosthetics and other therapeutic goods meant for treatment of individuals. These goods must conform to established standards. The Therapeutic Goods Advisory Committee was set up by the government to advise on acceptance of therapeutic goods as defined above.

The 1984 Act includes diagnostic goods for in vitro use other than for diagnosing pregnancy. Under the 1984 Act, a person appointed by the minister on the nomination of the Australian Medical Devices and Diagnostic Association and a person appointed by the minister on the nomination of the Institution of Biomedical Engineering (Australia) Incorporated serve on an Advisory Committee on Medical Devices.

JAPAN

The Pharmaceuticals Affairs Law of Japan includes provisions on medical devices. The term medical device in this law refers to equipment or instruments intended for use in the diagnosis and/or prevention of disease in man or animal, or intended to affect the structure or function of the body of man or animal. The Pharmaceutical Affairs Bureau of Japan has established a special office of medical devices which performs safety inspections.

NEW ZEALAND

The Medicines Act of 1981 and Medicines Regulation of 1984 comprise New Zealand's laws in this field.

The regulatory control of medical devices is still at a preliminary stage. A fair trading bill, now being considered by parliament, includes product safety and product recall provisions that currently are expected to apply to medical devices. Testing and evaluation of medical devices is under the Department of Scientific and Industrial Research at the request of the Director-General of Health. Inspection, labelling, marketing and promotion, and advertising are under the Department of Health. Government procurement of medical devices is under the individual hospital boards with advice from the hospitals and the medical profession. Reporting adverse reaction to devices, and education in medical device technology, are under the Ministry of Health.

New Zealand intends in 1986 to begin drafting legislation to control medical devices in a more standard way. Under the current legislation, the major problems identified, and to be rectified later, are:

1. knowing which products are being imported or locally manufactured to supply the local market;
2. finding out who was responsible for distributing a product found to be faulty;
3. obtaining information on overseas evaluation and adverse reaction reports;
4. recording local adverse events;
5. determining sterility of imported products; and
6. performing maintenance and replacement of parts and an inventory thereof.

SINGAPORE

Singapore's legislation primarily concerns irradiating apparatus under the heading of occupational health and safety (No. 6 of 1973).

The legislation also includes the issuance of licences for:

1. medical diagnostic purposes;
2. medical therapeutic purposes;
3. dental diagnostic purposes; and
4. veterinary diagnostic purposes.

It restricts the licensing to use by professionals involved in specific areas of specialty, such as radiologists; persons involved in treatment, such as physicians, and dentists; and specialists with knowledge of safe use of radioactive materials or irradiating apparatus.

WHO/WPRO SUPPORT OF MEDICAL DEVICE PROGRAMS

Developing countries also face the serious problem of maintaining equipment because they lack trained personnel and spare parts. To address this problem the Western Pacific Regional Office has sponsored training courses, particularly on radiological equipment, and has sent consultants to numerous countries to advise hospital personnel as to appropriate equipment management.

One type of medical equipment that has received considerable attention in the Western Pacific is that used for radiological technology. Improved prospects of providing basic radiological services to remote areas have made it possible to foresee the strengthening of diagnostic services at the first level of primary health care. Cooperation in the improvement of these services has continued. Support was provided to the Philippines for training in the maintenance and repair of x-ray and other medical equipment, and to the Republic of Korea for improving dosimetric procedures and radiation protection.

MEDICAL DEVICES IN THE WESTERN PACIFIC REGION CURRENTLY BEING IMPORTED

Dental equipment, wadding, gauze, bandages, surgical sutures, first aid kits, sterilizers and autoclaves, gloves, fiberoptic strands and cables, ophthalmic lenses (contact), unmounted eyeglasses, optical appliances and instruments, anesthetic apparatus and equipment, Bougies catheters, drains, basal metabolic and blood gas analyzers, hypodermic syringes and needles, pacemakers, diathermy units, ultrasonic therapeutic devices, electromedical therapeutic devices, electrocardiographs, electroencephalographs, patient monitoring systems, electromedical devices, medical and surgical appliances, mechanotherapy appliances, respirators and accessories, hearing aids, bone and joint prosthesis, orthopedic appliances, x-ray apparatus and parts, x-ray plates, wheelchairs, medical and dental furniture.

IIB1. ROUND TABLE REVIEW OF PROBLEMS, ISSUES, AND TRENDS INTRODUCTION AND SUMMARIES OF DISCUSSION: ROUND TABLES A - D (RTA - RTD)

Dr. H. Cordeiro presided over Plenary Session III and introduced the discussion topics of the four Round Tables. Dr. Cordeiro pointed out the importance of these Round Tables in the initial phases of the Conference as a mechanism to promote communication and exchange of information on national experiences among the participants of the conference.

The topic for Round Table A was "Appropriate Technologies for Health Care." Dr. Cordeiro stated that one of the central questions to be faced by this group was the validity of the concept of appropriate technology, particularly bearing in mind the technological advances and the health needs of the population of the less developed countries.

The topic for Round Table B was "Public Health Approaches to the Management of Medical Device Health Care Technology." The Chair suggested that the group consider a number of issues, including incorporation of new technology into the health care system of a country. Under which organizational and financial conditions can a new technology be adopted or incorporated? Dr. Cordeiro pointed out the importance of this topic because of the need to achieve an equilibrium, particularly difficult in the less-developed countries with their scarcity of resources, between very early incorporation with its risks of inefficiency, inequity, and malfunctioning, and very late adoption that would result in the incorporation of obsolete, inefficient technologies with risks that possibly have already been overcome.

The topic for Round Table C was "Risk-Benefit from Preclinical and Clinical Trials." In his introduction, Dr. Cordeiro emphasized the importance of identifying approaches for evaluating the efficiency and effectiveness of medical devices prior to their incorporation into the arsenal of health technology of a country. He submitted for consideration by the Round Table a mechanism to make that pre-evaluation effective, which he called "Certificate of Technological Need."

The topic for Round Table D was "Impact of Medical Technology on Health Care Cost." The Chair of the Session, in his introduction to the topic, pointed out that the sales policies of the firms producing medical devices, in his opinion, result in the introduction to the market of similar devices with great variations in price that do not correspond to the real costs of production and marketing. In addition he suggested that the group take into account in its debates the need to establish criteria that will assure adequate utilization of the new technologies. These should not be used abusively, endangering the doctor-patient relationship. In relation to this second topic, he also pointed out the importance of educating health professionals in general and the medical staff in particular.

The Round Tables provided a brief opportunity for participants to become acquainted and identify and initiate discussions of important problem areas that would be targeted for in-depth discussion later in the conference.

Summaries of the Round Table Discussions were presented in the plenary session that is transcribed in the following sections.

IIB2. ROUND TABLE A

APPROPRIATE TECHNOLOGIES FOR HEALTH CARE

This group began its discussion by defining appropriate technologies for health care as those technologies that are effective and safe, of a suitable cost for the population, and socially acceptable. The last two points have relatively greater priority in developing countries.

Various problems were mentioned, generic to countries that are not industrialized or whose industry is only slightly developed:

1. these countries lack an effective working relationship between the scientific community, industry, and the government, which must make policy decisions;

2. national industry, when it exists, is geared toward profitability and not toward the needs of the people;

3. while imports have become an important means for technology transfer in these countries, it was noted that authorities, who must make decisions, frequently lack information on safety and effectiveness, social acceptability, and the need for the technology being requested;

4. there is a lack of understanding of medical device technology, the technology development process as a whole, and the use and maintenance of the equipment in particular;

5. manpower training was identified as a priority activity, particularly for developing countries.

It was suggested that the World Health Organization could assist by encouraging the development of guidelines applicable to various levels of device manufacture, testing, and use. It was noted that WHO could play an important role in the facilitation of the flow of information on the technology development process, and on the characteristics of available technologies. It was further suggested that a data base on medical equipment be established in order to provide information on both medical device problems and new developments in health technology.

M. S. Valiathan, Chair
A. G Liedstrom, Co-Chair
D. Sanchez, Rapporteur
D. Banta, Rapporteur

IIB3. ROUND TABLE B

PUBLIC HEALTH APPROACHES TO THE MANAGEMENT OF MEDICAL DEVICE HEALTH CARE TECHNOLOGY

In order to obtain an overall view of the world situation regarding medical device regulation and controls, participants were invited to describe briefly the regulatory approaches adopted in their countries. The most striking, though not surprising, feature of the discussion was the wide range of management efforts and control activities related to medical devices in the various countries. These approaches ranged from no controls at all to laws covering the registration and approval of all devices.

In most nations, regulations covering foods, drugs, pesticides, or cosmetics have been in force for some time and these laws have been modified or extended to cover medical devices. This is an understandable but not a necessarily ideal approach.

Although a government health department is almost invariably responsible for the enforcement of health technology laws and regulations, it is not uncommon for some other government department to be involved with at least some aspects of the regulations.

LEVELS OF CONTROL OR MANAGEMENT

In general there were common objectives in the various control systems. The principal aim was to ensure the safety of patients, but the quality (good manufacturing practice) and performance of medical devices also figured to various degrees. Typically, levels of control included the following:

1. No laws
   - Government departments seek advice from users or foreign national bodies.
   - Hospital users obtain advice and guidance from expert national centers.
   - Government departments give advice to hospital users within a national health service.

2. No laws at present but regulations are under consideration or under development.

3. Laws in force (or under development) covering selected types of medical devices, e.g., heart valves, pacemakers, intraocular lenses, intrauterine contraceptives, drug infusion devices, implants, and single use devices.
   - Some national services effect management by their listing or recommendation of acceptable equipment.

L. Hernandez, Chair
T. Onitiri, Co-Chair
M. Slatopolsky, Rapporteur
D. Potter, Rapporteur

IIB4. ROUND TABLE C

RISK BENEFIT FROM PRECLINICAL AND CLINICAL TRIALS

The chairman opened the discussion by suggesting that the group focus on cost-benefit considerations for preclinical tests, and risk-benefit criteria for clinical trials. Speakers discussed factors that influence the need for preclinical or clinical trials. Device risk was one of those. Most countries treated imported and domestic devices differently, and distinguished between high-risk (typically implantable) and low-risk devices. Several speakers noted that country of origin was a significant factor affecting the degree of assessment needed. Actual conditions vary from among countries; all countries, however, are concerned that medical devices be safe and effective. Many countries desire that clinical trials address not only safety and effectiveness, but also long-term costs, and an appropriate match exist between the technology and the environment in which it is to be used.

It was clear that the costs of achieving basic safety were not perceived as an overriding factor. There was a perception, often expressed with frustration, that most countries are largely buyers of technology. Such countries are often at the mercy of a few selling countries. Buying countries see a need for exporting countries to pay closer attention to the needs of, and appropriateness of exported technologies for, the needs of developing countries. Important factors include maintainability of devices, and supply of spare parts. Feedback to device manufacturers from preclinical and clinical trials in developing countries seems to be particularly necessary.

This discussion group made a number of general observations:

1. The IEC (International Electrotechnical Commission) and ISO (International Standards Organization) appear to be well regarded as sources for criteria for preclinical testing. These groups should work with developing countries to ensure that their standards consider and appropriately address the needs of the developing countries.

2. There is a well-accepted need to develop a mechanism for the exchange of information on the results of clinical trials under recognized protocols for registered medical devices. This would give importing countries maximum opportunity to accept devices with confidence, without the need for their own duplicative, expensive, and time consuming clinical trials. It would be helpful if WHO could facilitate or establish a network that could serve as a focal point for the exchange of information on clinical trials. Mutual acceptance of the results of preclinical tests and clinical trials would be encouraged and facilitated by the development of generally recognized and appropriate guidelines for the conduct of clinical trials. Manufacturers that export medical devices should provide to importers all publicly available evidence on the safety and effectiveness of their exported products.

3. It was strongly urged that products for export be manufactured to a single standard of high excellence, particularly for the benefit of those countries that may lack the facility and resources to test the quality of imported devices.

E. Sommers, Chair
P. Mbumba, Co-Chair
D. Johnson, Rapporteur
M. Lieberman, Rapporteur

IIB5. ROUND TABLE D

IMPACT OF MEDICAL TECHNOLOGY ON HEALTH CARE COST

Participants in this discussion concluded that the cost of health care technology cannot be disassociated from its benefits. Cost-benefit must be determined for each specific technology in each specific nation's health care environment. Health care priorities in developing countries contrast greatly with those of industrialized nations. New sophisticated technologies used in industrialized nations may lead to incremental improvement in cost/benefit ratio or patient outcome in those nations, yet the same technologies competing with other priorities in the health care systems of developing nations may have very negative effects on costs, actual patient outcome and aggregate health care.

Each nation must take responsibility for establishing its own health care priorities and make its decisions to acquire and assimilate specific technologies within the framework of its priorities. Determining device acquisition priorities and selecting and purchasing devices are difficult tasks in all nations and at all decision levels, from administrators within responsible government agencies to individual hospitals. Such decisions are especially difficult in developing nations. Device acquisitions can prove to be not only extremely costly in resources, but also negative in their impact on health care.

The advanced technology found in some medical devices also are special problems in developing countries because of the very substantial costs of service and downtime. Frequently, the resources for the servicing and maintenance of sophisticated equipment are not available in developing nations.

WHO, as well as its component and collaborating organizations, may wish to consider two closely-related needs expressed by many conference participants.

1. Development of essential equipment lists for hospitals and clinical departments of various sizes and functions, scaled to various levels of sophistication and the differing health care priorities of developing and industrialized nations. Such lists will assist in resisting technologies that are inappropriate for specific health care systems at a given time.

2. Development of standard simple designs for very basic and needed equipment items that can be serviced at the component level in developing nations. These items are analogous to the BRS (Basic Radiologic System). Such equipment could be produced in developing nations.

Because developing nations usually cannot afford much of the sophisticated medical equipment offered by the industrialized nations, and lack the trained personnel to operate, support and service such equipment, the market for this equipment among developing nations is relatively limited at present. Instead, the need is for more basic equipment. By responding effectively to this need through the production of basic equipment that can be operated and maintained without difficulty in developing nations, firms in more developed nations could prosper, first by an expanded marketplace, and second, over time, by a marketplace with growing and increasingly sophisticated requirements. Far-sighted industrial organizations will understand that this technical and marketing challenge presents a new economic opportunity for them.

The real costs of medical equipment include not only the initial cost, but encompass the concept of life cycle costs (LCC). An LCC analysis should include the total lifetime costs, e.g., purchase, freight, installation, incoming inspection, user training, staffing, retraining, periodic inspection, preventive maintenance, calibration, repair, associated supplies, reagents and energy, disposal, and other factors. LCC analyses are useful in projecting actual total costs of ownership, cost per diagnostic or therapeutic unit of service and for comparing the costs of one brand and model with another. LCC analyses of different brands and models of the same type of equipment may vary greatly, sometimes by a factor of three or four.

Finally, there is a critical need to provide education on the limitations of health care technology to health professionals, especially physicians. They need to know when specific technologies are justifiable in specific health-care environments and when they are inappropriate. A greater general awareness of costs, and risk/benefit of technology must be encouraged and promoted.

In summary, the participants concluded that national medical device regulatory authorities traditionally concerned with safety and efficacy may wish to pay greater attention, especially in developing countries, to the costs of technology and the availability and costs of user training and service support.

C. Mulraine, Chair
B. el Azmeh, Co-Chair
J. Noble, Rapporteur
M. Torrealba, Rapporteur

IIC1. PUBLIC HEALTH MANAGEMENT OF MEDICAL DEVICES

INTRODUCTION

Session IV was divided into two parts. Dr. H. Martuscelli Quintana presided over the first part, with Drs. I. M. Arefjev and B. Wang acting as rapporteurs. Dr. J. Kouri presided over the second part, with Drs. J. L. Ngu and R. Lafetta acting as rapporteurs. Both Session Chairs, after pointing out the importance of the topics included in the session, presented each of the speakers. The following sections of this chapter contain the papers presented in Session IV.

IIC2. LEGISLATIVE AND REGULATORY APPROACHES

D. C. Jayasuriya

INTRODUCTION

Having some recent experience with remote control hospital beds, injections with large syringes and long needles, and finally with CT scans, I started looking at legal texts to find a simple definition of the expression "medical device." It seemed that legal draftsmen around the world have been determined not to formulate a simple definition. As I went though more and more texts, the confusion became more acute until I came across a new medical dictionary. The 1986 International Dictionary of Medicine and Biology defines a medical device as:

> Any item or piece of equipment used in health care, excluding drugs. Specific legal definitions may specify which items are subject to governmental regulation as medical devices." (*1*)

Legislative patterns do not reveal any consistency in the scope of the items or equipment subsumed by the expression "medical device" (*2*). Legislators, therefore, have a wide and unlimited choice in determining the parameters of the concept. Some might wish to formulate terminology such as "medical equipment" to regulate certain items, including hospital beds.

Statutory definitions are important because future regulatory decisions will depend on the extent and degree to which individual items or equipment are regulated. Not infrequently a fine distinction may have to be drawn. In one case, in the United States, it was held that a tape recording for self-hypnotic purposes dealing with "bust enlargement" but not "weight loss" was subject to the regulation (*3*). The case was decided on the basis that the tape was intended to be used to deal with disease or to affect the structure or function of the body. Different countries will define devices in different ways. I am reminded of a conversation between a communist, a capitalist, and a socialist who met a friend who had been delayed as a result of standing in a queue in a supermarket to buy ham. The capitalist asked: what is a "queue"?; the socialist, what is a "supermarket"?; and the communist, what is "ham!"

DYNAMICS OF REGULATION

My experience with the implementation of regulations in the field of pharmaceuticals is perhaps suggestive of both what is feasible and what is not feasible in device regulation. Extrapolating experiences from one field to another needs to be done with caution; I am concerned that we should try to avoid some of the mistakes we have made in the past in regulating pharmaceuticals. Many participants at this conferecnce have pharmaceuticals responsibilities. It is perhaps opportune to ask whether or not there is much similarity in the regulatory issues with respect to pharmaceuticals, on the one hand, and devices on the other.

Whatever may be the precise parameters of the scope of matters to be regulated, first and foremost we need a regulatory policy and an institutional mechanism. We need to recognize that importation, manufacture, exportation, sale and use of devices involve a number of entities - corporate, institutional, and individual. Their perceptions and attitudes are as important as their functional role in achieving the basic objective of

ensuring that only good quality, safe, and efficacious devices are available in the market. Both in formulating appropriate policies, including regulations, as well as in providing for representation on institutional mechanisms, we must ensure that all relevant interest groups are adequately represented. This is particularly important because some countries have faced difficulties in translating pharmaceutical policies into action; there have been endless and meaningless confrontations and lack of understanding of each others' views.

MECHANISMS OF REGULATION

In order to ensure the quality, safety and efficacy of devices, we need to adopt some fundamental measures. First, we need to establish a licensing system. Second, we need to specify standards or norms. Third, we need to regulate labelling and advertising and conditions of sale. And finally, we need to deal with defects in quality. The preliminary survey prepared by Mays Swicord and me deals with the state-of-the-art in some 20 WHO member states (*4*). Due to limitations of time, I will not go into details of the mechanics of regulation, except to draw attention to a few matters.

First, we have the WHO test of Good Practices in the Manufacture and Quality Control of Drugs, which deals with general aspects such as personnel, premises, equipment, sanitation, starting materials, manufacturing operations, labelling and packaging, the quality control system, self-inspection, distribution records, and finally, complaints and reports of adverse reactions (5). The text specifically addresses the manufacture of pharmaceuticals, but there is much that is directly applicable to the manufacture of devices. Argentina, for instance has already made legal provision for the text to apply to the manufacture of items other than drugs.

Second, a few countries, including the United Kingdom, have instituted administrative mechanisms for quality assurance. Until such time that standards are available for all devices and they can be universally implemented, an administrative scheme, which depends on the goodwill of manufacturers and distributors, will provide a sound basis for registration and quality assurance. Law reform is not necessarily the best first step.

Third, we have the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (7). This scheme enables importing countries to obtain information on whether the drug to be imported is registered in the country of manufacture (and if not, the reasons) and whether the manufacturing premises are subject to inspection to ensure compliance with WHO standards of good manufacturing practice. I find that the United States of America issues to exporting countries a similar certificate. Given the scarce resources of developing countries, such certificates go a long way in offering quality assurance. The scheme also provides for certificates for individual batches of products.

One of the standard examples at marketing seminars is about how one superpower placed an order for condoms which could stretch to some 25 inches. The other superpower, not wanting to be outsmarted, labelled the package as "medium size!" This illustrates the importance of labelling and advertising. With respect to devices, it is important that use instructions be given with some indication as to whether special expertise is needed to operate any particular item.

TOWARD THE FUTURE

Let me take a close look at the crystal ball to see likely future developments. Conferences of this sort tend to set a new trend, but I am concerned that we should not blaze a new trail studded with pitfalls.

At another marketing seminar I heard about the dismissal of the marketing manager of a multinational firm that sells shoes. He had been sent to a developing country to promote sales, but immediately on his arrival he had booked his return passage and cabled his superiors stating that no one in the country wears shoes and therefore there is no market! I am told that the firm had doubled its profits simply by selling shoes only in that country.

While I am convinced of the importance of medical devices, especially sophisticated equipment using high technology, I will be unhappy if countries were to open the floodgate for the entry of devices without being ready to cope with the regulatory problems they bring in their wake. Cost containment measures, such as prior approval for the purchase of very expensive equipment with regard to potential target groups of users, for instance, will help avoid the proliferation of products. We need to think more clearly on the rational use of devices from the outset. We need to cast a horoscope which will guarantee the reasonable and optimum use of devices not only for today but also for tomorrow. If on Friday we could leave with what may be called the "spirit of Washington," we will be able to demonstrate to the world that we are still capable of rational decision-making in a sober environment where the supply matches the demand and the user knows what he needs and has a free, but not too unlimited, choice. Each country must devise its own policy. We must allow a hundred, if not a thousand, regulatory approaces to blossom. There should be no standard models in this area. We should share experiences and learn from one and another without compromising the right to decide what is best for each country.

As Dr. Mahler said, in a different context, "So let us stop wasting our time on idle polemics about topic 'X' being globally more important than topic 'Y' in research, or trying to formulate a statement of 'global priorities'. What we need are nondogmatic approaches that together would make up a 'global strategy' to allow countries to achieve the aims they consider important (*8*)." We are now on the threshold of a new era in the domain of medical device technology. We have a great opportunity to experiment with different regulatory models and our experience in this field might well be suggestive of what is possible in other fields, including pharmaceuticals. In this context it is worth reminding ourselves of the words of a Danish poet who said "Err, and err and err again, but less, and less and less (*9*)."

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IIC3. NONLEGISLATIVE APPROACHES TO THE CONTROL OF MEDICAL DEVICES

G. R. Higson

All those receiving health care and those involved in its provision have the right to expect that all the products on which they rely are safe and fit for their purpose. Most countries have regulatory authorities whose job it is to ensure that this is the case.

Regulatory authories may set about their task in a number of different ways but the strict division is between the use of legislative or nonlegislative means. In the UK we have experience in both. Pharmaceuticals are controlled by the Medicines Act of 1960 and a small number of medical devices have been brought within its scope.

In common with similar legislation in other countries, the Medicines Act lays down precise requirements for manufacturers and for products. No one is above the law, the requirements permit no exception or variation, and failure to comply can constitute a criminal offense.

With these detailed provisions and sanctions there is a high degree of probability that the requirements will be met, but there are disadvantages. In order to permit a reliable prosecution or defense under law, very detailed records must be kept and a heavy bureaucracy is usually evident, and severe inspection requirements of both manufacturers and products impose costs, however inappropriate they may be for some products. To make changes in the law to take account of some new development requires passage through the full legislative process, which in all countries seems to take a great deal of time. This inflexibility of the legislative approach may easily delay the introduction of new technologies and, in my experience, is often used as a barrier to the entry of products made in foreign countries.

In the United Kingdom, there are no legislative requirements for medical devices other than for medicines, dental filling materials with a pharmaceutical action, intrauterine contraceptive devices, and contact lens fluids. We still want all medical devices to be safe and we still need sanctions but the sanction we invoke is an economic one. To make this work, the purchasers of medical devices must have a clear understanding of which products are satisfactory and must be educated and persuaded to buy only those.

There are three main parts to our system:

1. defining the safety requirements for major products or classes of product;
2. identifying manufacturers who are able to make products in accordance with those requirements; and
3. discovering any unsafe products so that warning and corrective action can be taken quickly.

PRODUCT STANDARDS

The requirements for products are embodied in standards and a suitable body of product standards is the foundation of any regulatory arrangement. A standard should represent the consensus of all interests and should be available to all.

A vigorous standards-writing activity is carried on within the British Standards Institution; more than 200 British standards for medical products have been published; 110 standards-writing committees are at work; and members of my Department are active in most of these committees.

Within the past 15 years or so, a substantial program of standards-making has grown up in the International Electrotechnical Commission and the International Organization for Standardization. The use of international standards is an important feature of United Kingdom standards activity and we are fully committed to participation in international standards work and the adoption of international standards.

COMPLIANCE WITH STANDARDS

Medical devices must comply with safety standards. In a legislative system, it is normally mandatory for them to do so. Compliance must then be without any uncertainty, and checking for compliance normally involves detailed testing of one or more examples of the products, possibly user trials, examination of manufacturing processes, and periodic sampling and testing of routine production.

Even if standards existed for all medical devices, measures as intensive as this for assuring conformity could not be contemplated. The demand for increased regulation of medical devices coincides with pressure to reduce public expenditure, and in order to establish any system it is necessary to demonstrate that it is efficient, economical and appropriate to the products under consideration. It follows that the emphasis may be different for different types of products and in different national situations.

In our nonlegislative system, we rely on the commercial pressures exerted by informed purchasers: "purchasing muscle." We advise all purchasers to demand from the manufacturers declarations of compliance with appropriate standards and to make compliance a part of the purchasing contract.

We increase confidence in the manufacturers' declarations by two steps: publishing a register of manufacturers whose quality assurance procedures are such that they can give declarations with a high degree of reliability, and publishing details of products that are found to be unsafe.

MANUFACTURER REGISTRATION SCHEME

The problems of registration are simplified if products can be gathered into a few large classes with general characteristics that can be the subject of general requirements, even though individual requirements may not exist.

The first class of devices identified in the United Kingdom was that of sterile products. For these products, sterility is the key characteristic and we learned some years ago that testing of finished products is not a sensible approach to assuring the sterility of devices made in large quantities. For these, only satisfactory standards of manufacturing, sterilization, and packaging could give the assurances we needed. Definitions of satisfactory standards for these processes are incorporated in a document drafted jointly by the Department of Health and Social Security and the major British trade associations and published first in 1979 and, slightly amended, in 1981 under the title of "Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products" (*1*).

This document forms the basis of the United Kingdom Manufacturer Registration Scheme which has been operating since 1982. Under this scheme, manufacturers whose manufacturing procedures are in line with the Guide are named on a register that is made available to the National Health Service. This register has been issued regularly since February 1983 and NHS purchasing officers are advised to buy only from manufacturers on this register.

The second, and major, class of device that we have identified is that which we call medical equipment - the definition being a medical device that depends on an external power source for its function. The safety requirements for this class have many common elements, as has been recognized by the IEC, which has produced IEC Publication 601-1 (2), embodying most of the requirements for medical electrical equipment that dominates this class. (The principles of IEC601-1 can easily be applied to the few examples of devices powered by sources other than electricity.)

Just as the safety requirements for medical equipment have many common elements, so have the manufacturing processes and the quality assurance requirements. We have found it possible to produce a GMP document for medical equipment (3) in conjunction with the United Kingdom Trade Associations. This document was published in 1983 and our manufacturer register was extended to include makers of medical equipment in 1985. The number of manufacturers is thought to be approximately 500 and the periodic inspection of these can be achieved with a modest resource.

Our GMP document is based on the British Standard for Quality assurance, BS5750, which is itself based on a NATO standard and is under consideration in ISO so that we have high hopes of eventual international acceptance. In drafting this document we also recognized that the Americans have had a GMP regulation in force for almost 10 years and are our major trading partner in medical equipment. We therefore added some clauses to BS5750 in an attempt to achieve compatibility with U.S. requirements and we now have reached an agreement with our American colleagues about mutual recognition of our inspection procedures. We are optimistic that economies for both regulatory authorities and for manufacturers can be achieved in this way and we hope to extend our mutual recognition arrangements to authorities in other countries.

Two other major classes of medical devices have been identified. The first of these is the nonsterile nonpowered medical device. In this class we have in mind devices to assist handicapped persons. Although these are important products, their construction is generally simple and the quality assurance requirements are not onerous. We are at present discussing with manufacturers the applicability of Part 3 of BS5750, which calls only for final inspection arrangements, to this class. The remaining class is diagnostic reagents and kits. Although manufacturers' organizations have begun laying the groundwork, a GMP has not been considered by DHSS as attention has so far been concentrated on the other classes.

The current state of the introduction of the Manufacturer Registration Scheme is shown in Table 1 and addresses from which further information can be obtained are listed blow Table 1.

Table 1. Manufacturer Registration Schemes

Product range	GMP guide	Registration
Sterile medical devices & surgical products	Published by HMSO 9/81	Register first published 2/83 regularly updated
Implantable cardiac pacemakers	Published by HMSO 11/81	Register first published 2/83 regularly updated
Medical equipment	Published by HMSO 6/83	Register entries first incl. 3/86
Orthopedic implants	Published by HMSO 2/84	Register entries first incl. 3/86
Walking aids	BS5750, part 2	1987
Surgical appliances	BS5750, part 2	To be announced
Wheelchairs	BS5750, part 2	To be announced

For information on products covered by the Medicines Act, contact:
Department of Health and Social Security, Medicines Division
Market Towers
1 Nine Elms Lane
London SW18 5NQ

For information on the Manufacturer's Registration Scheme, contact:
The Registration Scheme Officer
Department of Health and Social Security
14 Russell Square
London WC1V 6HB

IMPLANTED DEVICES

Regular inspections of manufacturers against a GMP document can be used to verify that the manufacturer is aware of the standards/requirements for the products that he makes; that his design and construction processes are aimed at producing products in conformity with those standards; and that his inspection procedures include adequate checks for conformity. Nevertheless, there remain some devices for which we may wish to add supplementary requirements to assure their safety and satisfaction. Implanted devices, which are increasing in number and variety, are seen as presenting special problems as in most cases it is not possible to ensure their adequate performance for a reasonable lifetime before they are used in patients.

We have developed special GMP documents for implanted cardiac pacemakers (4) and orthopedic implants (6). These GMP documents are essentially identical to that for medical equipment, but they impose special requirements for the traceability of components and record-keeping. They also allow the inspectors to seek and examine evidence of satisfactory laboratory, animal, and clinical trials.

The registration of manufacturers of these implanted devices is further supported by registration of the products themselves. Product registration requires the manufacturer to describe the technical characteristics of each device and clarify model number identifications. Some of those data are made available to purchasers and form part of the

purchasing contract. We also operate an implant/explant data bank for pacemakers which permits early warning of problems with any particular model and the identification of other recipients if any remedial action is necessary.

This approach goes some way towards meeting the special problems caused by implanted devices without being too onerous or introducing greater delays in introducing new devices. It is the model for a more general approach to the control of implanted devices now being considered in the United Kingdom.

Those which have been selected for special attention are: heart valve substitutes, vascular prostheses, drug delivery systems, intracranial shunts and valves, cardiac pacemakers and defibrillators, and extended-wear contact lenses. The procedures that have been suggested as necessary include: manufacturing procedures against a suitable Guide to Good Manufacturing Practices (such as that for pacemakers), product registration after the production of evidence of satisfactory clinical trials, controlled release of new products into general service initially through a chosen center under consistent conditions and with organized followup, and an implantation/explantation data bank for each class of product.

Discussion at present centers around the definition of "evidence of satisfactory clinical trials" and the feasibility of introducing controlled release of new products. These questions are now the focus of attention within the United Kingdom and are likely to be resolved during 1986.

DEFECTS

For many years there has been an Instruction to the National Health Service that any fault in a medical device that presents, or could lead to, a hazard to a patient or to a member of staff must be reported to the Director of Scientific and Technical Services at the DHSS. Approximately 1000 such defects are reported each year. Every one is investigated as a priority activity. Fortunately, many of these turn out to be non-systematic events without the need for followup. Another large proportion consists of relatively minor faults that may be sufficiently corrected, without need for the issuance of warnings or the need for retrospective action.

Some 10 percent of reported incidents call for warnings to be issued to the National Health Service. The organization of the NHS lends itself to the rapid dissemination of information and a system of warning notices on three levels of urgency has become well established. For several years, no warnings at the top level (Hazard Priority) have been issued. The numbers at the second level (Hazard Notice) and at the third level (Safety Information Bulletin) are shown in Table 2.

While these statistics have to be regarded as understating the number of defects in medical equipment in the National Health Service, they do offer some confirmation that the measures we are taking in the United Kingdom are in proportion to the apparent seriousness of the problem.

Table 2. Defective medical products reported to the DHSS

Year	Number of reports	Warnings issued via Safety Information Bulletins (SIB's)	Urgent warnings issued via Health Hazard Notices (HN's)
1982	969	79	13
1983	916	57	7
1984	908	51	16
1985	1011	48	9
1986*	223	30	5

* Year to date

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IIC4. HOMOLOGATION

E. R. Sachot

The increasing sophistication of medical equipment, associated with the fact that the "final consumer" is not in a position to evaluate its safety and effectiveness, has led some countries to set up a system to assure a minimum level of quality of marketed equipment. The rationale for doing so is briefly explained. The systems differ from country to country; main differences are shown. The French system for approval, called Homologation, is described. It is based on technical and clinical tests in order to check compliance with standards required for medical functions. In operation for 3 years, Homologation has had a positive effect on the performance and safety of devices. In some cases it allows the precise definition of the field of application.

NECESSITY FOR REGULATION OF MEDICAL DEVICES

In most developed countries, the necessity for drug regulation first became apparent approximately 50 years ago. Since that time, the relations between manufacturers and regulatory agencies have resulted in a cooperation that has been beneficial to both industry and users.

For biomedical devices, innovation has been so complex and original, that almost every new piece of equipment arriving in the marketplace represented a breakthrough in technology and health care. Even if the quality was not exemplary, it nevertheless represented an improvement for the benefit of mankind.

In the meantime, the concepts of reliability and quality assurance progressed rapidly in other advanced technologies, as, for example, in space and aeronautics. At this point, I would like to emphasize a few fundamental particularities of biomedical technology as compared to other advanced technologies.

1. For most advanced technologies, the buyer, the user, and other consumers are generally clearly identified. For biomedical technology there exists an inherent confusion of roles due to the social coverage of health care expenses.

2. The buyer of typical advanced technology has a high level of technical competence, while for biomedical technology the manufacturer's technical competence generally prevails.

3. The manufacturers and subcontractors involved in typical advanced technologies are able to handle reliability and quality assurance (in a system defined by buyers).

There is a great diversity in size and management of biomedical manufacturers and this results in a heterogeneity of ability to handle reliability and quality assurance. For typical advanced technologies, quality assurance considerations can be specified in the procurement process. Thus, contracts may include detailed specifications of:

1. performance,
2. reliability,
3. safety,
4. lifetime,
5. life cycle costs, etc.,

and also may impose detailed management rules for:

1. component selection,
2. subcontractor qualification,
3. quality management plan, and
4. detailed maintenance and training programs,

and may even include incentive clauses providing for a sharing between manufacturers and buyers of the financial benefits resulting from fulfillment of the objectives on or ahead of schedule. But for biomedical technologies, the delicate manufacturer-buyer relationships make application of those types of contractual clauses unlikely in the foreseeable future.

Because biomedical devices are not equivalent to devices produced from other advanced technologies, biomedical devices cannot be considered as common devices. For these common devices, where there is no implication that they are designed to support life, they have minimum social effects and the judgment of "good/not good" is easy to make. Free market rules can apply and, when necessary, minimum controls regarding safety and application of standards. We must nevertheless be aware of the importance of emotional criteria such as fashion and impression.

Medical device regulatory authorities must find an effective and practical way to provide the necessary assurance of device quality (including safety, reliability, and quality assurance).

GOALS OF REGULATION

The aim of medical device regulation is simply to be sure that correct answers are given to the four following questions:

1. Is the device safe enough for patient and personnel?
2. Will the device perform adequately for its intended use?
3. For a life-supporting device, is the reliability sufficient not to give unrealistic confidence?
4. For a complex and expensive device (with high operating costs), is the reliability adapted to the operational intended use?

In the long term, we can think of an ideal system of regulation that would answer the four previous questions and that would offer assurance of correct answers for every device in use or on the market, for a minimum additional cost, and that could preferably be a largely internationally harmonized system.

HOMOLOGATION

Because we are far from this ideal situation, each country must devise a compromise regulatory system, taking into account its specific market and industry. I'll now present the French Homologation. First, I must make a point of language. Homologation is a French term and I am not sure that the simple anglicization is a good translation. I didn't find it in any dictionary. This can be an explanation of the fact that French Homologation is sometimes not fully understood. For that reason, I shall say either Homologation or "approval."

This approval is mandatory for public hospitals and it applies to devices belonging to a limited and official list. I have summarized this official list below.

1. Medical imagery (x-ray tubes and generators, ultrasound imaging systems);
2. Surgical theater (electro-surgical units, lasers);
3. Anesthesia-resuscitation (ventilators, pumps);
4. Functional supply (hearing aids, pacemakers, artificial kidneys, chronotherapy pump); and
5. Function analysis and monitoring.

This list is progressively amended by inclusion and exclusion of devices.

What is the consistency of this approval? The interministerial decision setting up the approval is the "arrete" of December 9, 1982, which says "the approval will be given to devices after:

"technical and clinical tests in order to check their compliance with French standards, their safety in regard to patients and users, and their fitting to the use expected by patient and user, and

"examination of quality control rules used by manufacturers."

Tests are conducted in two phases.

1. Technical tests are performed by an official test laboratory, mainly GLEM. They concern compliance with such standards as IEC601, NFC 74.304, specific French standards or technical specifications when no standard exists, and checking of announced performances and manufacturers' notices.

2. Clinical tests are performed at two sites chosen at random from selected hospital services. (The manufacturer or suplier is able to ask for a third test in another site.) Clinical tests, by definition, occur when the device is in a condition of real use by routine personnel and the device is linked to the patient. The tests are conducted according to a protocol specific to each category of equipment.

The results of those tests are examined by the National Homologation Commission and the Ministry of Health, which can approve the device for a period not exceeding 5 years. If a device is disapproved, the manufacturer is notified of the reason for disapproval.

The holder of the approval has certain obligations. The holder must provide a sample of the device, accompanied by relevant disposables, and must pay for any expenses. The holder must also provide information regarding device life, mainly modifications and major failures, must assure conformity of commercialized devices to the approved model, and must provide for after-sale customer service.

For each approved device, an Identification Bulletin defining characteristics, performances and field of application is issued and approved.

During the lifetime of each piece of equipment, it is very important for the regulatory agency to be aware of incidents occurring in its use. For that purpose, an alert sheet has been developed and will be operational in the near future.

In conclusion, I would like to summarize the impact of Homologation in France in 1985:

1. Approximately 50 percent of the devices (including notices and labelling), had to be modified after technical tests.

2. Among a sample of 124 devices, the clinical tests resulted in:
   - modification of 33, 11 for vital risks;
   - restriction of field of application for 18;
   - modification of ergonomy for 3; and
   - modification of notices and labelling for 23.

These figures do not include one official device disapproval and devices that were withdrawn from the procedure by the manufacturer.

IIC5. REGISTRATION: REGULATORY CONTROL OF MEDICAL/SURGICAL PRODUCTS IN ITALY

A. Sargenti

The Italian government, like that of many other countries, devotes considerable attention to the safety and health of its citizens. In the field of biomedical technology particularly, there is a continuing trend to introduce, wherever possible, regulatory criteria that promote quality control for the medical device production processes and that promote high quality medical devices.

Considerable progress is being made in Italy in this field. The health authorities are undertaking a process of rationalization and of improvement of the regulatory processes that takes into account the situation in other countries.

Italy was the first country in Europe to study the problem of medical technology regulation, the basis of which was laid more than 50 years ago in law n. 1070, dated June 23, 1927, and consolidated in the Health Text-Law dated July 27, 1934.

These laws stipulate that devices manufactured in Italy must be produced at manufacturing sites authorized by the Ministry of Health, after visits by inspectors who ensure that the plant can produce devices in accordance with the rules of good manufacturing practice. The law does not require authorization of foreign plants manufacturing medical/surgical products.

In compliance with these laws, medical/surgical products manufactured in Italy or elsewhere must be submitted to the Ministry of Health for registration before marketing. These laws do not provide a definition of medical/surgical products, they merely list the product concerned. The number of devices listed, which are contained in the law of 1934, has gradually increased with the issuance of successive legislative decrees and has come to include extremely heterogeneous products. These products include:

pessaries;
irrigators, douches, syringes, vaginal insufflators, and vaginal cannulae;
disinfectants and substances such as bactericides or germicides;
appliances for controlling hernias affecting the intestines and the abdominal organs;
hearing aids, ear trumpets, and the like;
insecticides;
tubes, oxygen masks, and resuscitation appliances;
insect repellants;
disposable plastic syringes;
non-pharmaceutical products containing hexachlorophene;
plastic dripsets for blood and blood components;
plastic containers for blood and blood components;
plastic containers for saline and other solutions;
plastic drips for saline and other solutions;
tubing, containers and other equipment for dialysis appliances, including membranes;
tubing and parts for extracorporeal circulatory appliances;
catheters for cardiology and vascular prostheses;
electrodes for pacemakers;
orthopedic shoes for children;
eyedrops, eyebaths, and disinfectant solutions for contact lenses;

oral hygiene products containing fluorine;
mice and rat poison for household and public use;
intrauterine contraceptives;
slug-killers and insecticides for use on flowers and in the garden;
post-operational drainage catheters, stomach tubes, and breathing tubes; and
fungicides, slug-killers, and insecticides for flowers and gardening for outdoor and indoor use.

The same laws lay down rules for successive registration application.

If one considers the law at the time when regulations in this field were first formulated in Italy, even allowing for the fact that the list of medical devices has been updated, it is clear that the regulations have not taken account of technological advances and that the list of products for which registration is mandatory must be changed, as must the registration rules.

In light of these developments, the Italian government has recently approved a decree of the Minister of Health (n. 128 dated March 13, 1986) that contains the new Italian regulation of medical/surgical products. For the moment, there is no change regarding the authorization of production. Authorization is mandatory only for Italian plants. The most significant differences between the new and the old regulation can be summarized in four general points:

1. Registration - Authorization for Marketing;
2. Classification of the medical/surgical products in 3 groups
   a. chemical medical/surgical products
   b. medical devices, and
   c. in vitro diagnostic preparations;
3. Definition and classification of the products belonging to every group;
4. Registration of a single product.

Chemical medical/surgical products are defined as products to be used on humans or animals in domestic or work environments, and which contain one or more substances with disinfecting, disinfesting, insect repelling, detergent, or preserving properties, or with spermicide or other chemical contraceptive action. Sutures and other absorbable materials also belong to this class.

Medical devices, whose principal effect is not produced chemically or pharmaceutically, are defined as instruments, appliances, devices or the like designed for direct use in the diagnosis, treatment, prevention, and cure of illnesses and specific physiological conditions.

In vitro diagnostic preparations are products used for diagnostic laboratory testing and during physicians' house calls.

Classification of Chemical, Medical, Surgical Products

Class I - Disinfectants designed for human and animal use
Class II - Disinfectants designed for use on objects and in the environment
Class III - insecticides, insect repellants, and disinfectants designed for human and animal use
Class IV - Insecticides, insect repellants, and disinfectants for the environment, and other products intended to counteract animal and vegetable

organisms which are harmful to the environment, with the exclusion of products referred to in the regulation approved by D.P.R. in the August 3, 1968, decree n. 1255, and in its implementing measures

Class V - Products for the disinfecting, cleaning, preserving and lubricating of instruments and items to be used on the human body

Class VI - Spermicides and other products with similar contraceptive properties

Class VII - Products not pertaining to the above-mentioned classes

Classification of Medical Devices

Class A - Devices or products for personal external use, which do not have their own energy supply, and with the ability to support, limit, etc., provided for exclusively by mechanical means

Class B - Devices or products for the measurement, auscultation, or recording of organic function relevant to health

Class C - Devices or products without their own energy supply, designed to be introduced into the body by means of temporary connection, insertion, or penetration

Class D - Devices or products as defined in Class C, but whose introduction into the body is long term

Class E - Devices or products for personal external use, equipped with their own energy supply, with the function of electrical or mechanical stimulation or as an aid to motory or sensory deficiencies

Class F - Devices or products for personal internal use, equipped with their own energy supply, with analogous functions to those of Class E, but whose introduction into the body requires surgery

Class G - Equipment or instruments provided with their own energy supply, and designed to be connected or applied to the body for diagnostic, therapeutic or rehabilitation purposes

Class H - Devices or products for orthodontic use designed to be introduced into the oral cavity

Classification of In Vitro Diagnostic Preparations

Class 1 - Products for diagnostic tests in the laboratory, for human and veterinary use

Class 2 - Products for diagnostic tests "in vitro" for home use, for human and veterinary purposes

This new decree (n. 128) provides that the Minister of Health will promulgate a decree for a single product or a type of product for which the authorization for marketing is mandatory and in the same decree there will be an indication of conformation to the international standard if it exists, or if not, to the national standard. This decree will contain all the indications concerning the application for the authorization.

Obviously the decree will take into account every possible directive that the European Community will promulgate concerning the free market of the different kinds of products. According to the different kinds of products, the decree will define if the authorization for single product or for type of product is necessary. In the first case, the product is specified by every characteristic. In the second, only a general scheme of the product is indicated with the most important characteristics listed and, if possible,

the range of variations of the least important characteristics. Applications for authorization, together with information about the producer, the importer and the product itself (conforming to the requirements of the specific decree for that specific product), labels, and explanatory leaflets must be submitted to the Ministry of Health. While reviewing the application, the Ministry of Health can ask for any additional useful information it requires.

For the more complex and critical devices that affect human or animal interaction with the environment, and for which national or international standards have not yet been established, the Ministry of Health, on the advice of the Istituto Superiore di Sanita (which is the Technical Branch of the National Health Service), can ask the latter to carry out any investigation considered necessary to check the safety and the effectiveness of the product. In this case, one or more samples of the product must be available from the producer for technical evaluation.

Authorization for marketing a product is granted when a Ministry of Health decree is issued containing the trade name of the product, information concerning the label, and the explanatory leaflets on the product. Even when the product is on the market, the Ministry of Health has the power to arrange inspections at the production plant and to take samples from the market. If the sample chosen does not comply with the specifications on the basis of which the authorization was granted, and if the device proved to be defective in any way while in use, the Ministry can have it withdrawn from the market.

The old system of registration will continue to be valid for the medical/surgical products for which registration is mandatory today according to the previous regulation, until the moment when the specific decree is issued according to the new system of authorization. In the meantime, a working group set up by the Istituto Superiore di Sanita in which experts from the Istituto, CNR, universities, and industrial associations participate, is carrying out a study of the biomechanical instruments available on the Italian market. A classification of medical devices available on the market is being prepared, measuring every device against national and international standards, both regarding the device itself and the rules of good manufacturing practice, as well as a proposal for priority which the health authorities should consider while passing the decrees for the individual products in accordance with the new system of authorization.

In the process of classifying instruments within the single classes recognized by the regulation decree, the classifications made by other foreign institutions are being considered. Currently, the Laboratory of Biomedical Engineering is evaluating with great interest the ECRI classification and the GMP regulations, both prepared by the FDA, as well as by the technical branch of the Department of Health and Social Security in the United Kingdom.

IIC6. PREMARKET EVALUATION

A. K. DasGupta

The quality of health care is greatly dependent on the quality of devices used. The benefits from devices include: improved diagnosis, better therapy, safer self-care and home care, increased life expectancy, improved quality of life, reduced hospital stay, more effective rehabilitation, reduced cost/benefit and risk/benefit ratios, enhanced personnel efficiency, reduced pain and suffering, greater universality in health care, more reliable patient care, reduced nosocomial infections and better prevention of disease.

Unfortunately, unless adequate controls are exercised, the risks and concerns can be serious. These arise from: increasing dependence on medical devices; increasing diversity and complexity of devices; impact of new, untried technologies; limitations of technology; design, manufacturing, or materials failures; poor quality control; misleading claims; insufficient information to user; incompatibility of a device in total system; rapidly rising costs; misuse; obsolescence; lack of maintenance; inappropriate selection; and packaging and sterility problems.

The Food and Drugs Act provides exclusive authority for controlling the sale of devices in Canada. Its relevant sections are shown in the table below.

Title	Section	Contents
Definition	2	definition of a device
Diseases	3	mention of diseases listed in schedule A in advertising to the public is prohibited
Safety	19	sale of a hazardous device is prohibited
Effectiveness	20	misrepresentation in any manner or by any means is prohibited
Standards	21	claimed or implied conformity with a prescribed standard makes such compliance mandatory
Powers	22 23 24	powers of food and drugs inspectors to examine records, samples and materials
Regulations	25	powers to make regulations prescribing standards, labelling, processing, recordkeeping, testing, etc.

With the phenomenal increase in the variety and complexity of devices in recent decades, the need for a formal program to implement the provisions of the Act became evident and a Bureau of Medical Devices was established in 1974. The Medical Device Regulations were promulgated in 1975. Their main provisions are given in the table below.

Title	Sections	Contents
Labelling	6 - 13	minimum requirements for labelling
Testing	14 - 15	manufacturer must test before sale to justify claimed benefits and performance characteristics
Notification	24 - 26	a notification and updates must be submitted for devices marketed in Canada
Additional Data	27	on request, manufacturer must furnish data on: a) peformance characteristics b) accuracy, precision and reliability c) test conditions d) other data
Safety Deadline	28	on request, manufacturer must submit evidence establishing safety and effectiveness before a specified date
Recalls/complaints	29 - 31	manufacturer must maintain records of complaints, recalls, and corrective actions and notify the Director
Premarket review	32 - 41	specified new devices require review and a notice of compliance before sale
Standards	Schedules	requirements for safety, performance, and labelling of specific devices

Although the regulations allow the Department to request test results for every device sold in Canada, it is neither necessary nor possible to review the data for most of the several hundred thousand products on the market. Priorities must be set and must be based on the following factors:

1. magnitude and nature of hazard and ineffectiveness,
2. benefits from device,
3. population at risk,
4. magnitude of public and professional concern,
5. qualifications of user, and
6. potential effectiveness of regulatory action.

For devices of the highest priority it is considered necessary to evaluate the test data before the product is marketed. A special section of the regulations - Part V - lays down the requirements for premarket review. Products in this category are those for which most market corrective actions, such as recalls, do not provide adequate patient safety. Implantable devices are a case in point.

The need for premarket review of implantables was foreseen as early as 1976 when cardiac pacemakers and intrauterine devices were made subject to this procedure. Since April 1983 no new implantable devices may be sold in Canada until test results are evaluated and found to be acceptable. Manufacturers must supply the following:

1. label samples,
2. trade name and purpose,
3. performance characteristics,
4. material biocompatibility,
5. sterility,
6. manufacturing procedure, QC and packaging,
7. contraindications, and
8. results of tests, animal studies, clinical trials, or proof of probability of effectiveness in humans.

The submissions received are prioritized into the following categories for purposes of evaluation:

Category	Criteria	Evaluation Procedure
A	• device failure has a high probability of causing death or irreversible injury, • device failure may require emergency surgery for repair or revision, or • materials composition has unknown pathological potential	full scientific evaluation of evidence of sterility, biocompatability, manufacturing processes, clinical studies, as specified in guide to Part V
B	• device failure is not likely to be life threatening or cause irreversible injury, • device failure requires elective surgery for revisions or repair, or • materials composition requires routine biocompatability evaluation	scientific evaluation of selected characteristics affecting safety and performance (determined by the type of device)
C	• device failure is not hazardous but will cause inconvenience, • device failure will not require surgical intervention, or • materials composition is well known and has a good history of safe and effective performance in similar applications	verification of basic evidence of tests on safety and efficacy only

The review of the above leads to one of the following results:

Notice of compliance	authorization for general marketing
Modified device notice of compliance	authorization for general marketing valid for 1 year. The manufacturer must submit full data on safety and efficacy the end of the 1 year period
Approval for clinical trial	authorization for sale to designated investigators and centers, Valid for 1 year

Request for further information	authorization for sale cannot be granted until specific information is provided
Reject (Type 1)	the information submitted is insufficient for evaluation
Reject (Type 2)	information submitted does not support claims of safety and efficacy
Emergency release	authorization for sale of a specified quantity of a device to a named practitioner for emergency treatment of a patient

Since April 1, 1983, when all implantables were made subject to premarket review, more than 1200 premarket submissions have been processed as follows:

Year	MS Musculo-skeletal	CV Cardio-Vascular	AS Alimentary System	UG Uro-Genital	NS Nervous System	SS Special Senses	IS Immune System	Total
1983	58	88	2	5	4	120	0	277
1984	68	159	1	6	6	235	0	475
1985	157	198	2	10	4	216	2	589

Review of these submissions leads to the following conclusions:

- a high proportion of performance and safety claims are not supported by adequate tests;
- for many products of new technology, neither the benefits nor risks are fully understood before marketing;
- the profusion and growing complexity of medical devices have major impacts on health care, creating challenges and problems for hospitals, health care professionals and patients;
- the technological capability of many hospitals for judicious procurement, proper maintenance, and optimum use of devices is inadequate;
- product-related know-how resides with the manufacturer, rarely with the vendor, thus creating problems for importing countries;
- for new technology, the user is flooded with promotional literature but receives little information on performance characteristics, limitations, or other cautions;
- there is a need for mechanisms to collect, screen, and exchange device experience and evaluation results to develop selection and use criteria.

IIC7a. VOLUNTARY AND MANDATORY STANDARDS - INTERNATIONAL STANDARDS ORGANIZATION

E.A. Bridgman

I should mention at the outset that I am here on behalf of both the Association for the Advancement of Medical Instrumentation (AAMI) and the International Standards Organization (ISO). I would like to briefly describe these two organizations so that you will understand my perspective on medical device regulation and the role of standards.

AAMI is a private, nonprofit association based here in the Washington area. Our 5000 members are people who investigate, develop, manage, and use medical instrumentation. They include clinical and biomedical engineers, technical service personnel, and other health care professionals from hospitals, medical organizations, government agencies, academic and research institutions, and industry. While most of our members are from the United States, we have numerous Canadian members, and 35 other countries are represented by one or more members. In short, AAMI is an interdisciplinary medical technology organization, and a leader in the development of voluntary standards for medical devices and processes. Internationally, AAMI is responsible for the secretariat of the ISO subcommittee on cardiovascular implants.

ISO - the specialized international agency for standardization - is a nongovernmental organization based in Geneva. Its members are the national standards bodies of more than 80 countries, including for example the American National Standards Institute, the British Standards Institution, the Association Francaise de Normalization, and the Standards Council of Canada. ISO's international standards cover all fields of industrial activity except for the electrotechnical, which is addressed by the International Electrotechnical Commission (IEC).

I will tell you a little more about the specific activities of AAMI and ISO in a few moments, but first I'd like to talk about standards in general - what are they, what do they do, how are they developed.

In the simplest terms, a standard is a communication tool - a product description that is the basis of understanding between a manufacturer and a purchaser or user about the characteristics of a product. Standards take many forms. Some are simply lists of terms and definitions for a given technological field, others are very specific test methodologies. The medical device standards developed by AAMI contain both of these elements and others as well. A product standard offers a means of verifying whether specified safety and performance characteristics are met, and thus can be very useful to an agency responsible for regulating these characteristics. It is important to remember, however, that most of the medical device standards that currently exist are voluntary standards. The differences between voluntary and mandatory standards must be clearly understood, and I will discuss this at some length in a few moments.

In the United States a voluntary consensus standard is developed in accordance with due process requirements established by the American National Standards Institute. This means that all affected interest groups have the opportunity to participate, and a consensus of these groups must be demonstrated. AAMI's medical device standards are developed by balanced committees that include representatives of the health care professions, government, and industry. The FDA is represented on every one of AAMI's 21 committees, and frequently offers valuable comments to improve the quality of our standards.

I will conclude my discussion of what a standard is by describing the six elements that appear in an AAMI medical device standard.

1. Scope - describes the product covered by the standard and mentions any aspects specifically included or excluded.

2. Applicable Documents - lists the documents to which reference must be made in applying the standard. These may be other standards, regulations, or articles from the medical literature.

3. Requirements - sets forth the labeling, safety, and performance requirements that the product must meet and is the heart of the standard.

4. Tests - lists referee tests that may be used to verify product compliance with the requirements of the preceding section.

5. Glossary - presents definitions of terms used in the standard.

6. Rationale - explains why the standard was developed and why each of its provisions was included. Generally this section offers clinical and/or engineering justification for each of the requirements. It may also explain why a certain requirement was not adopted. The rationale substantially enhances the value of AAMI standards; it adds to their credibility and makes them truly educational. We feel that originating and implementing the rationale concept for standards is one of AAMI's greatest contributions to the field. In our opinion, all medical device standards, both national and international, should include rationale statements.

Having described what a standard is, let me mention a couple of things it is not, to dispel some common misconceptions. A standard - at least one that AAMI develops - is not solely an industry-oriented document. AAMI pioneered the involvement of health care professionals in the development of medical device standards; physicians and clinical engineers, among others, serve on virtually all AAMI device committees. We are committed to writing only clinically relevant standards, and we strive to accomplish this in our international standards work as well.

Another thing that a standard is not, whether it's a national or an international standard, is a stand-alone means of technology transfer. While we hope that less developed countries will take advantage of the work already done by bodies like AAMI and ISO, we know that no standard, taken alone, provides sufficient information to produce a product. On the other hand, an effective standard, backed up by additional technical information, can be an extremely useful tool in guiding a new manufacturer to produce a state-of-the-art, competitive product. I do not mean to suggest that standards have no role in technology transfer, only that they are but one element in meaningful technology transfer. We know, for instance, that Japanese medical device manufacturers have benefited from the availability of AAMI's industrial sterilization guidelines.

Before I discuss standards as potential regulatory tools let me give you a general impression of the scope of AAMI's and ISO's standards development activities. AAMI has completed nearly 30 medical device standards and recommended practices. These are primarily in the fields of cardiovascular monitoring and surgery, sterilization, equipment maintenance and electrical safety, nephrology, anesthesiology, and neurosurgery. We have another two dozen documents at various stages of drafting. One of these, which is nearly complete, covers reuse of hemodialyzers - a subject that is currently of

great concern to the FDA and that will be discussed at some length during this conference. While AAMI has not yet produced a great many documents, each addresses its subject comprehensively, as I described earlier.

ISO has published a bibliography that lists all final and draft international standards for medical equipment and materials, as of January 1986. The bibliography lists almost 250 ISO documents, 75 IEC documents, and 3 from the Organization of International Legal Metrology, OIML. The ISO standards fall into the following categories:

1. syringes for medical use and needles for injections surgical instruments

2. transfusion, infusion and injection equipment
   anesthetic and respiratory equipment

3. implants for surgery

4. prosthetics and orthotics
   dentistry

5. audiometry

6. medical radiography

7. optics and optical instruments aids for the handicapped, and

8. mechanical contraceptives.

I'd like to devote the rest of my time this morning to the use of standards, both voluntary and mandatory, in a regulatory context. AAMI and its members have given this matter a great deal of thought. In light of our extensive experience as a major developer of medical device standards, we have identified a number of key issues and concerns regarding the use of standards as regulatory tools; these have been recorded in a formal position statement that I believe contains valuable insight for the participants in this conference. I'd like to read you the major points contained in that statement.

1. Mandatory standards should be proposed only when there exists a clear need (based upon a documented rationale) and only when other less onerous voluntary or regulatory alternatives have been considered and/or utilized and determined to be inadequate for the protection of the public health.

2. There is a significant difference in the need for, objectives of, and uses of voluntary and regulatory standards. It should be understood that voluntary standards contemplate that government is only one of many users of standards and, as a result, the multiple intended uses of a voluntary standard may not serve the needs of government, the professions, and industry in a mandatory context.

3 Although specific provisions of certain voluntary standards may serve as the basis for regulatory standards, because of the differences in objectives, developmental procedures, and intended uses, any adoption of a voluntary standard for regulatory purposes must be carefully scrutinized. In many instances, the experience, knowledge, and expended resources of the industry and the professions in developing

voluntary standards may be very useful to a regulatory agency as an alternative to de novo development and acceptance of mandatory standards. Voluntary standards may often be alternatives to other forms of regulation (for example, the AAMI Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices as an alternative to sterility Good Manufacturing Practices).

4. Any mandatory standards development process must take into consideration that any voluntary or mandatory standard may be obsolete in a short period of time, and, consequently, any promulgation of a standard must inherently recognize and provide for revisions or withdrawal. It may be desirable for all mandatory standards to have provisions stating dates on which the standards will no longer be effective unless revised or reaffirmed.

5. A regulatory agency should consider adopting only those provisions of mandatory standards that are essential for regulating safety and efficacy. Some voluntary standards have been developed to cover numerous parameters of medical devices that may be useful in a voluntary context but unduly limiting in a regulatory context.

6. A regulatory agency should bear in mind that the promulgation of a mandatory standard is only the initial point of contact between the developer and the user of a standard. The process of interpretation and implementation of a mandatory standard will be as onerous and costly as the development and acceptance process. Unlike voluntary standards, mandatory standards may leave little latitude for discretion and interpretation by the professions or industry.

7. Mandatory standards for medical devices cannot be substituted for user education and practice and may, in fact, create a false sense of security. This concept is related to the need to clearly identify the reasons for a standard and to assure that the objectives of the standard and the ultimate standard respond to real and relevant needs.

8. A mandatory or voluntary standard should not exceed current manufacturing practice or the state of medical technology design or medical technology practice. In other words, standards should not try to define the ideal device or to "push" the technology.

9. Design standards should be avoided unless essential to safety and performance. Standards that prescribe criteria of performance are preferable.

In summary, AAMI believes that comprehensive mandatory standards are rarely necessary when there are or could be effective voluntary standards. A voluntary standard can, with agency "moral suasion" and regulatory creativity, accomplish almost all of the objectives of a mandatory standard at less cost to both government and industry. Other regulatory or quasi-regulatory alternatives are generally preferable to the promulgation and enforcement of a mandatory standard. The FDA, while bound by law to produce mandatory standards, has in practice, of necessity, relied largely on voluntary standards where they exist. The agency has formally acknowledged the value of voluntary standards by including them among the criteria it considers in deciding whether to initiate work on a mandatory standard.

I would like to leave you with a few key recommendations regarding your use of voluntary and mandatory standards.

1. Before proceeding with the development of a mandatory standard, be sure that no effective voluntary standard already exists, or is being developed. You will save your agency a great deal of time and money by relying on an effective voluntary standard rather than attempting to develop a mandatory one. Remember, too, that other regulatory tools, either in concert with voluntary standards or on their own, are often more appropriate than mandatory standards.

2. Participate in the voluntary standards process. Make sure your agency is kept informed about standards development activities, and contribute to them in whatever ways are most appropriate to the standards system of your country.

3. When you identify a useful voluntary standard, do not simply attempt to adopt or enforce it as a regulation. Be aware of the important differences between voluntary and mandatory standards. To state it in the strongest terms, remember that voluntary standards are not developed with the objective of regulating criminal conduct.

4. If you conclude that a mandatory standard is needed, follow these guidelines in writing it:

   a. Closely define its scope, to address only those characteristics that are essential to device safety and efficacy.

   b. Verify that the requirements you establish are clinically relevant.

   c. Write the standard in terms of product performance, not product design. Every mandatory standard requirement has the potential to restrict technological innovation and the creativity of the medical community. Applying performance rather than design criteria reduces the likelihood of such restriction.

   d. Establish a mechanism for frequent and periodic review of any promulgated mandatory standard, and ensure that your procedures enable you to readily withdraw a standard once it becomes unnecessary or obsolete.

Medical device regulatory authorities and voluntary standards organizations can and should cooperate and collaborate. Often we are pursuing the same goal, and by working together we can make our respective tasks easier and our objectives more readily achievable. It has been my objective this morning to convey this message. I hope you leave with a better appreciation of standards and their uses.

IIC7b. MEDICAL DEVICE STANDARDS INTERNATIONAL ELECTROTECHNICAL COMMISSION

G. R. Higson

IEC Technical Committee No. 62 (TC 62) is responsible for the field of electrical equipment in medical practice. It works through four standing subcommittees:

62A - Common aspects of electrical equipment in medical practice.
62B - X-ray equipment operating up to 400 kv, and accessories.
62C - High energy radiation equipment and equipment for nuclear medicine.
62D - Electromedical equipment.

Each subcommittee (SC) decides its program of work and sets up working groups (WGs) to develop the individual standards within that program. Having completed its work, the working group is disbanded. SC 62A is now up to WG 12; SC 62B is up to WG 17; SC 62C to WG 4 and 62D to WG 9. Subcommittees and working groups are composed of experts drawn from the 42 member countries and contain a mixture of manufacturers, users, and testing/regulatory authorities.

The philosophy within TC 62 has been to gather all those requirements which apply to every item of medical electrical equipment together into one publication: Publication 602 Part I, "General Requirements for the Safety of Medical Electrical Equipment" published in 1977. If a particular category of equipment has some features calling for special safety provisions, then a supplementary standard is written and published as Part 2 of IEC 601. Seven Part 2's have been published so far, four Part 2's will have been published in 1986 and seventeen Part 2's are due to be published in 1987. By the end of the decade almost all important products will have been covered. All these standards define the safety requirements for the equipment in question, describe methods of measurement and lay down acceptable values and limits.

In addition to these safety standards, aspects of performance which do not affect safety but which are important for the user to know are covered in Part 3 standards, which define those aspects that should be measured and for which measurement methods should be developed, but do not lay down limits. Eleven Part 3s are due to be published by the end of 1987 and eighteen other standards (non-602) have been published by TC 62.

Regulatory authorities worldwide are urged to discourage the development of national standards and to encourage the adoption of international standards in their countries. They should if possible take part in the international standards work. In this way, the available expertise in the world is shared for the benefit of all, wasteful duplication of effort is avoided and technical barriers to trade are minimized.

IEC standards should be available through your national standards organization, but can be obtained directly from the IEC Central Office, 3 rue de Varembe, 1211 Geneva 20, Switzerland.

Further information about the work of TC 62 is available from the Secretary, Ms. H. Bertheau, Postfach 630121, D-2000 Hamburg 13, Germany.

IIC8. GOOD MANUFACTURING PRACTICES

W. Gundaker

I would like to discuss briefly the medical device Good Manufacturing Practice regulations that are applicable to products that are manufactured or imported into the United States. I hope you will observe that these regulations are a valuable tool in assuring safe products. I will state right up front, however, that they are clearly not the entire answer to solving our public health problems.

The Food and Drug Administration has used Good Manufacturing Practice regulations for more than 20 years. With the passage of the Food, Drug, and Cosmetic Act in 1938, FDA had for the first time the authority to establish and impose reasonable sanitation standards on the production of foods, drugs, and cosmetics. The first drug GMPs were published in 1963 and they have undergone several revisions since then. In 1969 FDA promulgated Good Manufacturing Practice regulations for the manufacture of foods and they too have been revised since then. GMPs for blood and blood components were published in 1975 and as you will note, the Medical Device GMPs became effective in 1978. Thus, we have been enforcing this regulation for 8 years.

The purpose of the Medical Device GMPs is to provide a framework of manufacturing controls. We believe that manufacturers who adhere to these controls increase the probability that devices produced under these GMPs will conform to their established specifications. This means that if the medical device has been properly designed, the GMPs will ensure that there is consisent manufacture of that product with the appropriate quality control checks prior to distribution and use.

One other term that we use regarding these regulations is that they are "umbrella" controls. The term "umbrella" signifies that the GMPs apply to all device manufacturers. Since the industry is diverse and manufacturing processes vary significantly, we established a very general standard for manufacturing practices that took into account the complexity and diversity of the many products. The rule was designed so it would apply to all manufacturers and would avoid prescribing specifically to each of them the precise details of what must be done.

You will also note that the title of our regulations contain the word "current" as in "current good manufacturing practice." We consider that practices that are feasible and valuable means the same as current and good. Therefore, practices which are believed by experts to be feasible and valuable are by definition GMP requirements even if the practices are not followed by a majority of manufacturers. Therefore, the definition of current good manufacturing practices is not the lowest common denominator. Also, as times change, the definition of current will vary depending upon the state-of-the-art, available test equipment, and other quality control practices. Thus, what is feasible and valuable today will change over time.

The device GMP regulation includes several basic concepts. These include the following.

1. Adequate specifications and procedures (called the device master record) must describe the device and manufacturing process so that all employees know what to do in the manufacturing process.
2. Adequate training and process controls must be established and implemented to ensure that all activities are carried out properly.

3. A device history record must contain objective evidence demonstrating that all devices were manufactured in accordance with the device master record.

4. Experience with devices must be fed back into the quality assurance system so that, as necessary, changes can be made in the device or the manufacturing program to correct existing deficiencies that caused the nonconforming products.

5. Critcal devices present special hazards should they fail and therefore require additional manufacturing controls. Thus, we have a two tier GMP regulation in which some products, primarily implants, require special controls.

The regulation itself covers:

1. organization and personnel, which includes the requirement that firms conduct periodic audits of the quality control program;

2. building requirements such as adequate space and environmental controls;

3. equipment specifications, including a written schedule of maintenance and calibration;

4. control of components, including procedures for accepting, sampling, and testing and inspection of all lots of critical components;

5. production and process controls with particular emphasis on controlling any specification changes as a device is produced over a period of time;

6. packaging and labeling controls necessary to maintain the integrity and to prevent labeling mixup;

7. holding, distribution, and installation instructions, including written procedures for warehouse control and distribution of finished devices.

8. device evaluation, including written procedures for finished device inspection to ensure that the device meets the specifications; and

9. records maintenance in the manufacturing establishment or a reasonably accessible location. We require that records pertaining to the device be kept for the expected life of the device or at least a minimun of 2 years.

The current Good Manufacturing Practice regulation is a valuable tool in assuring safe devices. However, there are several things that the GMP does not cover and perhaps the most important is the design of the device itself. If the device should be poorly designed, the GMP program, if properly implemented, would simply assure that the poor design is consistently manufactured. In a similar fashion, if the manufacturing process is poorly designed, the GMP regulation that we presently have will not be useful in detecting that condition.

The device GMPs also do not apply to manufacturers of components who do not manufacture exclusively for use in medical devices. This includes basic component manufacturers such as electrical components, nuts and bolts, etc. The regulation also does not apply to manufacturers of human blood or blood components, which, as I mentioned earlier, are covered by separate GMPs published in 1977.

At this point I should note that the FDA is taking several steps to address the situation in which the device and process designs are not covered by the GMPs. We are currently developing a process validation document that will be useful in assessing the manufacturing process design. We are also developing guidelines for the preproduction design phases of the development of a medical device.

Having promulgated the regulation in 1978, there certainly is a cost of determining if manufacturers are complying with it. At the present time we are performing 1500 inspections per year to determine if manufacturers are meeting this regulation. These inspections are performed by our investigators in our FDA District Offices across the country. If we were to total up all of the operational resources that it takes to conduct these inspections, it would amount to about 70 person-years.

One method we have used to determine the effectiveness of these regulations has been to look at our experience with the recall of medical devices over the last several years. Manufacturers voluntarily conduct recalls of defective medical devices and the FDA keeps a close tab on them to determine what they are doing and why. We also look closely at the possible causes for these recalls and it is our estimate that approximately 43 percent of the recalls are attributable to manufacturers' failing to comply with the GMP regulation in some manner. Significantly, we believe approximately 51 percent of the recalls are being prompted by a failure of preproduction controls, which as I mentioned are not covered by the GMP regulation (See fig. *1*).

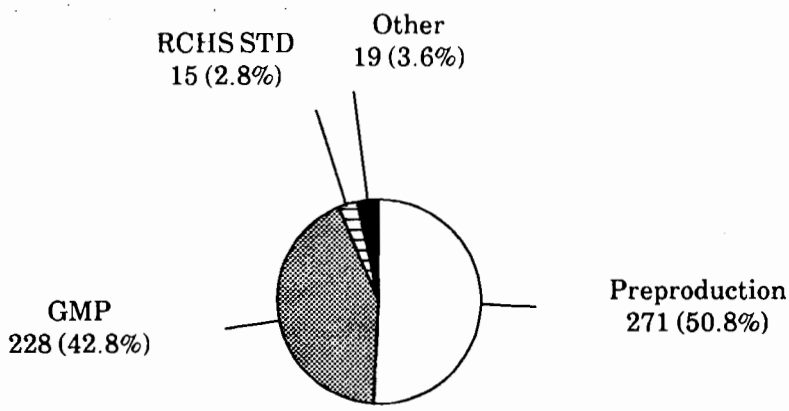

Figure 1. Problem Cause Data System: types of recall problems

Figure 2 provides a quick glimpse at the specific problems related to the GMP violations based upon our analysis of recent recalls. You will see that most of the problems are because of production difficulties caused by improper selection of components and labeling mixups. Poor change control procedures are also having an impact.

In summary, I hope I have given you a quick look at this basic tool used to assure that medical devices have adequate production and quality assurance controls. I look forward to our discussions of GMPs and the other tools of managing medical devices.

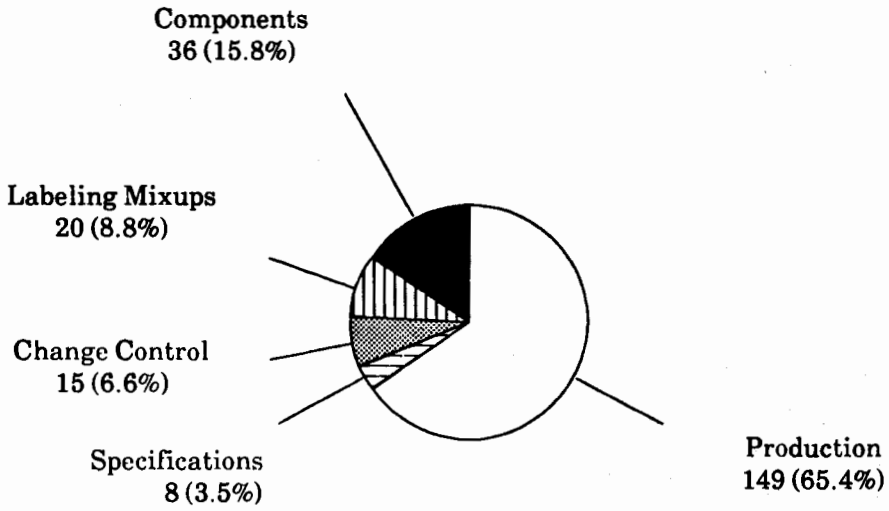

Figure 2. Problem Cause Data System: recalls related to GMP problems

IIC9. POSTMARKET SURVEILLANCE

K. G. Melin

During the lifespan of a medical device the responsiblity for its safety and effectiveness moves from the manufacturer towards the user. The manufacturer is responsible for the continuous performance of his equipment only under conditions that he states in the user's manual. The users must take good care of their equipment, maintain it, and train their personnel in its proper use. We consider it natural for a manufacturer to comply with good manufacturing practices or GMPs. The user should follow up with good user practices or GUPs.

PRE-USE INSPECTION

After procurement but before a medical device is used for the first time it must be inspected. If it is installed, the installation as well must be inspected. Our experience is that up to 40 to 50 percent of all medical equipment delivered to a hospital has some kind of defect that must be corrected before use. We consider it a serious defect if the equipment is not supplied with a correct and easy to use manual. The user's manual should describe not only the use of the equipment, but also how to control its functions, and information on safety. This should be carefully examined and assimilated before the device is used on a patient.

To ensure that the equipment continues to be safe and functions properly, a program for inspection and maintenance is mandatory. An important part of such a program is the inventory and report (IR) system. The amount of equipment in a modern hospital makes it necessary to use a computer to run an efficient IR system. Information available from such a system includes data on reliability of equipment, causes of service calls, cost, and downtime. The IR system is also an important tool for finding equipment mentioned in hazard reports.

All medical devices must be registered at arrival. Reports on inspections and maintenance, as well as observations on malfunctions and accidents, must be entered in the system.

A basic IR system has an inventory register for static information about the individual devices in a hospital or a health care region. It is important to use a standardized nomenclature and coding system to enable record searches. A second part of the IR system is the report register. This is used every time a device has been repaired or controlled. The report and inventory registers should be organized for easy processing of data.

NATIONAL HAZARD REPORTS

Information from a well managed IR system has a great impact on the safety of medical devices in the organization covered by the system. A national system to control the safety and effectiveness of medical devices must be based on a national report system. All parts of the national health care system must be encouraged to report incidents, accidents, or observations concerning the safe use of medical equipment. The national hazard report system must be run by an organization with access to qualified experts. All reports should be investigated in cooperation with the user and manufacturer.

It must be stressed that the main objective for a hazard report investigation is to improve safety, not to find a scapegoat. It is important that equipment as well as disposables involved in an accident or incident be saved for an investigation and not repaired or thrown away. It is also important that personnel involved write down their observations as soon as possible. If the accident is serious, an investigation team should be available without delay.

Information obtained from hazard investigations is used in several ways. Users are alerted to take precautions, to control or modify equipment, or to inform personnel about restrictions in use. Evaluation of hazard reports over a period of time may provide insight into problem areas and problem devices, and suggest corrective actions to be taken.

To facilitate the analysis of hazard reports we have developed a computerized system where every report is classified according to:

1. type of equipment (electromedical, x-ray, lab, implants, etc.);
2. situation (test, use, inspection, etc.);
3. level of risk (critical, serious, minor risk, no risk);
4. cause of incident (design, manufacture, documentation, wrong use, wear, bad maintenance); and
5. suggested measures to prevent similar incidents (redesign, type test, inspection before use, training, GMP, etc).

INTERNATIONAL REPORT SYSTEM

The market for medical devices is international. It is thus important that national centers for hazard reporting and evaluation establish an international information network. I sincerely hope that this conference will promote an international exchange of critical information on medical devices.

IIC10. COMPARATIVE EVALUATION OF MEDICAL EQUIPMENT IN THE EUROPEAN COMMUNITY

B. van Eijnsbergen

INTRODUCTION

The European Community (EC) was founded by six European countries in 1957 in the Treaty of Rome. With the recent admission of Spain and Portugal, the EC now consists of 12 countries. The goals of the EC mentioned in the Treaty were: harmonic development of economic activities, steady and balanced expansion, increased stability, and an improved standard of living.

It should be emphasized that the original treaty was entirely oriented towards economic and industrial activities; health care was not even mentioned.

The structure of the EC is similar to that found in various countries' governments. Decisions are taken by a council of ministers, controlled by a European Parliament. Initiatives, preparations, and executions of orders are handled by the Commission.

Since 1970, the EC has had financial means of its own, derived from taxes on agricultural products, import taxes on goods entering the EC and 1 percent of the value added tax (VAT) in all EC countries. This amounts to approximately 2 percent of the total public spending in the member states. In 1983, the total budget was about 24 billion ECU's (1 ECU = $1).

RESEARCH IN THE EC

In 1974 the Council decided to develop a general policy in the field of science and technology. This field initially included energy, agriculture, and the environment, but was later extended to raw materials, social and sociological areas, and development aid.

Research projects that come before the EC are evaluated using criteria from three categories: the effect of the project on the general political and legal framework of the community and vice versa; the general aspects of project effectiveness, transnational nature, large market potential, and common requirements so that projects satisfy needs common to all member states; and specific criteria, to be used as a checklist.

The specific criteria are: cost too high for one country; national R&D capacity insufficient; combination of national and international research yields a greater efficiency; R&D is in initial phase and there is potential for international co-operation; a community project has innovative power; the research is part of a pilot project; EC funding prevents divergence in R&D policy or long-term goals supplemental to national short-term R&D-goals; the project seeks to standardize and harmonize methods, measures, and information systems; the project requires supranational service and infrastructure, databanks, etc.

It is obvious that there is some overlap in these criteria, but they can be useful in the decision-making process. Implementation of research activities in the EC is done in the following three different ways.

1. Direct action, through the operation of a joint research center. There are four such centers: Ispra, Italy; Geel, Belgium; Petten, The Netherlands; and Karlsruhe, FRG. Direct actions account for approximately 23 percent of the total R&D budget.

2. Indirect actions, operating through research contracts with institutions and industry. ESPRIT (European Strategic Programme for Research and Development in Information Technology) is a recent example. Indirect actions account for approximately 75 percent of the total R&D budget.

3. Concerted actions, in which programs are defined in general, but the individual components and activities are financed by the member states. Concerted actions represent approximately 2 percent of the total R&D budget.

Presently, EC research is being performed under the Framework Program (1984-1987), which was approved by the council in 1983. This framework defines seven community goals as listed below.

1. promoting agricultural competitiveness,
2. promoting industrial competitiveness,
3. improving management of raw materials,
4 improving management of energy resources and reducing energy dependence,
5. reinforcing development aid,
6. improving living and working conditions, and
8. improving the efficacy of EC's scientific and technical potential.

Medical and biomedical research comes under the heading "improving living and working conditions."

MEDICAL RESEARCH

The Scientific and Technical Research Committee (CREST) was set up in 1974 to co-ordinate medical research at policy level and to improve common action and program management in this field. CREST, composed of senior officials of the member states, advises both the Commission and the Council and is suported by the General Committee on Medical and Public Health Research (CC-CRM).

This GC-CRM is assisted by four concerted action committees (COMAC's), composed of experts nominated by the competent authorities of the member states. These COMAC's are: Epidemiology, statistics and clinical trials (EPID); Biomedical engineering, evaluation of technology transfer and standardization (BME); Applied biology, physiology and biochemistry (BIOL); and Health services research (HRS). The task of these COMAC's can be described as initiating and preparing proposals, supervising and evaluating the progress of projects, giving guidance to the project leader, and taking care of clerical details. The COMACs are assisted by the staff of the Commission and by a secretary, and they advise the CG-CRM, which approves the proposals."

The EC does not finance research work, but provides funds for the co-ordination of research that is already funded out of national sources. The number of medical research programs in the EC are growing rapidly. In 1981 the program was composed of three concerted actions and 230 participating national institutions. In 1983, the program was composed of 33 concerted actions and more than 860 institutions.

THE BIOMEDICAL ENGINEERING PROGRAM

COMAC-BME has approximately 20 projects and is the largest program of the four COMAC's. The main objectives of COMAC-BME are promotion and co-ordination of research and development, transfer and harmonization of medical technologies in order to

improve the quality of health care and rehabilitation, and increasing the application of new technological developments in Europe.

The management and co-ordinating activities of the COMAC-BME concentrate on:

1. the development of appropriate and problem-oriented technologies in the health and rehabilitation field to maintain and improve the health service in Europe;
2. the transfer of new and/or improved concepts and techniques into health practice in order to reduce the gap between R&D, industry and clinical application; and
3. the clinical and technical evaluation of medical devices and procedures, including an evaluation of their cost/benefit aspects. This evaluation should lead to the provision of objective information to justify the introduction of new techniques.

The BME projects of the third medical program, which will finish at the end of this year, are: perinatal monitoring, chromosome analysis, hearing impairments, visual impairments, aids for the disabled, replacement of body functions and biomaterials research, general standards for quantitative ECG, objective clinical decision making, positron emission tomography, nuclear magnetic resonance, ambulatory monitoring, blood flow measurements by ultrasound, ultrasonic tissue characterization, comparative evaluation of medical equipment, automated and analytical cytology, accelerated fracture healing, and medical telemetry. For a description of these projects and their project leaders the reader is referred to Beneken, Brown, and Skupinski (1985).

The fourth medical research program (1987-90) is already in preparation.

COMPARATIVE EVALUATION OF MEDICAL EQUIPMENT IN THE EUROPEAN COMMMUNITY

One of the projects of the COMAC-BME is Comparative Evaluation of Medical Equipment (CEME). This concerted project started in 1982 and is financially supported by the EC for an indefinite period. As said before, the funding of a concerted project is limited to co-ordinating activities, exchange of personnel, meetings, and centralized facilities. The main reason for starting such a project was that several evaluation centers existed in member states, but often did not know each others' activities. Moreover, there was a certain overlap in the evaluations done by these centers. Member states that are active in the field of comparative evaluations of medical equipment are the United Kingdom, Federal Republic of Germany, France, Italy, and The Netherlands.

There are several good reasons for performing comparative evaluations, the three most important ones being the rapidly increasing cost of medical technology, the considerable amount of equipment offered for sale in each country, and the complexity of medical equipment. These factor mandate that hospitals have access to unbiased advice when purchasing new medical equipment.

The main objectives of the project are to co-ordinate activities, exchange knowledge and experience, draft mutually agreed upon test protocols, perform evaluation studies within more than one member state, and set up a data bank on medical devices. To meet these goals, the following activities were developed.

- Every year, all member states, and occasionally nonmember states, are invited to participate in a 2-day workshop designed to facilitate an exchange of knowledge, experiences, and ideas.

- Small groups of three or four evaluation experts are organized to draft test protocols that deal with a certain kind of medical device. A group on infusion systems has already drafted an evaluation protocol and a group on ultrasound diagnostic equipment will soon be meeting. The availability of international standards and recommendations (IEC for example) is not sufficient for evaluation studies, but these standards are an effective aid when drafting test protocols.

- A planned evaluation study on external insulin infusion pumps is an example of co-operation between countries. This study, which will be carried out by the TNO Medical Technology Unit in The Netherlands in co-operation with U.K. and U.S.A., is being funded by the three countries. Each nation will prepare its own publication based on the results of the study. I shall come back to the differences in publications in the various countries.

- The publications of evaluation studies in a non-English language are translated into English, so that they can be read in other countries as well.

- In The Netherlands a data bank on medical devices has been set up in the Advisory Centre for Medical Technology of the TNO Medical Technology Unit. A considerable part of the system is used for storage of reports of comparative evaluation studies and market surveys of medical equipment from the member states, Sweden, U.S.A., and other countries. These publications for the most part cannot be found in the usual data retrieval systems. Therefore, this data bank can be looked upon as an additional information system Twice each year, a list of publications is issued in which the following information is presented for each study: title, author, publication source, the evaluated aspects as well as standards, and types and brand of the evaluated devices.

The evaluated aspects of the devices can be divided into three parts: the technical, the clinical and the economic part (Fig. 1). The first part is obvious, it can be performed in the test laboratory, based on given standards, protocols and "home-made" standards. The second part is more complex; a close collaboration between the evaluation center and one or more hospitals is essential. This part of the evaluation has two important components, the clinical users' trial and the determination of medical efficacy. The latter is important but difficult to assess, especially if you want to compare different methods or instruments. The last part of an evaluation examines the economic aspects of the device. It is very important to know the investment in personnel, facilities, peripheral equipment, maintenance, etc., that must be made.

If an evaluation comprises all these aspects, one can speak of a Medical Technology Assessment. But in the comparative evaluations with which we are dealing, seldom are all of these aspects involved. For the greater part, they are limited to a technical evaluation and a users' trial.

The publications containing evaluation studies conducted by various member states are different in content, structure, and size, and especially in which the results are presented But every country draws a conclusion concerning the comparison of the instruments involved. The Netherlands go furthest by assigning a priority to the acceptability of the instruments. To that end a system of weighting factors for the various aspects is necessary, but is difficult to make up and can never be objective. But by presenting the weighting factors, the reader can recalculate the results as necessary.

From 1976 to the present, the number of comparative evaluation publications in the member states has increased (Fig. 2). In 1976, only The Netherlands published these

studies, in 1979 the U.K. became active, followed by France in 1980 and F.R. Germany in 1982. The U.K. is increasing the number of its studies rapidly and in 1984 and 1985 the number of its publications exceeded those from The Netherlands and F.R. Germany. In 1985 Italy established an evaluation center in Trieste, a move sure to increase the number of Italian studies.

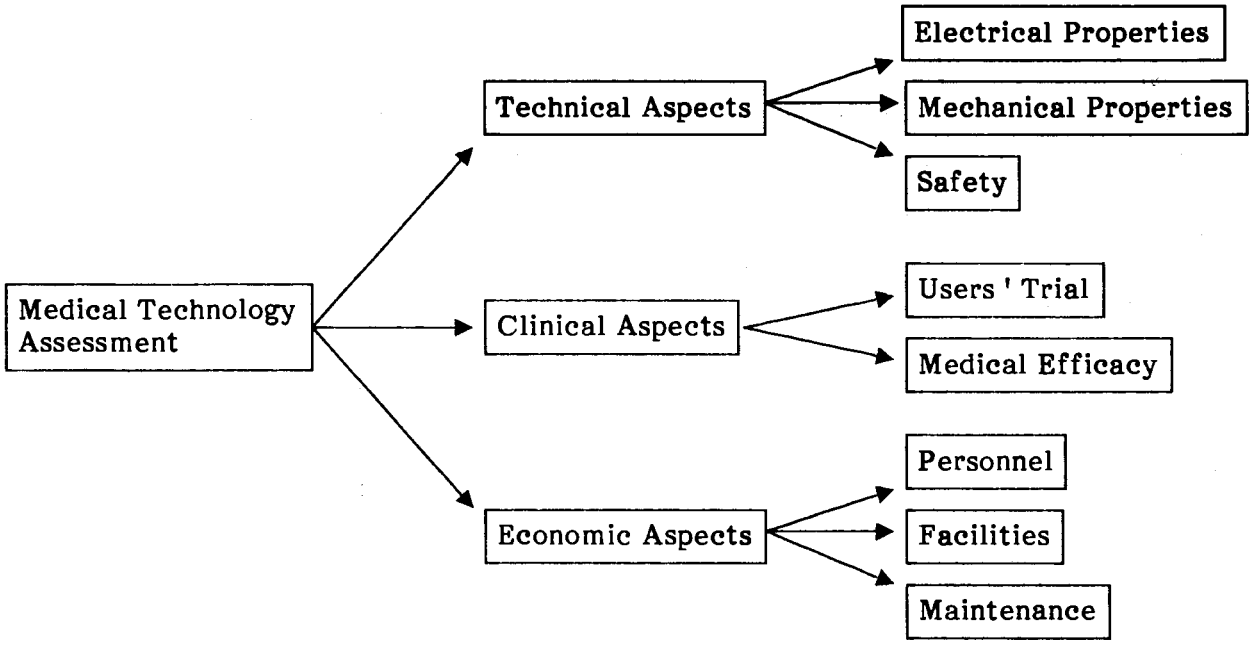

Figure 1. Medical technology assessment

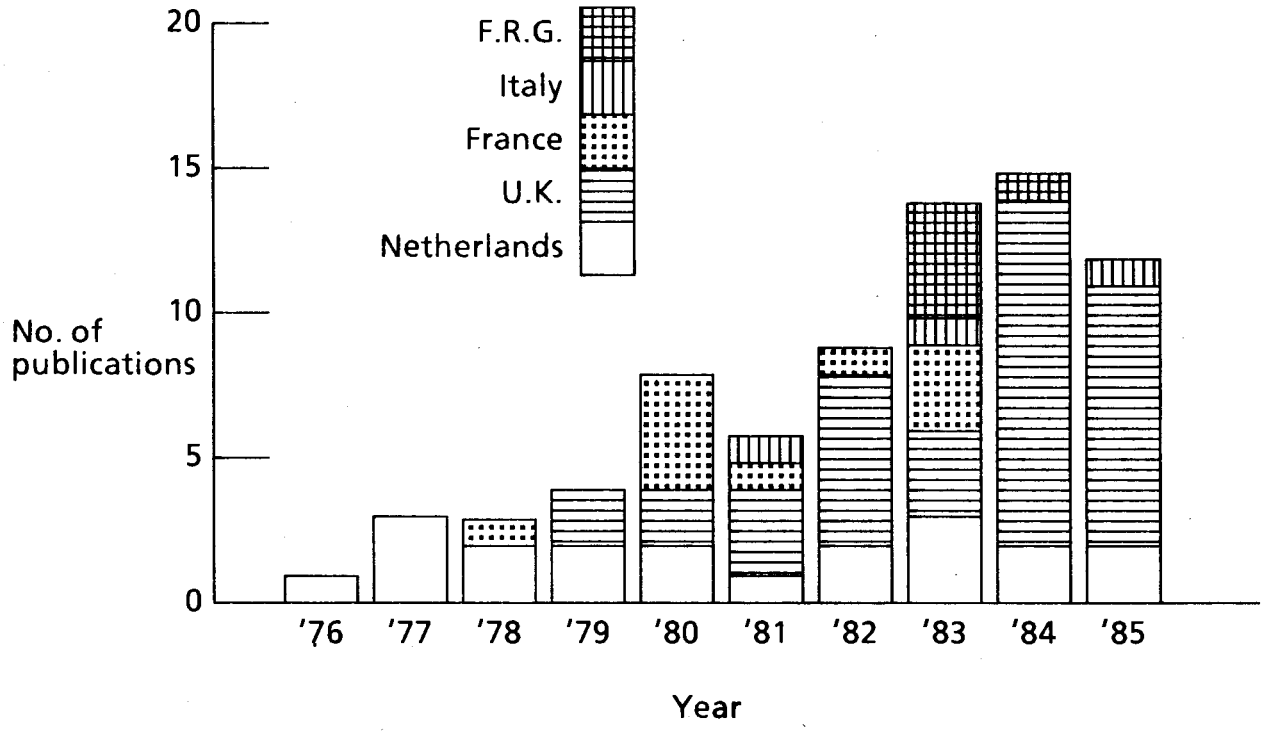

Figure 2. Number of publications on comparative evaluations in EC member states

CO-OPERATION WITH COUNTRIES OUTSIDE THE EC

In the yearly workshops mentioned above, Sweden is invited as a representative of the Nordic countries, to provide a link between the European Community and these countries. In the data bank of medical devices, publications of these countries are also listed.

Last year, ECRI, in the U.S.A., and a number of member states established a regular contact. ECRI publishes a monthly journal (Health Devices) that reports, among other things, a comparative evaluation of medical devices. These studies are also listed in the data bank. Two meetings betweeen ECRI and representatives from the member states of the U.S.A., F.R. Germany, Italy, France, The Netherlands, Sweden, United Kingdom, and EC, have been organized, one in Washington in June 1985, and a second one in Rome, in April 1986. In these meetings, it was agreed upon that an information exchange between the members of the group will be started on a formal and regular basis and that the group members should cooperate in setting up an evaluation study. As mentioned before, a project of this nature, on insulin-infusion pumps, already has started between the U.S.A., U.K., and The Netherlands.

CONCLUSIONS

Within the EC cooperation between the evaluation centers is clearly growing and increased confidence in mutual activities leads to the use of the results of each other's studies.

In the future, it is foreseen that the information in the data bank concerning a device will go beyond comparative evaluations and market reviews. Moreover, a direct link with a similar data bank of ECRI will increase the usefulness of the two banks.

Because the problems in several countries are to a great extent identical and moreover, comparative evaluations are extensive and expensive, mutual cooperation. is essential. A start was made in the EC and with the U.S.A. It is hoped that such cooperation will lead to even more successful results.

REFERENCE

Beneken, J.E.W., B.H. Brown, and W. Skupinski. Biomedical eningeering program of the European Community. J Med Eng Tech. 9/2:61-68 (1985).

IID1. PUBLIC HEALTH MANAGEMENT OF MEDICAL DEVICES: THE FDA EXPERIENCE

INTRODUCTION

Mr. J. Benson presided over Session VIII with Dr. E. March and Mrs L. Suydam serving as rapporteurs. Mr. Benson indicated that the session would present a general overviesw of FDA medical device responsibility. Mr. Benson indicated in his introduction that the Center for Devices and Radiological Health, FDA, had approximately 750 staff members in its central headquarters, of which approximately two thirds are concerned with medical devices. In adddition, it has 400 field staff members and an annual budget of US$ 40 million; approximately 1700 types of products representing more than 50,000 brands and models are controlled.

Mr. Benson indicated that the Center for Devices and Radiological Health (CDRH) has two separate but interrelated statutory obligations: the Radiation Control for Health and Safety Act of 1968 (RCHSA), and the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act (MDA).

The RCHSA provided authority to FDA for the regulation of electronic products that emit radiation, including equipment for radiology, diagnostic and therapeutic ultrasound, lasers, television receivers, microwave ovens, light bulbs, etc. The MDA provided FDA with authority for the regulation of medical devices. Many of the electronic products regulated under the RCHSA were also medical devices.

The responsibilities of the FDA in the field of medical devices include the regulation of new products introduced into the marketplace after the effective date of the Medical Device Amendments, and regulation of preamendment medical devices.

The FDA identifies and attempts to solve public health problems related to products in the marketplace (for example, deaths associated with the use of anesthesia machines, from rupture of cardiac valves, etc.). The solutions are sometimes regulatory (letters of warning, withdrawal orders, confiscation of material, penal procedures). Sometimes the approach is educational, and represents an attempt to avoid the misuse of products and promote safety by altering the behavior of the user, physician, technician, or consumer.

After this brief introduction, Mr. Benson introduced each of the speakers.

IID2. MANAGEMENT OF MEDICAL DEVICE TECHNOLOGY

K. Mohan

I would like to describe briefly FDA's role in the context of social control of medical technologies in the United States. This will include a brief description of some of the mechanisms used in the control.

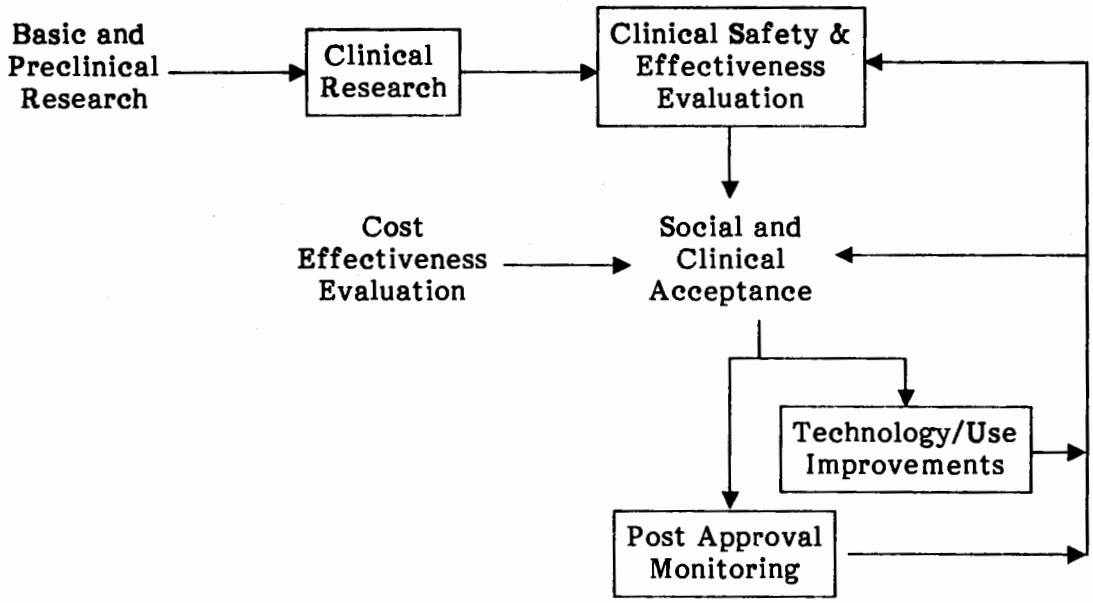

Fig. 1. Evolution of technology

The evolution of medical technology is the journey from a gleam in a scientists's eye to the development of a technology or product that is beneficial to people. The first step in the journey includes basic and preclinical research. This is followed by clinical research in which the concepts and discoveries of the earlier research phases are linked to specific human problems or needs. The results of this research are evaluated to determine if the technology is safe and effective. The clinical evaluation of safety and effectiveness alone is not enough to ensure that a technology achieves social or clinical acceptance. Acceptance is influenced by the cost effectiveness of the technology.

Improvements in or modifications of the technology can be assessed by post-approval monitoring activities. This assessment in turn affects the continuing social or clinical acceptance and serves to protect the public health.

The control mechanisms in the United States related to the evolution of technology are divided among government and nongovernment agencies and the private sector.

The federal government supports and conducts basic and preclinical research through such institutions as the National Institutes of Health and through contracts and grants with universities or other research institutions. Universities themselves support and conduct basic and preclinical research, although to a more limited extent, using non-government funds. In addition, industry may support or conduct such research.

Table 1. Control mechanisms in the United States

Stage	Controlling Agency
Basic & preclinical research	Federal gov't (supports, conducts)
Clinical research	Federal gov't (FDA regulates, NIH conducts) Industry (supports) Universities (supports, conducts)
Safety & effectiveness eval.	FDA conducts based on industry & univ. data
Cost effectiveness eval.	No clear focus Hlth Care Financing Admin (HCFA), Ofc. of Tech. Assessment (OTA) & some universities conduct
Ensuring effective use	Medical profession and state gov't control, HCFA influences FDA plays some role
Postapproval monitoring	FDA regulates, industry, consumer groups, & judicial system influence

The federal government supports and conducts clinical research through the same mechanisms used for basic and preclinical research. Industry also supports clinical research because it wants to, and in some cases must, demonstrate the clinical safety and effectiveness of a technology prior to marketing. The federal government also regulates clinical reserch. As an example, the Food and Drug Administration (FDA) enforces regulations governing the conduct of clinical investigations of new drugs and medical devices.

FDA plays a key role in the evaluation of safety and effectiveness data relating to drugs and medical devices. Such data come primarily from industry, which has conducted clinical investigations and trials or supported such activities at universities or other institutions.

There is not a single focus in the United States for cost effectiveness evaluation. This is, however, one of the factors that lead to social and clinical acceptance of a technology. Responsibilities for cost effectivenesss evaluation are found in several government agencies and nongovernment organizations. Federal agencies include the Health Care Financing Adminstration, popularly known as HCFA, which develops policies concerning reimbursements for health care costs, and the Office of Technology Assessment, part of the legislative branch of government, which conducts analyses of technologies for the Congress. Some semiprivate organizations, such as the National Academy of Sciences and the Institute of Medicine play an evaluative role as do some universities which conduct technology assessments.

A critical control is ensuring the effective use of an otherwise accepted technology. It is not enough that a technology gains initial social and clinical acceptance. It must be

continuously evaluated and monitored to ensure that it is used effectively. The medical profession, federal and state governments, and other agencies that play a role in influencing the practice of medicine, have some influence in this area. Although the FDA role is limited, it is an important one. It creates voluntary education programs and disseminates information.

FDA has an important role in postapproval monitoring, including the evaluation of adverse effects and taking appropriate followup action as a result of such information. The industry, consumer groups, and other sectors in government, including the legal system, also play effective roles.

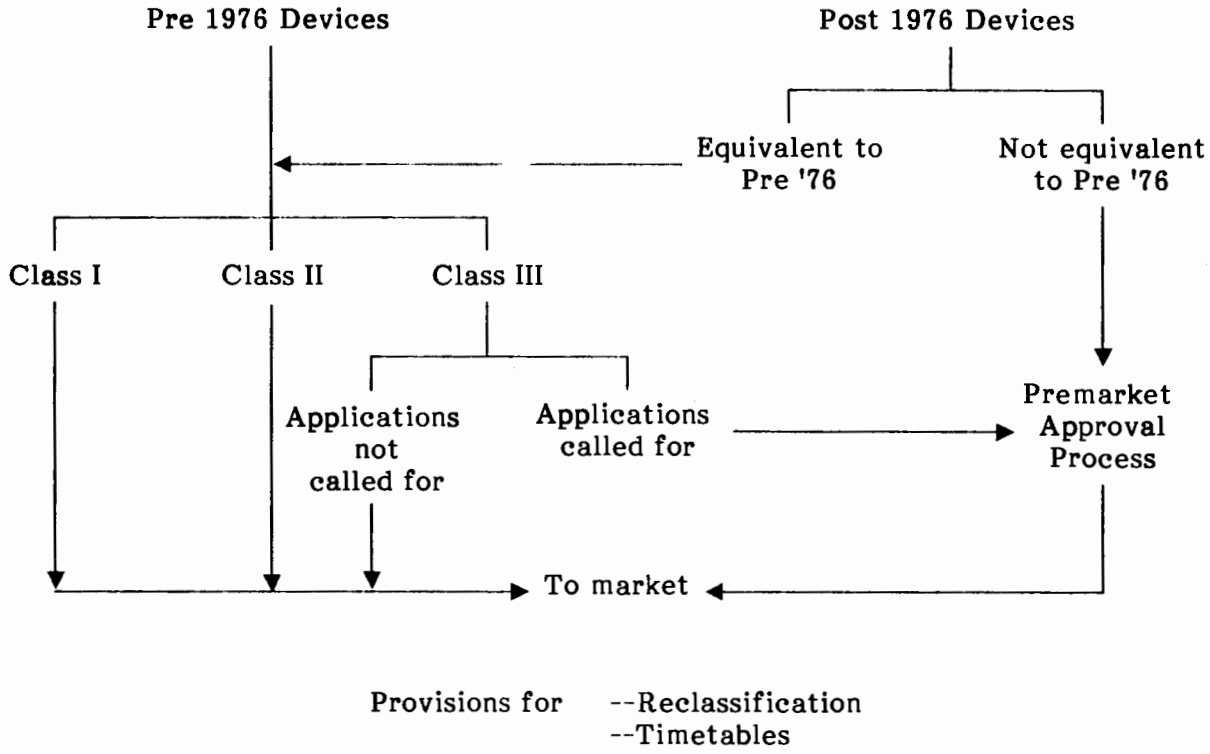

Figure 2. Safety and effectiveness evaluation

FDA plays a major role in the evaluation of the clinical data submitted concerning the safety and effectiveness of medical devices. This role was strengthened by the Medical Device Amendments of 1976 (the "Amendments") which established a framework for the regulation of medical devices.

There were many devices in use at the time the amendments were enacted in 1976 and it was not possible to evaluate and bring all these devices under regulation overnight. Congress, therefore, made a provision for a transitional period in implementing the amendments. The amendments establish somewhat different rules for preamendments versus postamendments devices.

The amendments require that all devices on the market before May 28, 1976, be classified into one of three classes. Class I is for the least risky devices, such as tongue depressers, bandages, etc. The general controls of the Food, Drug, and Cosmetic Act are judged adequate to ensure that devices in this class will be safe and effective.

These controls include prohibitions against misbranding or adulteration, adherence to good manufacturing practices, and registration as a device manufacturer.

Class II devices are defined as those for which the general controls are not adequate to assure safety and effectiveness but for which adherence to a performance standard, in addition to general controls, would provide such an assurance. Devices in this class are to include those for which the technology is reasonably mature, for which the problems and the safety risks are reasonably well known, and for which it is possible to define a set of parameters in the form of a performance standard.

Class III is the class into which devices posing the most significant risks, such as devices supporting or sustaining human life or devices presenting a potential unreasonable risk of illness or injury, are placed. This class includes devices that pose unknown risks or which could cause very serious harm if they did not perform properly. Class III devices require premarket approval before they may be marketed. This allows FDA a pro-active role in the evaluation of data relating to the safety and effectiveness of medical devices.

Pre-amendments devices could be placed in Class III if they meet the criteria in the amendments and if the classification panels recommend that this level of regulatory control is necessary. Although placed in Class III, the amendments make provisions for allowing these devices to remain on the market until FDA, by regulation, calls for premarket approval applications. Premarket approval applications will be required for these devices based upon priorities involving health risks and benefits.

There are two ways in which postamendment medical devices can get to the marketplace. One way is that the manufacturer may demonstrate that the device is substantially equivalent to a device that existed before 1976. If FDA determines that the device is substantially equivalent to a pre-amendment device, it may be marketed. If the device is not substantially equivalent to a pre-amendment device, it must go through the premarket approval process.

The amendments also make provision for changing the classification of devices. Reclassification thereby allows changing the regulatory requirements for a device based upon new or advancing technology and upon medical knowledge.

In addition, the amendments mandate the timetables for these processes. Accordingly, FDA does not have the luxury of letting things go on indefinitely.

The approval process for medical devices may require substantiating research, including fairly extensive clinical investigations. Questions may arise concerning the ethics of using a device that has not been proven on human beings. To answer such concerns, the amendments allow for clinical investigations or trials to be conducted under an investigational device exemption (IDE).

An IDE provides for controlled circumstances for carrying out the clinical research. Before starting a clinical investigation, all research and scientific information relating to the safety and effectivness of the investigational device must be submitted. This includes evidence from preclinical research, which may include animal trials, etc; that the patients are aware of the degree of risk involved; and that the study is being conducted in a scientifically valid manner so there is a good likelihood that the information will be useful. To do this, sponsors must obtain FDA permission, in the form

of an Investigational Device Exemption, to conduct such an investigation. In addition to a sponsor, there is also a person or persons who monitor the study independently.

Table 2. Investigational Device Exemption

Purpose:	Encourage device development Protect patient health/rights Maintain ethical standards
Participants:	Sponsor Monitor Investigator Institutional review boards Food and Drug Administration

The investigators must follow a specific protocol that has been reviewed and approved by an institutional review board. Institutional review boards (IRBs) exist within a university or academic community. They review studies and give permission to conduct human trials at a particular institution and oversee, on a day-to-day basis, the conduct of the investigation.

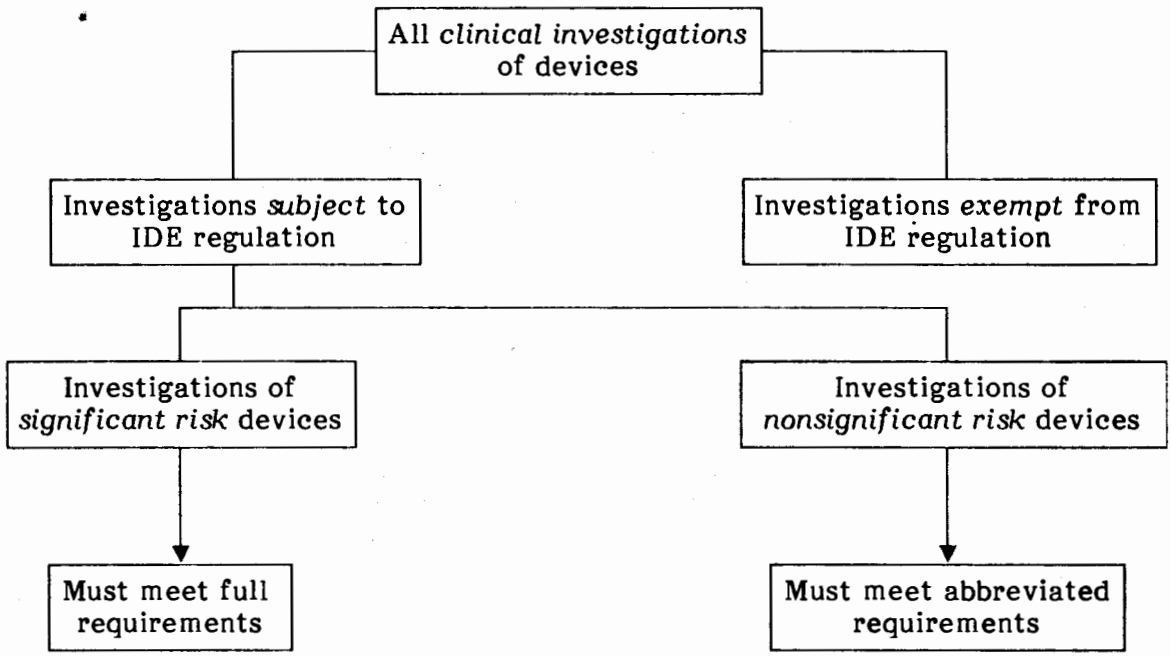

Figure 2. Control of clinical investigations.

Some clinical investigations are not regulated by FDA (exempt) and are conducted as an adjunct to other mechanisms. Such clinical investigations pose no risks to patients. For example, an investigation of an in vitro test may involve human patients and not require an IDE because the results are not used in the diagnosis or treatment of those patients. In this case, diagnosis or treatment is being based upon an alternative accepted test.

Nonexempt investigations fall into two classes, significant risk and nonsignificant risk, depending upon the risk posed by the device involved. An example of a nonsignificant risk device is a daily-wear contact lens. Local institutional review boards have the authority to review and approve nonsignificant risk investigations. FDA approval is not required prior to starting the investigation. Investigations of new heart valves, on the other hand, are significant risk investigations. They require review and approval by both the local IRB as well as FDA before they may be started.

As the clinical trials are being completed, the sponsor may begin the premarket approval process. This process is intended to evaluate the safety and effectiveness of the device.

Table 3. Premarket Approval process

- Filing
- Review
- Panel recommendation
- Summary of safety and effectiveness
- Plant inspections
- Challenge procedures
- Monitoring

The premarket approval process starts with the filing of an application, followed by an initial review within FDA, followed by a review and recommendation of an expert panel. FDA reviews the recommendation of the panel and prepares a summary of safety and effectiveness data in which the bases for the decision are discussed. The PMA approval process includes inspections of manufacturing facilities to ensure that the devices are manufactured under good manufacturing conditions. The law makes a provision for industry or other outside groups, in a fairly easy though not a trivial process, to challenge the decisions. There have been challenges to some of the decisions under this provision.

The process also makes provision for postapproval monitoring. FDA's role in postapproval monitoring includes a requirement for annual reports on devices. This information allows FDA to determine if things are going wrong with the device, or if there are adverse effects, so that corrective actions may be taken.

The goal of premarket approval is to establish the safety and effectiveness of a device. This requires rigorous evidence on the risks and the benefits of the device under evaluation. The risks are weighed relative to the benefits to be derived. For example, if it is a breakthrough device, life saving, and there is no alternative, a greater degree of risk will be tolerated. If, on the other hand, the device is primarily cosmetic in nature, the degree of risk that will be accepted will be less.

The PMA regulations require valid scientific evidence consisting of well-controlled trials or legitimate types of studies, etc. Testimonials are not viewed as valid scientific evidence. The concept in the the device amendments is one of reasonable assurance of safety and effectiveness rather than proving safety and effectiveness to the nth degree.

Table 4. Premarket Approval

- Establish safety and effectiveness
- Rigorous evidence
  - risk/benefit
  - valid scientific evidence
  - reasonable assurance
- Rigorous procedures
  - timetable
  - external panel
  - documentation
  - economic protection

The procedures relating to PMA submissions include a timetable that has been provided by Congress: FDA must process each PMA within 180 days of its receipt. The amendments also require that external panels, consisting of experts in a particular clinical specialty, review the data about the device and make a recommendation for action on the application. The scientific rationale upon which the decisions are based are documented. The process provides a certain degree of economic protection to the manufacturer who gets a PMA approval. This incentive encourages people to be innovative, to come out with new devices and to spend money, time, and effort to research new technologies and show that they are safe and effective.

Table 5. Premarket Notification (510k)

- Notify FDA 90 days prior to marketing
- Establish substantial equivalence
- Focus on
  - unanswered questions
  - new indications

The amendments also include a grandfathering clause that allows FDA to compare new devices to devices that existed before the law was passed, or that have been reclassified from Class III to Class I or II, and determine whether the devices are substantially equivalent. As previously indicated, manufacturers must submit sufficient information to establish that the device they propose to market is like a pre-amendment device.

Table 6. Summary of control features

- Control based on risk
- Burden of proof on sponsor
- External review
- Encourage innovation
- Accountability and deadlines
- Economic incentives/protection
- Flexibility/rigor

The level of control applied to a device is based on the level of risk that the device poses. The principal burden of proving a device is safe belongs to the sponsor, who is usually the manufacturer. External reviewers, such as peer review groups or advisory panels, examine the data and make recommendations for action. The regulatory controls are strict enough to be a challenge and yet not so strict as to stop innovation.

In summary, we are accountable, and as Federal employees we have deadlines. We get called upon by legislative parts of the government and others if we are not doing things right. Our law builds in a certain degree of economic incentives and protection in order to encourage innovation and to allow people to make the investments necessary to bring new technology into the marketplace. There is a certain degree of rigor in our procedures, such as in the case of premarket approval applications. And there is a certain degree of flexibility in our procedures, as in the case of our premarket notification (510k) process.

Table 7. The U.S. experience

- Process cumbersome
- Technology evolution delayed
- Requires large resources
- Problems with control of pre-'76 technology
- Provides consumer protection
- Process equitable to firms
- Economic incentives built in
- Deadlines for processing applications

Although our experience could be presented in more detail, I have tried to cover the major aspects of our system. I have included both negative and positive factors.

Yes, the process can get cumbersome. It takes immense amounts of regulatory and managerial skills to limit the cumbersomeness, but it is not always possible.

To a certain extent technology does get delayed - as well as solutions. Perhaps this is unavoidable. The process requires large resources. At the same time, however, our system does provide consumer protection, and new technologies can be brought to the marketplace with relative speed.

IID3. ROLE OF SCIENCE IN FDA DECISION MAKING

E. Jacobson

INTRODUCTION

The Food and Drug Administration's Center for Devices and Radiological Health expends significant resources and effort to maintain a research-based science group as part of its medical device and radiological health organization. CDRH is making these expenditures at a time when resource constraints face all public health institutions. Why are scarce resources being used to support a research base?

The practical answer is that the research base provides benefits that are not available from any other source.

Generally speaking, CDRH medical device laboratories provide crucial support and input for the Center's product approval, postmarketing surveillance, and user education programs. They also provide the Center with independent means for addressing fundamental public health issues, both in forecasting upcoming problems and in developing technological "fixes," i.e., technological improvements that solve key problems. The lab program includes a mix of both forward-looking developmental projects as well as work of immediate applicability on problems facing us now. This includes the analysis of phenomena that cut across broad device areas, such as understanding the properties of the various types of materials used in devices, and problems of equipment automation.

Research efforts are enhanced through collaboration with other scientific groups outside the Center, both in the U.S. and in countries around the world.

COLLABORATION

Working, scientist-to-scientist collaborations have allowed CDRH to multiply its resources substantially in many areas. Within the U.S., CDRH maintains cooperative efforts not only with the other parts of the Food and Drug Administration, but also with the National Institutes of Health, the National Bureau of Standards, the Occupational Safety and Health Administration, and the National Aeronautics and Space Administration (among others). Research collaborations and measurement intercomparisons involve many countries in the Western hemisphere and Europe, as well as Australia, Japan, and the Soviet Union. This effort includes not only continual interlaboratory contact and collaboration, but also a Visiting Scientists' program in which senior professionals actually spend extended periods working on projects of joint interest in the Center's laboratories. In addition to these governmental collaborations, CDRH collaborates extensively with university and other research groups.

DEVELOPMENTAL PROJECTS

The field of medical devices is so broad that CDRH must focus its developmental work. There are four categories of work that CDRH undertakes: first, things others cannot do, perhaps for lack of expertise or equipment; second, things others will not do, for lack of adequate incentive, financial or otherwise; third, things others should not do, such as maintaining the only source of information on product failures; and finally, things others have not done, to fill gaps in our knowledge.

A major area of CDRH developmental work is metrology. CDRH scientists frequently find that in dealing with a specific technical problem, the basic means for measuring the relevant parameters are lacking or unreliable. Consequently, the Center has consistently devoted a portion of its resources to developing the specific instrumentation required to answer key questions, and to evaluating important product failures. Among the areas where such efforts have played a key role are medical ultrasound, in which we have developed the hydrophone probes needed to characterize fetal and other exposures, and image characterization, in which we have developed several techniques for assessing image-quality and information-content for radiologic and other medical images.

CDRH effort also has led to technological advances in ultrasound. The development of "explososcan" is a good example of using sophisticated processing techniques to reduce diagnostic ultrasound exposures significantly with no deterioration in image quality. We call it "explososcan" because many lines of ultrasound information can be accessed from a single outgoing ultrasound pulse. Other such "technological fixes" have included advancements in hyperthermia for cancer therapy, diathermy, and safety of dental photopolymerization devices. Developmental work of this sort often has gone on to improve the state-of-the-art in medical devices as the Center's research results and patents derived from these results have been placed in the public domain.

Another area of developmental work is the evaluation methodology for x-ray intensifying screens. CDRH effort has contributed to a considerable improvement in the sensitivity, or speed, of screen-film systems used for diagnostic radiology today. Appropriate use of these systems significantly reduces the radiation dose delivered to a patient during a diagnostic radiology examination. Because standard evaluation methods did not exist when these products were first introduced, they were not optimized for clinical practice. Moreover it was difficult to compare them with the then currently accepted systems. This resulted in a reluctance to adopt the new technology in routine clinical work.

The Center moved aggressively to develop its competence in imaging performance evaluation. CDRH has produced many scientific publications that document both measurement methodology and the performance characteristics of most commercially available screens. CDRH sponsored conferences on image performance evaluation and initiated laboratory intercomparisons of film sample measurements. A steady stream of researchers visited the Center laboratories from the manufacturing, academic, and clinical communities. Most importantly, a consensus emerged in this area, greatly contributing to the increasing acceptance of the new technology screens. Because the dose reductions that are achieved by switching from older, less-efficient, screens are on the order of 50 percent, this effort has had a very large public health impact.

CDRH research has been instrumental in documenting UV hazard to the eyes and helping approval of an important new device designed to match the protection offered by the natural crystalline lens. The natural lens of the eye absorbs ultraviolet radiation, but this absorption is lost when the lens is removed. So UV absorbers added to intraocular lenses were intended to improve the safety of the lenses by "adding back" protection from UV. But questions were raised: Is the protection necessary? Is that radiation damage significant? CDRH research in monkeys has demonstrated that ultraviolet radiation at 300 nm can damage the retina in the intact eye, and shows that high-energy photons are very hazardous to the retina. In addition, it demonstrated that moderate levels of ultraviolet radiation at 365nm can produce severe retinal damage in eyes lacking the natural protection of the natural lens.

Using technology developed by the National Aeronautics and Space Administration, CDRH pursued techniques for calibrating fluorescence or luminescence measurements. At first, this work was intended to apply to the evaluation of immunofluorescent techniques for in vitro diagnostic devices. However, work has been extended to biosensors. Recently, research in several fields has merged in the development of chemical bio-sensor technology for the evaluation of blood chemistry. It is easy to envision devices based on fiber optic technology in which the ends of individual fibers are treated with passive or active chemicals sensitive to changes in blood analytes or conditions in the circulatory system. CDRH measurement techniques have proven useful in the establishment of methods to measure the specificity and sensitivity of these products. When these devices are submitted to the agency for approval, many of the evaluation techniques will already be in place. Most importantly, CDRH has been able to raise important technical questions about performance while the products are still in developmental stages.

One of the considerations in choosing a material for a medical device is its bio-compatibility. The majority of the concern with bio-compatibility is the toxicity of the material in the body. However, with the increasing length of time over which devices are expected to function in the body, the bio-stability or bio-degradation of the material is becoming increasingly important. For example, CDRH has devoted a relatively large effort to the study of polyurethanes, not simply because there are problems with products containing them, but also because there are increasing numbers of uses for these products.

APPLIED PROJECTS

Another area of activity concerns projects oriented toward immediate crises and evaluations of problem products.

One good example of a project presently underway is the evaluation of implantable intraocular lenses. Current techniques are simply not adequate to assess the optical quality of these lenses. In fact, CDRH laboratory analyses of these devices indicate a serious deficiency in the voluntary standard that has been used to evaluate these products up to now. The aim here is to combine the image-evaluation techniques discussed above with the optical techniques developed by CDRH optical engineers and physicists to achieve a new and more reliable method to assess the optical quality and performance of these devices. Ultimately, that methodology should feed back into the voluntary standards effort in this area.

With the advent of implanted electronic devices, there was a need to protect the components and circuitry by hermetically sealing the unit. This raised the obvious question: How do you evaluate the effectiveness of the hermetic seal?

Classic testing techniques for the integrity of hermetic packages did not work for polymer packages. We knew, however, that holographic techniques had been used in the aircraft and space industries to detect subsurface flaws in aircraft tires and solid rocket motors. CDRH scientists felt that, with some adaptation, holographic techniques could also indicate local areas of distortion such as might occur with a leak.

After some development work to improve the sensitivity of the technique and allow it to quantify the actual leak rate, CDRH scientists were successful in providing FDA with a tool that could be used to verify the seal integrity of all implanted electronics.

Several years after this initial work was done, a large botulism scare from leaking salmon cans, which had been improperly sealed, occurred in the U.S. Using the same holographic techniques, full cases of cans were inspected as they emerged from the cannery, and those not properly sealed were rejected.

In a similar application, it is possible to verify the seal on drug ampules as they are being boxed prior to introduction to the marketplace. CDRH is currently working to develop a holographic method to determine patterns of wear on prosthetic devices, such as artificial knees and hips.

The last topic under applied projects is statistics and epidemiology. These two disciplines play an important role in all aspects of medical device regulation. They provide the tools to measure the value of laboratory and clinical data.

The statistics staff has undertaken the process of educating manufacturers and health industry professionals on the form, content, and quality necessary in data submitted to the agency. The form of this education has varied. It has included draft statistical guidelines, several technical publications, a videotape, and numerous presentations on the statistical aspects of medical device submissions. The message has been clear: The review process is expedited when submissions contain appropriately described study objectives, statistical procedures, and data analysis. And the study objectives and results must be linked to the medical claims made for the device.

A major recent contribution of statistics to the area of postmarket surveillance involved a case in which we had a heart valve that seemed to be failing at an unacceptably high rate. The situation was very complicated: data on valve fractures were presented to CDRH piece-meal and the sponsor had done several previous recalls. In order to determine the actual failure experience, CDRH statisticians devised an actuarial life table format for submitted data. Analysis of the data using this format allowed a direct comparison of fracture rates over time. The resulting trend of increasing fractures over time provided the agency with strong leverage to have the company withdraw the valve from the market.

The importance of epidemiology in risk determination has been clearly documented beginning with Snow's work on cholera in London in the 1800's. Epidemiology is a powerful tool, when properly employed. The long and difficult history of the Dalkon Shield IUD included analyses of human studies performed by other researchers, which showed that the rate of pelvic inflammatory disease among Dalkon Shield users was much greater than that among users of other IUD types. Clearly, a number of such studies had confirmed that IUD use in general resulted in an increased risk of pelvic inflammatory disease. CDRH recognized the flaws in the previous epidemiologic analyses. The impact of selective patient recall and publicity could have easily influenced the magnitude of risk reported in the Dalkon Shield studies. Thus, while CDRH has generally supported (and monitored) the Dalkon Shield recalls, the Center believes that IUD's, as a class of devices, are of concern, and CDRH has, therefore, called upon manufacturers to demonstrate their safety and effectiveness.

It is obvious that CDRH believes a strong statistics and epidemiology program to be important in maintaining its science base and regulatory competence.

Four hundred years ago, in his treatise on Advancement of Learning, Francis Bacon wrote:

> "If a man will begin with certainties, he shall end in doubts; but if he will be content to begin with doubts, he shall end in certainties."

The experience of CDRH shows that when we assume we have all the answers, we end up in self-doubt. The use of our science base allows us to make the best use of available information, and to generate new information at times, so we can be more comfortable with our public health decisions and our evaluations of problem products.

IID4. TRAINING/EDUCATION IN THE MANAGEMENT OF MEDICAL DEVICES

J. Arcarese

As many speakers at this Conference have already emphasized, medical device safety and effectiveness is the result of a number of factors, including the device itself (its design, its reliability, its state of repair, etc.) and the interaction between the device and the people who use it to achieve some medical purpose. It is axiomatic that the most perfectly designed and properly functioning device can be misused and cause harm, so that device safety and effectiveness is a function of not only the way devices operate but also the performance of the people who use them. The Center for Devices and Radiological Health conducts activities that address both the device and the user.

Some Offices in the Center oversee the regulatory processes, which ensure that devices are designed properly and function as intended, and that their function is effective in achieving their medical purpose. The Office of Training and Assistance looks at the ways those devices are used and at the people who use them. For example: Do users take proper precautions while operating the device? Are users well trained and motivated to use devices properly? Are users properly informed about problems with specific devices or specific models? The two different focuses in the Center, regulatory processes directed at the device design and function and the educational processes directed at the way devices are used and the knowledge and motivation of the device user, complement each other to achieve our overall goal of safety and effectiveness.

To help you understand how we work to improve the way devices are used, let me anticipate several questions that might occur to you.

First: On what kinds of devices does CDRH focus, or does the Center somehow concern itself with every device and device user?

CDRH cannot and does not try to focus on every kind of device or device user. The Center depends upon the information in the scientific and clinical literature concerning the relative risks posed by a device, and upon reports of actual problems, to be its guide to those devices and device users that need special attention. Sometimes, we can anticipate hazards. For example, in the fields of anesthesiology and respiratory care CDRH receives many reports of deaths and serious injuries associated with the use of gas machine and ventilator apparatus. Sometimes we cannot anticipate hazards, as was the case when the Center received reports of toxic shock syndrome in young women who had been using certain kinds of tampons.

Second: Which medical device users are our audience?

Our audience can include any interested person in our society. Medical device users include everyone from the most highly skilled anesthesiologist using an anesthesia gas machine, several electronic monitors, and a ventilator during surgery, on the one hand, to the teenage girl using a menstrual tampon. Medical device safety and effectiveness in each case requires that the user be informed about the proper use of the device, and motivated to use it properly. Therefore, depending upon the particular device problem, CDRH works with physicians, nurses, other kinds of health professionals, or consumers in the general public.

Third: How does CDRH reach users with information?

Because the total number of actual or potential medical device users is the population of the country, it is obvious that a government agency such as CDRH can only serve as a catalyst to help ensure that medical device users receive the training and information they need. In rare instances, such as when the number of users of a particular kind of device is small, and CDRH has some means of access to them, CDRH might reach them all with a letter or other notice providing information crucial to the safe and effective use of the device. However, most commonly, CDRH works with intermediaries. For example, when the users of a particular kind of device are health professionals, CDRH works in cooperation with the representative professional associations to reach their membership with information. Often CDRH also works with manufacturers in order to reach health professionals. When the users of the medical device are members of the general public, then CDRH often relies on transmitting information through the popular press or through multiplier associations such as consumer organizations, which communicate with certain segments of the general population.

Fourth: Is there a standard technique that can be applied to solve problems of medical device use?

CDRH has certain general ways in which it solves problems. For example when the problem involves physicians, CDRH always works with the professional medical organization that represent them. However, there isn't a single simple standard formula that can be used to solve all user problems. Aside from the obvious technical differences from device to device, there are unique problems posed by the behavioral incentives and disincentives associated with use of the device. If a problem occurs because the device users lack certain critical knowledge, then the problem can theoretically be reduced (or addressed) by making the needed information available to them. However, many problems occur even when the users know how to operate the device correctly, but choose not to for other reasons. When that is the case, solving the problem depends on overcoming the disincentives to appropriate behavior. And that is a much more difficult proposition. Each problem requires its own analysis and its own unique solution strategy. Whatever the cause of the device problem, there is often involved some related regulatory activity, because device problems often occur due to some aspect of the interface between device and user. Consequently there is a close liaison between the regulatory and educational components of the Center.

A few examples will illustrate some current medical device use problems, in anesthesiology, hemodialysis, and toxic shock syndrome, on which the Center is working. The first example is anesthesiology.

The anesthesiology literature contains estimates that avoidable anesthesia deaths and serious injuries may number in the tens of thousands each year in the United States. Although the risk to any one patient is small, perhaps one in a thousand or less, the large absolute number of tragedies is a justifiable cause for concern. Many of these outcomes involve injudicious use of the anesthesia and ventilation equipment or lapses in the user's attention, or simple user error; only a very small percentage are apparently due to outright equipment failure that could not have been anticipated. To help solve this problem, CDRH has joined with the anesthesia health professions, the anesthesia machine manufacturers, and other involved organizations in a major cooperative effort to study and solve these problems. One of the most important solution strategies we have jointly addressed involves checking anesthesia equipment before actual use. In an effort to encourage the regular checking of anesthesia equipment, CDRH has recently published a

draft generic equipment checkout procedure, which was developed by anesthesiologists, manufacturers, and biomedical engineers. As soon as the final version is available, the professional organizations and manufacturers have committed themselves to disseminating it to all anesthesia professionals. Through this concerted effort, CDRH is convinced that the use of this or similar checkout procedures will become a standard of care.

The Center also is producing, in cooperation with the American Society of Anesthesiologists, a series of educational videotapes that will be used by the Society for residency and staff education. The series emphasizes pre-use equipment checkout, the appropriate use of monitoring and recordkeeping, equipment maintenance, and other important techniques that anesthesia health professionals can use to reduce the risk of anesthesia tragedies. It is unlikely, of course, that these videotapes in and of themselves will directly cause major changes in anesthesiology practices. But there is little doubt that they are stimulating interest and attention by the profession in patient safety, and that, in a cascading fashion, this interest and attention will spawn additional creativity and efforts by the profession itself to solve the public health problems in anesthesiology.

The next example is hemodialysis. Hemodialysis is a life-saving technique for many people whose own kidneys have failed. Unfortunately, this critical care technology is also associated with many deaths and serious injuries. CDRH has received reports indicating that performance at some dialysis facilities varies widely from acceptable standards of care. In an effort to address this complex situation, The Center is working with dialysis equipment manufacturers and the dialysis health professions to develop an educational program that addresses four major areas of common performance problems: water treatment, dialysate, general equipment maintenance, and clinical protocols. This educational program will be made available to all dialysis facilities in an effort to help health care personnel be more aware of those factors crucial for safe and effective dialysis.

The last example is toxic shock syndrome. Toxic shock syndrome is a rare but debilitating and sometimes fatal condition. Although it can occur in either males or females at any age, it is most commonly associated with otherwise healthy young females using some types of menstrual tampons. Early treatment is crucial. CDRH developed a poster educational unit, to be used in health classes in junior and senior high schools, which emphasizes the symptoms associated with toxic shock syndrome and recommends several important actions to be taken if the symptoms are experienced. The front cover of the poster summarizes the symptoms of toxic shock syndrome. The reverse side of the poster has eight panels of information and suggestions for the teacher. Thus, this poster is a completely self-contained educational unit. Last year, CDRH distributed this poster learning unit to all the secondary schools in the United States, and a copy of it was inserted into an issue of the Health Education Journal, which is read by many health educators in this country, and was another important way to bring the poster learning unit to the attention of health education teachers.

General public education campaigns such as this one often leave lingering doubts about their effectiveness. However, it was with great satisfaction that the Center was informed about the case of a young woman who developed toxic shock syndrome and was able to recognize the symptoms in herself based on information from our materials. She took quick action, which her physician later testified saved her life.

These examples, anesthesiology, hemodialysis, and toxic shock syndrome, illustrate the wide scope of technical difficulty that is often associated with problems of medical

device use and that we encounter as we attempt to learn about and deal with some of the intricacies of user behavior. CDRH believes that the combination of the Center's educational and regulatory activities provide a sensible and effective approach to ensuring that medical devices are safe and effective.

IID5. POSTMARKET SURVEILLANCE ACTIVITIES

W. Damaska

Even under the best conditions, neither laboratory nor clinical data will predict with 100 percent certainty how well a new product or a redesigned old product will perform over a long period of time when used in a large and diverse population of patients.

Therefore, we need effective postmarketing surveillance tools to assist in monitoring the performance of devices under a variety of use conditions. For example, the type and variety of available information necessary to continuously monitor the performance of implanted life-sustaining devices, emergency use equipment, and home-use test devices varies significantly.

The following are the most significant postmarketing surveillance systems currently used by the Center to identify problems that need to be addressed immediately by way of some action, either voluntary, regulatory, or, at the other end of the spectrum, to identify long range product-performance trends.

The Center for Devices and Radiological Health receives information about device performance from many sources, such as the various levels of medical personnel or consumers, who in many cases are the patients themselves.

For a number of years CDRH had a voluntary system through which people who use devices, mainly health professionals, although consumers were included, could report directly to us when they experienced a problem. Now we have a mandatory system, called Medical Device Reporting, or MDR. This system was initiated on December 13, 1984. The MDR Regulation requires device manufacturers and importers to report directly to FDA whenever they receive information that reasonably suggests that one of their products may have caused or contributed to a death or serious injury or has malfunctioned in a way that, if it were to re-occur, could result in death or serious injury. During the first year that the system was operational, 15,915 reports were received. The current reports for 1986 indicate that the number of reports received will probably be about the same as in 1985.

The MDR regulations also require manufacturers and importers to establish and maintain a complaint file and to permit any authorized FDA employee to have access to and to copy and verify the records contained in this file. This is particularly important in enabling CDRH/FDA field investigators to conduct followup investigations to evaluate the significance of complaints in light of information the Center may have about the particular device or type of device.

What is "information that reasonably suggests" a failure or malfunction of a device? Basically, there are two types: information (such as professional, scientific, or medical facts or opinions) from which a reasonable person would conclude that a defect exists, or statements to a manufacturer or importer by a health care professional reaching the same conclusion.

The sources of information for MDR reports can be oral or written complaints. It is important to note that the complaint need not be written, because health care professionals frequently may simply not have the time to complete the forms necessary to submit a complaint.

Medical or scientific literature, as well as the manufacturers' own research testing, product evaluation, and information obtained through routine service and maintenance, provide valuable information.

Reports received by the Center are evaluated carefully to determine what, if any, immediate action is necessary. Some reports result in the Center issuing assignments to FDA field offices to conduct inspections at the manufacturing facility; others result in requesting that the manufacturer provide additional information relative to their assessment of the problem; while still other reports result in various followup activities within the Center, such as identification of product performance trends. To provide some idea of the magnitude of this program, since January 1, 1986, 6891 reports have been received.

Another important source of postmarketing surveillance information is based on information obtained during regularly scheduled inspections of manufacturers to assess their adherence to good manufacturing practices (GMP). Section 820.198 of the Good Manufacturing Practice for Medical Device Regulation applies specifically to the requirements for evaluating, investigating, and maintaining complaint records. The inspections of the approximately 10,000 manufacturers, producing some 40 to 50 million devices, routinely assess manufacturers' handling of complaints concerning the safety and effectiveness of their products, as well as their adherence to manufacturing and quality control.

A complaint as defined by GMP regulations is a written or an oral expression of dissatisfaction regarding identity, quality, durability, reliability, safety, effectiveness, and or performance of a device. Each manufacturer is required to designate a unit to be responsible for reviewing complaints. This unit must review the complaints and evaluate their significance in terms of the safety or efficacy problems arising from intended use. The unit must decide if a more in-depth investigation is necessary. The designated unit also is responsible for maintaining a complete record of the investigation, including the reasons for determining that no further followup is required and the identity of the person responsible for the decision. In short, complaints involving a device's failure to meet performance specifications must be reviewed, evaluated, and investigated. Complaints involving injury, death, or hazard to safety must be immediately reviewed, evaluated, and investigated; and the record must be maintained in a separate part of the complaint file.

Records of complaint investigations must include the following:

1. device name;
2. control number, if any;
3. name of the complainant;
4. nature of the complaint; and
5. reply to complainant

If the formally designated unit is located at a different site than the manufacturing operation, a copy of the complaint file must be kept at the manufacturing site.

GMP inspections, and tracking and evaluation of complaint records, is costly and labor intensive. In order to conserve resources, CDRH recently initiated a Two-Track GMP Inspectional Strategy. This program requires that field offices conduct a comprehensive GMP inspection of a device firm every 4 years and will substitute a limited GMP inspection at the intervening 2-year mark. If, for example, a firm has

significant problems related to quality assurance identified during the limited inspection, a comprehensive inspection is required. Failure to adequately assess complaints is considered a failure that will trigger a comprehensive inspection. Approximately 1600 GMP inspections are planned for Fiscal Year 1986.

To provide an idea of the scope of the various compliance programs, the programs for field testing of radiation-emitting products will use approximately 20 person-years of field time this year; the sterility program will use approximately 15 person-years.

CDRH also uses a number of compliance programs to continuously monitor the activities of manufacturers in specific areas. These are programs designed to provide field offices with guidance necessary to assess compliance with the provisions of the Food, Drug, and Cosmetic Act and the Radiation Control for Health and Safety Act. Examples are those used to monitor compliance with the performance requirements for x-ray standards, various radiation-emitting electronic products, sterility of medical devices, and adherence to registration and listing requirements.

In evaluating the problems identified with specific devices, as a result of CDRH postmarketing surveillance activities, one of the Center's concerns is to always identify, as completely as possible, all consignees if a defective or potentially hazardous devices is found, for use in possible followup actions that may be indicated.

IIE1. MEDICAL DEVICES AND GOVERNMENT POLICY

INTRODUCTION

Dr. S. Umashankar presided over Session V, with Prof. A. Amedome and Dr. F. Lobo serving as rapporteurs. In his introductory remarks, Dr. Umashankar made the following points.

In the presentations made during the Opening Session of this Conference, the importance of medical devices in health care programs has become evident and has been clearly articulated.

With the rapid progress in biomedical technology, medical devices will assume increasing importance in health care programs. Even the countries wherein technology is not advanced will feel the impact of medical device development that is occurring in industrialized countries. There are a number of interested parties and agencies in the health technology area. These include: doctors, paramedics, investigators, innovators, manufacturers, importers, distributors, experts; and finally, users, patients, and the general public.

Outstanding questions include: the desirability of technology, technology transfer, cost-effectiveness, importation policies, intentions to manufacture, surveillance of proper use, the creation of an information system, and effects on the allocation of resources for the general programs of health care. National authorities cannot remain passive. They need to enhance their preparedness: they need to outline appropriate policies for their countries. These may include legal regulations. Health authorities should carefully study the national health picture and scrutinize not just tertiary health care needs or pressures from urban groups but the total panorama. The rural areas and needs of the primary health care system should receive careful consideration. The need to promote research and local innovation should be balanced against the need to maintain standards. Imports should be handled carefully. With respect to the latter, where national standards do not exist, standards of the exporting countries could be considered. Facilities for operation and maintenance should be provided prior to importation of devices.

Each nation, with the available support of WHO, should develop a program of information, continuing education, and cooperative arrangements with other countries .

After the introduction, Dr. Umashankar invited participants to present their papers.

IIE2. RESEARCH AND DEVELOPMENT

M. H. Repacholi

ABSTRACT

Many countries such as Canada and the United States have well-developed medical device control programs that complement government policies, and programs to support research and develop these devices. Other countries, such as Australia, are in the process of developing these programs and are promulgating the necessary legislation. Most developing countries lack resources for conducting or supporting research and have very limited capabilities for manufacturing any but the most basic medical devices; the available resources of these developing countries have more pressing priorities.

Research and development leading to manufacture of devices is to be encouraged where possible because it can improve the level of health care and the local economy. There are many policies and programs that can be incorporated by governments to encourage research and development. These include incentives, grants, cooperative funding, joint research and development initiatives, and funding for patient protection. New devices should be evaluated for safety and effectiveness; governments are frequently involved in this evaluation. In some instances this may involve clinical trials or other experimentation involving, devices or materials.

INTRODUCTION

Responsible governments are concerned that devices used for health care be safe, effective, and provide the benefit intended. The cost of useless, defective, or hazardous medical devices in terms of human suffering, incorrect diagnoses, or poor treatment, and their drain on available resources, is well understood. On the other hand, the economic cost also must be addressed. Countries do not have unlimited resources, and many must control imported devices, especially high-priced technology for which benefits have not been substantiated.

Some countries have already promulgated or proposed legislation that will establish programs to assure the safety and effectiveness of medical devices. Most developing countries would like to have such programs, but lack resources to implement them.

Some of the benefits derived from initiating and encouraging research and development leading to manufacturing devices used in the health-care industry do not come from high-technology research and development. Countries can benefit significantly from developing and manufacturing "low-technology" devices such as prostheses.

Potential benefits from effective medical devices research and development programs include higher employment, and retention of high level expertise and interest in the product, which in turn results in: lowered medical device cost, improved product marketability, increased developments/improvements, increased product reliability, increased income (taxes, exports), and reduction of imports.

Research and development programs in developed countries usually have the advantage of large local or nearby markets and are encouraged by governments. It has been estimated that for every dollar contributed to such programs by a government an

average return of $10 to $100 can be expected. Furthermore, these programs can generate pools of expertise useful to related industries.

Statistics from Singapore demonstrated beneficial economic results of research. Between 1978 - 1981/82, with government policy encouraging research and development, industry expenditure on R&D increased 72 percent, the number of research scientists and engineers increased 46 percent, total manpower involved in R&D increased 64 percent, and the number of research establishments almost doubled. Most of the research is carried out in private industry and in higher education sectors. Although these percentages involved industrial research, it is reasonable to assume similar increases occurred in medical technology research and development.

OBJECTIVES OF RESEARCH

Research in medical device technology has one or more of the following objectives:

1. developing an application to newly discovered ideas, materials, or techniques (a solution looking for a problem);

2. identifying existing problems and developing cost-effective technological solutions;

3. advancing knowledge of medical biophysics and biomedical engineering; and

4. increasing medical device reliability; thus decreasing potential manufacturers' liability.

In general, these research objectives are more appropriate for the developed countries. Major technological advances in medical devices normally come from a well-funded research program-producing device that can be converted into a saleable product ahead of the competition. Developing countries, lacking resources and expertise to conduct this type of research should encourage more basic lower-technology programs and concentrate their efforts partly on determining the efficacy and cost-effectiveness of medical device technologies now so costly to them.

Specific objectives of these research programs should include:

1. development of devices basic to local needs;

2. development of new design concepts suitable to local environmental conditions;

3. establishment of protocols and performance of clinical trials;

4. use of epidemiology or research to establish where and what the problems are, and how to best apply technological solutions;

5. investigation of diagnostic and therapeutic claims for both new and established procedures;

6. establishment of methods to assess safety and efficacy;

7. exploration of device failure causes and potential remedies;

8. determination of suitable materials used in implants; and

9. development of standards for selected medical devices, e.g., those available to the general public (conforming to or influencing international standards).

APPROPRIATE RESEARCH

In the publication *Appropriate Technology*, Katherine Elliott identifies six criteria appropriate to technology in developing countries.

1. Effective. It should work and fulfill its purpose where it is used.

2. Culturally acceptable. It should be appropriate to the hands, minds, and lives of users, and not disruptive of the social fabric. Necessary change should be introduced thoughtfully and carefully.

3. Affordable. There must be an informed, considered trade off between cost and effectiveness. The technology must be sustained locally, and not overly dependent on imported skills for its function, maintenance, and repair.

4. Measurable. Impact and performance of any technology needs proper evaluation if it is to be recommended.

5. Politically responsible. It is unwise to alter the existing balance in a counter-productive manner, e.g., unwise to encourage minimally trained health workers to take the initiative without making sure medical leaders in the area favor the delegation of this responsibility and agree to help health workers encountering difficulty.

All of these criteria can in varying degrees be applied to the identification of the type of research that can be conducted in a developing country. However, basic incentives to research and develop medical devices derives from their costs. A review of the expense of imported devices that are used in sufficiently large quantities may reveal that local products, properly researched and designed to meet the conditions, are less expensive and more effective. Even if few devices are needed and must be customized (e.g., prosthesis) to the patient, local design and manufacture could be advantageous.

Local research and development will mean that the expertise to continue development and use of a product remains within the country and could contribute to an expansion into related industries.

Following are some sample questions from a survey of government policy and programs for research and development of medical devices:

1. Are medical devices manufactured in your country? If so, please give some typical examples.

2. Describe any government programs or policy designed to encourage or assist with research and development of new medical devices.

3. Describe briefly any whole or partial funding programs for these projects.

4. Is there a government policy to encourage development of medical devices that have a specific need in your country.

5. Is there a program for evaluating the safety and effectiveness of medical devices newly developed within your country.

Table 1 below presents a summary of results of the responses from countries in South East Asia and the Western Pacific region.

Table 1. Medical device manufacture in South East Asia

Country	Manufactured medical devices	Research and Development policy of government
Australia	Many, including high tech, (e.g., bionic ear)	• no specific policy • general funding • Therapeutic Goods Act • Medical Device Review being established
Kiribati	Orthotic products	none
Malaysia	Blood transfusion kits, sutures, scalpels	none
New Zealand	Contact lenses, anesthetic equipment	• no specific policy • general funding • monitors selected devices
Papua-New Guinea	Orthotic products	• no specific policy • Therapeutic Goods and Substances Act • Wants to encourage R&D of medical devices
Singapore	Many - including kidney dialysis	• no specific policy • general funding
Thailand	Gastric suction, stimulators	none - general encouragement for research and development
Vanuatu	Orthotic products	none

It was not surprising to find that some countries have no specific policy for research and development of medical devices although some were interested in encouraging research in general. Still others had Therapeutic-Goods-Act type legislation which empowered them to set standards for medical devices, but had not developed nor were developing standards. A few countries monitor and evaluate selected medical devices.

Countries such as Australia, New Zealand, and Singapore, encourage research and development of medical devices under general industrial research and development incentive schemes. Those in Australia are described more in detail in the next section.

Although many of the smaller developing countries have a limited capacity for manufacturing medical devices and even less ability for research and development of new devices, some of the schemes identified in the next section could be considered for their own programs.

FUNDING PROGRAMS IN AUSTRALIA

A summary of various programs aimed at funding and stimulating research and development in Australia is given in Table 2. Similar programs will be available in other countries.

Table 2. Programs in Australia to fund, assist or provide incentives for research and development of medical devices

Source	Assistance	Comment/Criteria
Banks or finance company	Loans	No high-risk project
Charitable societies	Grants	Basic research
Government Ressearch grant agencies	Grants	Basic research (NH&MRC)
University, hospital, private company	Res. - budget	Part of ongoing research
Government teaching company scheme	50% of salary Educ. sector	Improve links between indust. and tertiary
Public Interest Program (PIP)	up to 100%	Government assists companies formed with CSIRO, Universities - projects of public interest
Australian Industrial R&D Incentive Scheme (AIRDIS)	50% of Company expenses	Commence and project grants, academia/industry contracts
Private sector	Funds	May purchase an interest MIC's, share, joint vent.

Many countries suffer from an "inferiority complex" when it comes to investing in devices researched and developed in their own country. It is not uncommon in Australia, for example, to find local stockbrokers or financial institutions recommending investment in overseas high-tech enterprises, but they regard local high-tech as highly speculative. This is obviously a situation that must be remedied by government policy.

Traditional avenues for funding development of ideas through research for the commercialization of a product have been banks or financial institutions. Eligibility for loans is assessed on the potential success of the venture. Thus, projects having a high risk of failure will generally not be funded from this source.

Many charitable societies such as the National Heart Foundation, anticancer foundations, Dyslexia Association, etc., fund and associate with research projects in their respective areas to help progress in the field and because it will improave their profile or publicity.

Private sector funding can take a number of forms, including: use of own funds generated from product sales to continue research and development of the product line; sale of shares in an enterprise devoted to a particular product; and joint venture funding with other organizations (hospitals, universities, government research laboratories, and other private institutions).

Universities, other tertiary institutions, and large teaching hospitals normally have small research budgets of their own, but obtain most of their funds from such research grant agencies as the National Health and Medical Research Council (NH&MRC).

More recently the government has been encouraging research through cooperative ventures between private enterprise companies and universities or the Federal Government Research Agency, Commonwealth Scientific and Industrial Research Organization (CSIRO). One avenue of government encouragement has been the introduction of Public Interest Projects (PIP) under the Industrial Research and Development Incentives Act. Projects that are deemed in the public interest and provide substantial social and economic benefits to the community are funded (up to 100 percent). Examples of projects funded under PIP are:

1. multi-channel implantable hearing prosthesis (bionic ear),
2. biomedical diagnostic system - immunoassay project (assay kits),
3. ultrasonic breast scanner, and
4. microprocessor-based training aid for handicapped persons.

Under the same Act, companies that never undertook serious research and development may apply for commencement grants to start research. These grants comprise 50 percent of a company's eligible expenditure (maximum $40,000 per company per year). Project grants under this Act provide support to 50 percent of the assessed project costs up to a maximum of $750,000 per year.

A recent amendment to the Act enables project grants to be awarded research companies to undertake research and development on behalf of two or more unrelated corporate clients. This academia/industry contract was specifically introduced by the government to provide opportunity for CSIRO, universities, tertiary institutions, teaching hospitals, and other academic bodies to undertake research projects for industry.

The government initiated a Teaching Company Scheme (April 1986) to improve links between industry and tertiary educational institutions. Its aims are to develop new and lasting partnerships between tertiary educational institutions and industry to conduct IR&D programs in order to:

1. raise industrial performance through effective, long-term access to academic expertise and research facilities;

2. improve manufacturing methods by the effective implementation of advanced technology;

3. stimulate industry's interest, investment, and R&D capability as a means to increase industrial performance;

4. give academic staff a sound knowledge of industry, enhancing the relevance of the research and teaching to the needs of industry;

5. provide talented graduates with training for careers in industry;

6. develop and retrain existing company and academic staff; and

7. open employment doors in Australia for capable graduates.

A grant from the government (usually to a maximum of $15,000 per annum) is made to the tertiary institution to cover one portion of the salary (usually $20,000 - $25,000 per annum) and salary-related costs; the participating company usually contributes the remainder.

Another innovative government program to assist research and development is Management and Investment Companies (MIC) program introduced in early 1984. The MIC program is aimed at encouraging development of the venture capital market in Australia and in attracting management and financial support for the start up and earlygrowth of Australian-based enterprises that have potential to grow rapidly into substantial businesses, are export oriented, and use innovative technology. The government has recognized the need to provide a stimulus to encourage the development of a vigorous, formal venture capital market and has provided a taxation incentive for equity investors in licensed MICs. MICs are licensed and monitored by a licensing board but have a high degree of commercial discretion in the identification, selection, investment in, and support of new and developing enterprises. Investors in MICs are eligible for a tax deduction against assessable income of 100 percent of the amount invested in an MIC if left in for 4 years (deduction of 25 percent per annum).

To further promote research and development in the business sector, the Australian Government announced that as of July 1, 1985, 150 percent of the cost of research and development work can be claimed by companies through ordinary tax returns. The cost of work contracted out to other companies, to institutions such as CSIRO, and to universities, which already handle the bulk of research and development work, can be claimed under this concession. The total cost of research must generally exceed $50,000 except for smaller claims contracted out to approved research institutions.

Government Multiplier Agency Programs assist research associations and a range of other organizations that promote technology transfer (5) providing an industry extension service that reaches many thousands of manufacturing enterprises each year. In a research association, firms within an industry combine to carry out or arrange scientific and industrial research, technology transfer, and associated activities for their mutual benefit. The work of these associations is financed by members with grants from the Department of Science and Technology. This Department is currently supporting many organizations including the Medical Engineering Research Association which is involved in research and development of medical technology.

An example of how a number of funding sources can be combined to make a project viable is one in which this author is involved. The Royal Adelaide Hospital has a contractual partnership with Australia's leading laser manufacturer, Quentron Optics, to develop a neodymium: yttrium-aluminum-garnet (Nd :YAG) laser to be used for surgery. Experts from Quentron and a multidisciplinary team of medical specialists from the Hospital are using scientific, engineering, and technical knowledge to develop the laser. Funding for the project has been obtained from the hospital's research funds, the Anti-cancer Foundation, and Quentron's research funds. Quentron has also obtained an Australian Industrial Research and Development Incentives Scheme (AIRDIS) grant. When the laser has reached the stage where clinical trials are necessary, a grant from NH&MRC or a similar government research grant organization will be obtained. The surgical laser will then be put into commerical production by Quentron, and the Royal Adelaide Hospital will not only obtain sales royalties to be used for further research and development, but will become the center for continuing development of this and other medical lasers for Quentron.

There is little doubt that growth in Singapore's economy over the past 10 to 15 years has been little short of miraculous. Part of this growth has been due to Singapore's industrial research and development programs. Their tax and financial incentives for R&D are similar to those existing in Australia. These include: investment allowances; double deductions for R&D expenses; Product Development Assistance Scheme (PDAS) - 50 percent grant for costs; Research and Development Assistance Scheme (RDAS)— encouraging private sector companies to work in collaboration with government bodies and tertiary institutions; and new technology initiatives.

TECHNOLOGY EVALUATION

Most countries have had to stem the rapidly increasing costs of health care. High priced technology is seen as a potentially increasing burden on overall health costs. The cost-effectiveness of this technology has not always been determined before its introduction. In Australia the Committee on Applications and Costs of Modern Technology in Medical Practice recommended establishment of a panel of experts to advise the government on the impact and the cost-effectiveness of medical technologies.

Establishment of this panel was considered necessary in view of continued, rapid expansion of health technologies and the absence of an effective mechanism for assessing whether benefits to the community of the new technologies are commensurate with their costs. The National Health Technology Advisory Panel (NHTAP) was formed in 1982 with the following objectives:

1. establish and maintain a process for identifying emerging medical technologies;
2. examine significant existing medical technologies to determine whether their present application should be reassessed;
3. determine methods of and priorities for assessment based on criteria such as safety, efficacy, appropriateness of use, cost, and social impact;
4. recommend to the Minister for Health specific areas for research that would facilitate the assessment of medical technologies;
5. recommend whether payment of medical benefits for medical technologies should be restricted until assessment is carried out, and review results of technology

assessment to decide whether the implications of findings require action at Federal or State level;

6. disseminate implications of findings for medical practice to all relevant parties.

For the purpose of the panel's work, medical technology is defined as those activities and procedures involving use of devices or equipment to prevent, diagnose, treat, or cure disease, and that contribute, substantially or potentially, to the total cost of health care. Devices do not include chemotherapeutic agents.

Devices reviewed by the panel include:

1. Medical cyclotron - for production of radioisotopes, including those short-lived positron-emitting isotopes used in positron emission tomography (PET). This device is not recommended by the panel at this time.

2. Magnetic resonance imaging (MRI) device - the panel recommended MRI be evaluated with Government funding in five selected Australian hospitals before setting a medicare fee schedule allowing private clinics to use it.

3. Extracorporeal shock-wave lithotriper - this device uses ultrasonic shock waves propagated from outside the body and focused onto the kidney or upper ureter to disintegrate stones without surgery. It was found to be safe and effective and reduces complications and length of stay in hospital. Recommended that three units be installed in appropriately located hospitals. It is regarded as a national resource.

Other technologies being studied include:

1. lasers in medicine,
2. digital subtraction angiography,
3. endoscopy,
4. rotational testing of vestibular function,
5. suture stapling,
6. cochlear implants,
7. hyperthermia for cancer treatment,
8. high-energy radiotherapy, and
9. doppler ultrasound in cardiology.

It is apparent that technological evaluations such as those provided by NHTAP will allow the government to make more informed decisions on introducing high-cost technology into the health-care system.

TESTING AND EVALUATION PROGRAMS

Basic procedures for work in research and development must be valid and reproducible. Consistent units of measurement must be used and equipment must be calibrated to recognized standards. The National Association of Testing Authorities (NATA) monitors the calibration of testing equipment and, through recognized procedures, provides Australia with a national network of accredited laboratories. A collaborative

venture between government, industry, and regulatory interests, NATA monitors and accredits facilities in the following areas (5):

1. measurement of noise and vibration;
2. biological, microbiological, and biochemical testing;
3. chemical detection and analysis;
4. testing of electrical and electronic instruments;
5. heat and temperature measurement;
6. measurement of strength of materials and assemblies;
7. tests associated with human health;
8. precise measurement of mass, structures, and components;
9. nondestructive testing of structures and components; and
10. optical and photometric testing.

Although the initiative for forming NATA came from government, and NATA has no legal authority, subsequent development has been characterized by a progressive increase in the relative contribution of private enterprise. One Australian State government (Victoria) requires that its departments and agencies needing to use, for statutory purposes, private laboratories for test results have those laboratories endorsed by NATA.

The Australian federal agency most recently responsible for ensuring quality, safety, and efficiency of medical devices is the Medical Devices and Dental Products Branch (MDDPB) of the Commonwealth Department of Health. Their mission is to be a "clearing house" for information and their program is to establish a registry of medical devices wherein information associated with medical device problems is collected and disseminated. MDDPB evaluated the effectiveness and safety of certain high-risk devices prior to marketing (premarket approval) and is establishing a facility for developing standards and determining standard compliance.

Both the Therapeutic Goods Act (6) and customs legislation can be used to regulate medical devices, however, neither takes proper account of the problems associated with the control of these devices. New legislation dealing with both locally manufactured and imported medical devices is being considered at the present time.

New medical devices resulting from local research and development programs are not required to be tested and evaluated by the MDDPB, although it has provided advice to some local manufacturers (e.g., advice on materials for the bionic ear). Under Federal-State divisions of responsibility, only State governments have authority to regulate the manufacture of new devices within that State. Unfortunately, this authority is not always used resulting in many large hospitals, with qualified medical and technical staff, conducting their own testing and evaluation programs on selected medical devices prior to allowing their use within the hospital. MDDPB encourages the reporting of medical device problems, collects and reports this information from state and national governments, and compiles a national registry of data on their safety and effectiveness. Registry data is available to all who need to have more information on medical devices.

The MDDPB is taking the Canadian approach and moving towards an evaluation program of selected imported medical devices as well as cooperation with State programs to provide premarket approval for a limited number of locally made medical devices.

Such a service will be invaluable for the evaluation of prototype devices resulting from research and development programs.

REGISTRIES

All countries should compile or have access to medical device registries. Registries could be enlarged to collect research data and the results of clinical assessments, safety and efficacy, from recognized agencies. Sharing of such registry data would be of invaluable assistance to many developing countries unable to evaluate devices themselves—an extremely useful means of international cooperation on medical devices. These registries will ultimately reduce unnecessary research and assessment of devices—a great saving of resources. Devices evaluated in one country and found acceptable by a recognized agency could be accepted by other countries without further testing--reducing delays in use of products beneficial to health care.

CONCLUSIONS

Research objectives and benefits have been identified along with means by which governments can both encourage and participate in research and development programs. The important thing is that types of research programs be appropriate for the country. Research, in many cases, should be carried out by collaboration among government agencies, universities, hospitals, and industry. The overall benefits of this are not only a safer and more cost-effective health care system, but increased domestic research, development and manufacturing, and progress towards self-sufficiency in basic medical needs.

Sharing of medical device registry information is one means of reducing unnecessary research, and of providing tangible benefits derived from international cooperation.

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IIE3. MANUFACTURING

M. Saito

INTRODUCTION

Medical engineering and technology has provided positive health-care benefits both in diagnosis and therapy; enhancing its rapid development. The rapid development of medical technology and its involvement in the medical and health care systems in recent years has stimulated discussions concerning the appropriate role of technology in health care. The essential role of medical technology should be to ensure quality and uniformity of health care as regards needs of the society, and the role of the administrative policy should be to reflect this.

Technology assessment may be an important tool in medical device management where effectiveness is compared with cost. Medical care is not simple, and methodologies should be developed to improve the quality and uniformity of care. In the past, most administrative efforts have been directed toward safety and reliability, and the basic idea of a straightforward mechanism that could rule out unsafe technologies prevailed. However, in recent years the complicated situation has produced another role for the administration: exploring adequate criteria for assessing the effectiveness or efficacy of the technology.

In view of the complex man-machine interaction system present in the medical and health care enviroment and of the massive need for care, it is time now to introduce modern notions of engineering: system design, standards, and modular structure. On the other hand, a firm idea still exists that in medical care, the traditional treatment of an individual is best. We are in a transitional period with the two streams of ideas combining, creating a new medical-technology environment. The administration now needs not the philosophical, idealistic approach but rather one of flexibility to cope with these gradually changing situations and match policy with the diversified needs of the various sectors.

SYSTEMS ASPECTS

One of the greatest changes in medical technologies in recent years is that individual devices are becoming far more complex. Additionally, a large number of diagnostic and therapeutic devices have combined to form a system physically or. Such a situation makes analysis of safety and reliability much more complex than in the past.

The expectation in the past was for the manufacturers to produce reliable products efficiently conforming to established regulations, and the user to use the devices relying on the reputation of the manufacturer and the regulatory standards. Although this idea is not practical in principle, it often worked well as long as manufacturers and users were dealing with the relatively simple individual devices. However, this situation no longer applies. In the case of a misoperation or misapplication of a system's device, for example, various points can be argued as regarding the responsibility of manufacturer, user, and administration.

Some statistics indicate many serious incidents occur because of misuse or misoperation of devices thereby indicating the importance of design not only for hardware reliability but for proof against careless operation. Actually, the medical professional

should not be blamed for a careless handling, because his attention is directed toward the patient and he cannot devote much effort to the device. Manufacturers should be guided to achieve a high man-machine reliability. Standardization will help. The responsibility of the user to select, use, and maintain the device should also be considered in improving reliability of medical technology as well as the manufacturers' responsibility.

SCALE OF MANUFACTURERS

There now exists a tremendous number of different technologies in the health-care field. Estimates range from several to several tens of thousands different technologies currently in use. Such a tremendous number may be due to the lack of standardization and modular design which may be ameliorated in the future. On the other hand, it can be due to the tremendous number of different diseases and the different means of cure, and can also be a reflection of the rapid progress of medicine.

Although there are many devices large manufacturers can produce using mass-production, there are still devices that must be handled in small quantities. The lack of standardization in system construction further necessitates individual design for devices and interfaces that should not have been necessary.

With such a situation, the manufacturers must have flexibility and be able to quickly adapt to the progress and changes of medical care. This inevitably generates the need for flexible small-scale companies, which produces problems concerning product quality assurance.

There are a number of small-scale manufacturers who have reputations for unique and high-performance products in their specialized field. They have specialists in particular techniques but it is difficult for those manufacturers to prepare the vast information concerning human factors, engineering or reliability design, either from the viewpoint of funding or human resources. There must be a certain supporting function for those manufacturers, such as an information service, testing facility, etc., in addition to a rigid framework of approval and regulation. It is crucial to encourage development of technologies by small manufacturers in medical technology,something that has been the role of the private sector and of governmental organizations in the past.

ROLE OF CENTRAL ORGANIZATION

Because of the existence of diversified technologies and of small-scale manufacturers, it is difficult to require that all manufacturers in this field have sufficient knowledge of, and the facilities for, testing and realiability of design (from both hardware and the human aspect). Consequently, in order to help those manufacturers with their technical development, a national center of information and technical assistance needs to be established. Actually centers have been established in several countries but their resources are limited.

The first service needed is to provide manufacturers with information as regards to where the device will be used, and the real and current need for it. However, there are many ambiguous points in the technological assessment of medical technology what should be carefully considered. For example, evaluation of need should be based not on present status and cost of technology, because depending on utilization of the technology factors affecting assessment may easily change. The medical technology

touches social problems on three points: economy, reliability, and ethics. Each of these, conversely, is affected by the use of technology. Mass-production, for example, has great influence on price and reliability, and the ethics surrounding a technology depends on how widely utilized it is.

Medical professionals have no idea how they feel about a technology until it is in their hands. Consequently, one should not assess technologies based solely on present situations but on projected situations also.

The next service needed is information on reliability of parts and devices useful to both manufacturers and users. For example, case studies of accident(s) will be an invaluable data base to those involved. Already it has been recognized that the simple system of reporting the accident and failure of a medical devices is not an adequate assessment tool. In some device failures the device may have failed simply because of a minor defect. It would be a great help to the manufacturer if specialists could give advice on how the problem could be solved.

STANDARDIZATION

One of the most urgent problems in medical technology is how to introduce modern engineering practices into medical and health care. Among these, standardization is the most important. It is obvious that standardization is useful in ensuring the quality of technology and in improving the user-manufacturer communication. Sometimes it is not in accordance with the traditional idea of medicine that technologies and care be tailored, in the optimum way, to meet the satisfaction of the individual patient. Standardization, however, is a mandatory procedure in present medical and health care.

It is recognized that standards can be at various levels, from very weak to very strong. In medical technologies, however, the notion of standardization should be a still wider one. Even if the technology is not matured enough to consider standardization, it is better to try guiding manufacturers by publishing even elementary guidelines, recommendations, and manuals. This is a way to cope with the rapid development of device technology which makes it difficult for standardization to keep up with hardware changes.

Human engineering is one of the important aspects of standardization. If crucial aspects of the important devices such as the operation of important controls, meanings of warning signals, important connectors, etc., are standardized so that the operator can handle the device without watching the panel, it will be of great value to improving the reliability of operation. Because it is difficult at the present stage to specify in detail to these aspects, it is wise to prepare even a weak guide enabling us to reach a standard in the future.

In imported products, symbols and marks from manufacturer to user are a better means of communication than the written language, which can be a problem. The idea is that symbols and marks used in communicating have the same character as a formal language insomuch that a new meaning can be conveyed by combining basic symbols, just as combining words by following a rule can produce a sentence.

Finally, there should be a wide range of guides, from weak recommendations to strong standards, for the manufacturers. In the same way, there should be a wide range of guides for users. And there should be guides for manufacturer-user communications. Those guides and standards should be considered together, and a bridge. Even if it is

difficult to specify standards in certain conditions, policies must be carefully prepared to lead people to ultimate standardization.

ROLE OF ENGINEERS

It is often emphasized that engineers play a crucial role in medical and health care sectors. It is indeed very important that engineers with appropriate education and training be given the role of ensuring proper use of the devices and maintaining the reliability of the whole man-machine system of care. And they should also have the role of transmitting necessary information among manufacturers, users, and other related sectors.

The administration, which has been dealing with legal mechanisms for regulation and financing, is now required to have a certain knowledge about engineering and technology, not in the sense of detailed practical aspects but in the ability to evaluate the adequateness of the engineering approach and the ability to look into the future. Some means to include engineering staffs in the medical and health care administration should be considered.

INTERNATIONAL COOPERATION

Because of the large number of different devices and the huge resources sometimes required to develop and evaluate technologies, the possibility of international cooperation is often discussed. Scientifically it is easy to exchange information at the developmental stage, preventing waste of resources by useless effort. For this purpose, presentations of negative results should be encouraged.

Policies for research and development of medical technologies may vary in different countries because of accommodation to the needs of society. In the case where several countries have similar social situations, there can be cooperation in developing particular technologies for a particular requirement, e.g., circulatory disease technology and rehabilitation technology. However, this cooperation cannot cover the whole spectrum.

Standardization should be made on an international basis as far as possible. If standardization has to be made, as at the present time it is based on international agreement, progress is too slow to catch up to the rapid change of medical technology. It would be helpful if all national efforts toward standardization, even at the very weak level, could be exchanged among concerned countries. This is not to regulate the marketing of products, but to encourage mutual understanding and the smooth transfer of technologies.

Information concerning the regulation, on the other hand, should be more carefully handled. Warnings about the device, for example, are of a delicate nature; the accident may have been due to any number of different factors, such as maintenance system, utilization environment, and user's level of education. Information concerning accidents should be exchanged quickly among the authorities without generating unnecessary notoriety and national authorities should take responsibility for scrutinizing dangerous aspects of the device and determine how to best disseminate their conclusions. Merely transferring this kind of information is harmful rather than positive. It is desirable that each national authority have a neutral testing facility to make fair judgement from its own viewpoint.

CONCLUSION

Because of the particular nature of medical technology in supporting medical and health care in coping with the diversity diseases, mass of people, and traditional ideas of medicine, there exist a number of problems such as small-scale manufacturers, lack of modern engineering ideas such as systems design or standardization, and differing ideas and requirements of different countries.

Medical technologies in most of the advanced countries are in a stage of transition. They are in a transitional stage also in other countries, in a different sense. The exchange of information for solution of problems will be useful at this stage. International cooperation is difficult to start up all at once but should be initiated step by step. In an international exchange of ideas, we should be aware that what applies to one country may not be true in other countries.

IIE4. THE IMPORTATION AND EXPORTATION OF MEDICAL TECHNOLOGY IN LATIN AMERICA AND THE CARIBBEAN

M. Guerrero

INTRODUCTION

Technological dependence is the main characteristic of the current condition of health technology development in Latin America. Almost 90 percent of the technology used is imported, with the exception of production in Brazil, Argentina, and Mexico. There is a lack of knowledge and reliable data on the importing of medical equipment. Current customs classification of foreign commerce is unsuitable as a basis for generating information. However, the U. S. Department of Commerce compiles data on exports. Based on this information, it can be seen that a given group of countries imported US$ 1.53 billion of a group of products from the United States from 1979 to 1983. This figure represents 35-40 percent of the total imports of these countries. It is estimated that during this period the United States exported a total of US$ 4 billion in medical equipment. These figures show that Latin America is an important market for U.S. products. Major suppliers to the region are the United States, Great Britain, other European countries, and Japan. The selection of equipment is an important process that is based on the identification of needs. Little knowledge is available on this process. Buyers generally have access to limited information, compared to representatives and distributors who are specially trained and have information available to them. Argentina and Brazil are the main exporters in Latin America. Argentina exported US$ 3.6 million in 1979, dropping to US$ 1.7 million in 1980, and US$ 2.1 million in 1981. Brazilian exports have risen from US$ 14 million in 1979 to US$ 38 million in 1983.

GENERAL CONSIDERATIONS

Technological dependency is one of the elements that most clearly characterizes the current state of development in Latin America. Approximately 90 percent of the technology that is presently in use was imported. The desired level of assimilation has not been attained to enable these technologies, designed for use in a totally different environment, to provide the benefit expected of them by the importing countries. This situation has been cause for great concern and extensive analysis in Latin America. At first, concern focused essentially on the industrial sector, and in the late 1960's, efforts were made to study this problem within the context of the health sector.

Studies carried out with advisory services from the Harvard Mission in Colombia produced unexpected results as regards the status of the pharmaceutical sector. These studies were further analyzed by the governing bodies of the Andean Group, an integration mechanism formed at that time by Bolivia, Colombia, Chile, Ecuador, Peru, and Venezuela. The conclusion was that the situation described in Colombia applied also to all the other countries, with slight differences. Thus, light was shed on the actions and abuses of large laboratories: overbilling of raw materials and intermediate products, lack of controls on production, retaining of captive markets through the application of an outdated patent system, restrictive clauses, etc.

In response to this situation, the member countries of the Andean Pact enacted legislation that was aimed at improving the conditions for procuring imported drugs and their respective raw materials and intermediate products. This legislation was also geared toward eliminating limitations contained in agreements concerning importation

of technology or use of patents and trademarks. Subsequently this position was assumed by other countries as well, e.g., Argentina and Mexico.

Enthusiasm spurred on by this investigation into Latin America's pharmaceutical sector led to an exhaustive analysis of most of the elements of this sector, but overlooked other aspects of the health sector that were just as important as those indicated above. It was thought that this situation could be easily projected to other sectors of regional activity. This led to a head-on clash between developing countries and transnational companies, even reaching some United Nations agencies in a search for international actions codes and other equally illusory formulas.

Despite the importance of the health sector in all areas of national activity, it is cause for concern that it is precisely this sector that has a noted lack of explicit and coherent policies in virtually all the countries of the region. The one explicit standard that could be found in almost all these countries was the result of the aforementioned pharmaceutical sector studies, which were translated into a statement prohibiting granting patents for such products. In recent years, medical equipment has sparked the interest of problem analysis in the health sector.

PAHO is sponsoring a study on the conditions under which medical equipment is imported and the current situation and outlook for regional production as part of its mission to secure improvement in health conditions in the region. The lack of suitable national policies in this area is having a serious effect on the delivery of services in the health sector. The technology being purchased is unsuited to the environmental conditions in which it will be used. This squanders resources allocated to health, shrinking as a result of balance of payments problems.

IMPORTATION OF EQUIPMENT

With the exception of Argentina and Brazil, which have a considerable level of domestic production, virtually all medical equipment in use in Latin America is imported from developed countries. This is disquieting proof of the high level of technological dependency of these countries, and in the case of these products, this has special significance.

In all the studies undertaken on technological development in Latin America and the causes that gave rise to such a large gap vis-a-vis the developed countries, one of the most negative elements detected, and unfortunately one of the most common, is the lack of information on the part of the users of technological devices. Information compiled in research carried out under the sponsorship of PAHO categorically confirms that this situation appears repeatedly in the procurement of medical equipment.

This gap in knowledge is present at all levels and is of particular concern in regard to the lack of reliable information for carrying out a comprehensive analysis of the current status of medical equipment imports. The lack of in-depth national studies, discontinuity in existing data, and the various methods for grouping medical equipment under national statistics systems considerably limit the possibilities for undertaking a consistent analysis under current circumstances. Furthermore, for unexplained reasons, present customs classifications for foreign trade place medical equipment in categories that are known as group headings, which cover many products having only one point in common, and these are then subject to the same customs duty. This may be suitable for the purpose of customs classification but is totally unsuitable for the application of a selective policy in the health sector. This is a case in which we face an implicit health

policy that excludes the possibility of variable handling that could possibly benefit domestic production.

An interesting example of the limiting factors produced by situations like this one is found in the difficulties encountered in drafting a commercial agreement within the framework of the Latin American Association for Integration (ALADI) for importing "articles and apparatus for hospital, medical, odontological, veterinary, and other related uses." This agreement involved Argentina, Brazil, and Mexico and established preferences to be given certain products imported by these countries. One of the clauses of the 3-year agreement incorporates a commitment to examine the possibility of extending its effects to countries not currently participating in it. The problem that most delayed the agreement was the difficulty in identifying which products it would include, a consequence of inappropriate customs nomenclature in this area.

This customs identification problem complicates the preparation of detailed information on imports considerably; not only because of the existence of group headings as mentioned above, but also because each nation's customs system has a uniquely tailored structure. Considering, also, that the annual data on foreign trade encompasses different periods in each country, it is easy to see that it would be difficult to carry out a comparative analysis based on information prepared separately by two or more countries.

In the search for information that could be used for purposes of comparison, data that was chosen included U.S. exports to Latin America. This information, prepared by the U.S. Department of Commerce (USDC), covered a given group of exported products and was supplemented by studies carried out in each country by a commission of the Department of Commerce based on USDC guidelines. There were two limitations even in this case. First, information was not available for the same period for all countries analyzed. Second, the category "equipment" included elements that did not fit this description, such as bandages, gloves, syringes, surgical thread, furniture, scales, etc.

According to the U.S. Department of Commerce, United States exports of medical equipment to the following countries from 1979 to 1983 were (in US$ million):

Argentina	148.34	Peru	34.42
Costa Rica	29.05	Uruguay	15.66
Chile	58.89	Venezuela	217.11
Ecuador	51.16	Bahamas	7.36
El Salvador	23.44	Barbados	2.89
Guatemala	30.38	Bermuda	4.56
Honduras	15.95	Guyana	1.20
Mexico	342.77	Dominican Republic	21.55
Nicaragua	7.64	Jamaica	10.39
Panama	44.85	Trinidad and Tobago	15.04
Paraguay	5.01		

For these countries, total U.S. exports of the group of products pertinent to the above studies was US$ 1.3 billion for the period between 1979 and 1983.

Also based on USDC data, the U.S. share of medical equipment imports by these countries ranged between 35 and 40 percent of the total medical equipment imported for this period. Total medical equipment imports in these countries was nearly US $4 billion during this period.

These figures, combined with data collected in studies by national consultants, provided the following information on imports in Argentina and Brazil from 1979 to 1982. The following figures represent total imports for each year and the percentage of U.S. products.

Table 1. Imports in Argentina and Brazil, 1979-1982

	Argentina		Brazil	
Year	Total imports US$ millions	U.S. share in US$ millions	Total imports US$ millions	U.S. share in US$ millions
1979	38.90	10.01	82.00	26.00
1980	82.94	30.94	71.76	20.40
1981	92.16	37.68	49.93	17.30
1982	35.90	12.48	57.05	19.02

Using 1978 as the reference year because information is available from a single source for that year, total imports and the U.S. share were, in millions of U.S. dollars:

Table 2. Total imports and U.S. share

Country	Total imports	U.S. share
Colombia	23.64	7.84
Chile	8.53	3.04
Guatemala	4.97	3.75
Mexico	37.14	14.75

Another interesting aspect that is noteworthy is shown by the comparative sample in US$ of a few imports in four countries of different sizes and characteristics. The year selected was 1983 and the countries considered were Brazil, Colombia, Mexico, and Panama. The imported equipment was gauze-bandages; surgical thread; catheter and drains; hypodermic syringes; electromedial equipment; electromedical equipment parts; medical, dental, and surgical equipment; and x-ray film.

Table 3. Comparitive amounts of medical equipment imports to four countries, 1983

	Gauze & bandages	Surg. thread	Cath. & drains	Hypo. syrgs	Electro-med eqpt	Electromed eqpt parts	Med, dent, surg eqpt	X-ray film
Brazil	172	681	669	6	3730	3900	3670	1837
Colombia	263	691	774	170	2450	1920	1950	1578
Mexico	1132	627	3394	104	6350	4880	4560	290
Panama	1072	578	513	524	805	284	612	83

Although it has been pointed out repeatedly that available information is very limited, data that can be used for comparisons allow some interesting conclusions to be drawn concerning the importation of medical equipment.

1. General figures indicate that the Latin American market is an important one, and a high percentage of its demand is currently served by imports from other countries.

2. The largest supplier to Latin America is the United States, followed by continental Europe, Great Britain, and Japan. Other countries such as Spain, Sweden, and Holland have made minor entries into Latin American markets.

3. The only regional suppliers are Argentina and Brazil, with Brazil playing a larger role.

4. The similarity among the imports of almost all the countries of the region appears to indicate a common purchasing pattern that covers essentially the same products, although amounts vary significantly. Additional studies appear to confirm this and indicate that the persons responsible for procuring medical equipment and devices prefer complete "packages" that include everything required. Frequently, a central supplier is made responsible for preparing the required package.

5. The above explains the strange combination of purchases that may include, in a single transaction, such major items as high-technology equipment together with bandages, cotton thread for sutures, furniture, beds, syringes, scales, autoclaves, etc.

6. Argentina and Brazil are the only countries that exercise some degree of selection in the importing of medical equipment, based on national legislation that favors the purchase of local products. Although these standards are not always observed, undoubetedly they have a beneficial effect on the domestic production of medical equipment and products.

7. The information used to analyze imports from 1979 to 1983 shows that, between 1970 and 1981, there was a marked increase in imports virtually throughout the region. Since then, there has been a sharp decrease in imports in all the above categories in these countries. Subsequent studies have indicated that this decrease was a direct result of the restrictions imposed on each country as a consequence of balance of payments problems, and therefore does not reflect a decline in demand or a larger share of domestic production in the local market.

The most significant decreases in the above period were, for the following countries:

Table 4. Decrease in imports, 1981 - 1983

Country	From (US$ millions)	To (US$ millions)
Argentina	47	13
Chile	14	7
Costa Rica	7	3
El Salvador	8	4
Guatemala	10	2
Mexico	99	46
Venezuela	54	24

These decreases show that in most cases involving financial problems, the authorities in charge of domestic resources did not hesitate to make the first and largest cuts in health care funds.

SELECTION PROCESS

Medical equipment is one of the essential elements in the health care delivery service whose principal objective is to promote and support a healthy population. Consequently, much of the effectiveness of medical technology depends directly on the characteristics and proper operation of the medical equipment that is involved. This is why equipment selection is such an important process within the activities of health services delivery.

The equipment selection process involves several steps. The first step is detection of a need that should be met through a particular kind of medical technology. This step is usually performed at a hospital by persons providing the service.

After detecting a need, the next step is to study various methods to satisfy the need, giving consideration to a series of closely related elements. For this purpose, it is necessary to determine whether the technology used so far is the best suited or if it needs to be modified or replaced with new technology. It is also necessary to consider the flexibility of the equipment, its possible intensive use in several areas, the characteristics of the environment in which it will be used, the availability of professionals trained in its use, and, in general, all those aspects dealing with the best and most appropriate use of the technology incorporated into the equipment.

Third, after the appropriate type of equipment has been chosen, the next step is to determine, which equipment that is available in the marketplace, best meets the pre-established requirements. In addition to considering the pertinent technical aspects that define the equipment that best responds to the pre-determined needs in step 2, the health care administrator should analyze the experience of any health service agencies that have used such equipment, the level of difficulty of using the equipment, the availability of support and repair facilities and their efficiency, and the existence of warranties and other related elements.

Finally, and just as important, there is an element that in many cases affects the final decision: the financial aspect.

For a basic selection process such as the one described here to be properly carried out, it is necessary to have complete information that provides the greatest possible detail on all the elements directly or indirectly affecting the final decision. This occurs only when the person responsible for making that decision is duly advised by an interdisciplinary group which includes the physician that will apply the respective health technology, persons who will operate the equipment, maintenance and repair staff, and staff responsible for financial management of the institution.

Among hospital administrators, the impression exists that, in most countries of the region, procurement of medical equipment is not based on a selection process that has the aforementioned characteristics. Usually the decision is left in the hands of the professional who will use the equipment. The professional's decision is usually based on experience acquired during practice or during advanced medical training in developed countries, without considering that the conditions under which the equipment will be used in the home developing country are totally different from those of the developed

country. This practice is of even greater concern in public health services where there is a continual turnover of professional managerial staff, and each new manager makes decisions based on personal preference without taking into account the consequences of the decision. The result of this type of selection process has been the accumulation of idle equipment in hospital storerooms or the transfer of such equipment to hospitals located far from major cities, where the possibility of effective use is usually overestimated.

In contrast with the uninformed buyers stand the knowledgeable equipment suppliers, acting through representatives or distributors, who are specially trained in aggressive sales practices. In the case of governmental purchases, these sellers have access to a flow of information that greatly surpasses the limited knowledge of purchasing authorities. The case of private institutions is different because the institutions have a more thorough decision-making process in which the cost-benefit factor plays a major role.

The accumulation of idle equipment is compounded by the lack of equipment maintenance, control systems, and a properly trained staff. This is aggravated by non-compliance with some essential standards of use and prescribed maintenance, which results in the forfeiture of manufacturers' warranties provided with the equipment at the time of purchase.

EXPORTATION OF EQUIPMENT

Of all the Latin American countries, the only ones that export medical equipment are Argentina and Brazil with Brazil having a greater and ever-increasing role. It is interesting to note how the circumstances surrounding procurement of this equipment have prevented local producers from taking full advantage of the regional market, which, we already pointed out, should be of interest to all producers. To summarize the current situation: there is a marked lack of information on products made in Latin America, and a lack of knowledge about the regional market. There is an enormous potential of possible mechanisms for regional cooperation among Latin American producers. This is especially important when the unavailability of outside resources forces developing countries to seek mechanisms that facilitate using the various counter-trade systems that have begun appearing in different regions.

It is not a matter of seeking schemes of independent development within the field of medical equipment production, nor is it a question of eliminating imports from outside the region. On the contrary, formulas should be sought to promote regional production of equipment which uses technology that is accessible within the level of development that has been reached within the region (especially in the form of finance and payment mechanisms). Such mechanisms should be extended to external producers of more sophisticated equipment who wish to contribute to the development of industry in developing countries by choosing a Latin American country where they could manufacture some of their equipment.

Argentina

Available information indicates that medical equipment exports from Argentina reached their highest point in recent years in 1979 when they hit US$ 3.6 million. In 1980 this figure fell to US$ 1.7 million and then moved up again in 1981 to US$ 2.1 million.

In 1979, electromedical equipment was first among exports, accounting for 86 percent of the total. Starting in 1980, orthopedic apparatus became the largest export, representing 56 percent in 1980 and 1981. In 1981, there was a notable increase in the export of x-ray apparatus which climbed from US$ 31,000 the previous year to US$ 735,000.

As for the destination of Argentine exports, most go to Latin American markets such as Bolivia, Brazil, Chile, Uruguay, Mexico, and Venezuela; particularly the first four. These exports to other countries of the region will surely increase when the agreement signed within the framework of the Latin American Association for Integration, mentioned at the beginning of this document, goes into effect. Despite the fact that Argentina has exported these devices to other countries, such as France, Italy, and some nations in Northern Africa, until now they have exported only small amounts. In some countries, the device exports have been rather uncommon, e.g. orthopedic devices exported to two European countries.

Brazil

Brazilian exports have increased consistently in recent years:

1979	US$14 million
1980	26 million
1982	36 million
1983	38 million

The most commonly exported products are hospital medical devices, representing approximately 90 percent of the total. Special mention is made here of electromedical apparatus of simple technology and orthopedic apparatus.

The recipients of Brazil's exports have been Argentina, Bolivia, Chile, Uruguay, and Mexico. Brazil has a considerable domestic market, and is also the Latin American country with the most aggressive export mentality. Thus it has become an exporter of locally developed technologies, exporting even to countries in Africa.

Mexico

Although available information is very limited and contradictory, based on market research carried out by the U.S. Department of Commerce in 1982, Mexico is reported to have exported the following (in US$ thousands):

	Mechanotherapy & resp dev	Orthoped apparatus	X-ray eqpt
1979	328	165	558
1980	47	91	256

IIE5. DISTRIBUTION AND DIFFUSION

M. Slatopolsky

This presentation is based on the studies of distribution and diffusion of medical devices carried out in Argentina under the direction of Dr. C. Canitrot. We will focus on certain types of major high technology devices and examine their pattern of incorporation into the health care system of Argentina.

First of all, we need to note certain geographical characteristics of the country. Argentina has a very large surface area, almost 3 million square kilometers, and it is very long. It takes approximately 3½ to 4 hours to fly from one end of the country to the other. The distribution of the population in Argentina is very nonuniform. While the average population density is 10 persons per square kilometer, fully 45-50 percent of the population is concentrated in the metropolitan areas which comprise one tenth of one percent of the area of the country (approximately 4000 square kilometers). The distribution of medical device technology does not correspond to this demographic and geographic distribution.

The amount of equipment incorporated into the health care system is substantial. In January 1985 there were 45 CT scanners in Argentina. Of these 93 percent (42 units) were in the private sector. Less than 7 percent of the CT scanners (3 units) were owned by the government. Geographically, 69 percent of the CT scanners (31 units) were concentrated in the metropolitan areas which represent approximately one-tenth of one percent of the area of the country. On the other hand, only 31 percent of the CT scanners (14 units) were distributed in the remaining 99.9 percent of the area of the country.

With regard to gamma cameras, as of the same date there were 88 units in Argentina. Of these, 84 percent (74 units) were in the private sector, and 16 percent (14 units) were owned by the national, provincial, or municipal governments. Gamma cameras were also distributed nonuniformly. Metropolitan areas had 61 cameras (approximately 70 percent of the units distributed in approximately 0.1 percent of the area of the country).

With regard to linear accelerators, Argentina had 10 units. Seven (70 percent) were in the private sector and three (30 percent) were government owned. The same problem of nonuniform distribution exists with regard to these devices. Eight linear accelerators (80 percent of the units) were in metropolitan areas, and only two accelerators (20 percent) were left to cover the needs of the remaining 99.9 percent of the area of the country.

There were 80 cobalt radiation units in Argentina in January 1985. Of these, 61 units (76 percent) were in the private sector and 19 (24 percent) were government owned. These were also nonuniformly distributed. Fifty four units (67 percent) were located in Buenos Aires and the remaining 26 (33 percent) were spread throughout the rest of the country.

Thus it can be seen that medical device technology is distributed very nonuniformly in Argentina. Metropolitan areas have high concentrations of major high technology, and the remainder of the country is very poorly supplied with major medical device technology.

There are several reasons for this gross nonuniform distribution of health technology. The most important was the improper application of incentives for the incorporation of high technology. These incentives involved tax exemption of imports. General Decree 732 of 1972 exempted charitable organizations and foundations from payment of duties on imports. A special law of the military government in 1978 permitted duty-free import of equipment that met certain characteristics, i.e., high technology and not manufactured in Argentina. These duty free imports cost Argentina $38 million in duties not imposed. The legislation established certain requirements that were to be met by the importers. Subsequent analysis demonstrated that almost none of these legal requirements were met by the importers of major medical high technology devices. The tax exemptions were granted without compliance with the requirements of the military government for the distribution of devices.

For example, it had been determined that one CT scanner would be necessary for each 2 million persons. This was to include those units already in the country and those that would be imported duty free. The same numeric determination had been made for gamma cameras. Because Argentina has a population of some 28 million people, a maximum of 14 CT scanners were authorized within the country. In fact, 29 CT scanners were imported duty free. This was twice the maximum that should have been allowed for duty free import, even without taking into account the units already present within the country.

In addition, the existence of third party payers, who do not receive services but provide payment through the social security system, serves as an incentive for the use of these technologies. The existence of third party payers who cannot control the excessive use of these technologies, coupled with the aggressive marketing policies of many companies, contribute to the excessive and unjustified import of equipment.

In a case involving ultrasound equipment, the terms of the purchasing agreement included a training course and certification following testing of the trainee in Buenos Aires. In fact, a single office in Spain issued 322 certifications to practice to Argentinians after 1 year of sonogrophy training, certifying that the individuals had passed the course and completed an internship in either Spain or Florida.

A second factor in the sale of equipment is the unit of payment. In Argentina the galena is the theoretical unit of payment for medical services used by the medical insurance system. Each treatment is valued at a certain number of galenas and is reimbursed on that basis. When equipment is purchased by a professional, he is shown how to make the most effective use of the equipment for the rapid recovery of his investment. This has produced a stimulus for the diffusion of technology that has exceeded the real health needs.

Medical care in Argentina is practically out of control. Only recently has legislation begun to be passed to regulate health care. However, it is difficult to influence technology that is already in the country, and is distributed in a completely irrational manner.

IIE6. EVALUATION OF MEDICAL TECHNOLOGIES IN TERMS OF HEALTH OUTCOME

R. B. Panerai

The point is that invention had become a duty, and the desire to use the new marvels of technics, like a child's delighted bewilderment over new toys, was not in the main guided by critical discernment: people agreed that inventions were good, whether or not they actually provided benefits, just as they agreed that childbearing was good, whether the offspring proved a blessing to society or a nuisance.

Lewis Mumford,
Technics and Civilization, 1934.

Medical devices comprise all medical technologies that have a physical nature, with the exception of drugs. Devices have been used for medical purposes since time immemorial. Since the 19th century however, following the evolution of science and technology, their range of application, numbers, level of complexity, and pervasiveness have reached an intensity that has changed the structure of medical practice (*1*) and is now affecting society as a whole (*2*).

The technological revolution in health care has been largely the history of medical devices. After World War II the application of new developments in electronics, physics, and biochemistry led to some "sensational technologies" that bewildered physicians and patients alike, creating the myth that the solutions to any health problem lie in the discovery of a new machine.

In the United States, the Food and Drug Administration regulates more than 3500 generic types of devices (3) and approximately 5000 new products are launched in the market every year (*4*). As a consequence of this rate of innovation, medical devices are responsible for 25 percent of the total increase in health care costs (*5,6*).

The obvious contribution of medical devices to the increase in the cost of health care motivated efforts by many countries to limit the diffusion of new expensive technologies (*7*). Concomitantly, regulatory and surveillance action has also been taken towards assuring the safety of medical devices because of their intrinsic potential to damage health (*3*). Undoubtedly, government policy towards medical devices has concentrated almost exclusively on licensing, based on safety information, and control of diffusion and adoption, based on cost. The general rule is that information regarding the health benefits of new devices is not frequently incorporated in decision making and has never been part of regulatory action. Should this laissez-faire attitude towards the effect that medical devices, and other health technologies, have on health continue to be the rule?

If the regulation of medical devices is intended to protect public interests, the answer to the above question should clearly be "no." In their efforts to curb rising health care costs, governments should look not only to financial costs, but they should assure that a fair return in terms of benefit derives from the expenditure of people's money paid either as taxes or insurance premiums. As observed by Warner (5), the costs of capital-embodied technology cannot be evaluated in an "output vacuum." Developed countries are now facing the threat of health care rationing as one way to limit expenditures (*8*). Without detailed analysis of the health benefits yielded by different technologies, it would be unethical to limit certain practices solely on the basis of

cost (*8*). In addition, consumers must be protected in the imperfect market of health care where they cannot exert their discretionary power and the supply side is totally controlled by health providers.

The need to evaluate medical devices on the basis of health outcome is particularly acute for developing countries. Because of their resource limitations, poor countries need to choose carefully which technologies to adopt, taking into account their appropriateness, cost, and effectiveness in dealing with local health problems. Sadly, none of these factors has been taken very seriously and many hospitals in third world countries have become "junkyards" for equipment that has never operated satisfactorily or contributed to the solution of local problems (*9,10*). In developing countries, the lack of regulations covering technological effectiveness is even more damaging because of the wide spectrum of health problems requiring attention. Many of these countries now have incidence rates of chronic and degenerative diseases that seem to justify large capital investments in equipment and specialized medical centers. On the other hand, there is a persistence of infectious and parasitic diseases, and high rates of infant mortality, demanding different kinds of resources. The fact is that in most developing countries, resources for health care are limited and inelastic. Therefore, the risk is not only that some medical devices are ineffective, but that they may also become a health hazard by stealing resources from other key sectors that may be more critical, such as primary health care.

Although most health decision makers would agree that government policies in health care should take into account technological effectiveness in addition to safety and cost, formidable difficulties stand in the way because of limitations in the current systems of technology assessment and the many interest groups involved. As outlined in the next section, medical devices have intrinsic characteristics that make assessing them objectively even more difficult than other technologies. Whatever the level of difficulty involved though, the problem of evaluating the health benefits of medical devices has social implications that merit a well-directed effort to bring about solutions that are both technically sound and politically acceptable to society. In subsequent sections of this paper some methodologies for assessing effectiveness are briefly reviewed and the current possibilities for monitoring effectiveness are discussed.

THE NATURE IS THE MESSAGE

The physical nature of medical devices detaches this group from other medical technologies and is responsible in large part for the difficulty of evaluating the contribution of medical devices to the health of individuals and populations.

Like the hammer, television, and the motorcar, medical devices are extensions of human capacities and, as such, have an intrinsic appeal because of the power they give health providers either as human beings or as social groups who are represented by medical specialties that can control the delivery of a new technolgy (*1*).

Unlike drugs, which also have a physiochemical nature, medical devices have an image-value, which markedly affect their role in medicine. Although lacking the lure of the "magic bullet," medical devices are the symbol of modernity and scientific endeavor of the 20th century medicine and, as such, give health providers considerable prestige among peers and patients. More than any other medical technology, medical devices are easy to advertise and sell, perhaps because of their toy-like attractiveness.

These two factors create a drive for adoption and utilization decisions that are frequently unrelated to health needs and stimulate a frame of mind oblivious to the need for the evaluation of outcome and health benefits.

The most conspicuous characteristic of medical devices, though, is their appendage to a large and powerful manufacturing industry whose profit interests are above public health. Medical practice can be largely influenced by this industrial complex with its continuous effort to promote artificial obsolescence and technological innovations which can guarantee the industry's own survival and growth (*2*). Although some assessment of the health benefits of each new medical device is usually performed before it goes into industrial production, it is not in the industry's interest that evaluations of effectiveness be pursued much further. Moreover, with the high rate of innovation and turnover, it is extremely difficult to keep track of the marginal benefits of new models of devices in relation to their predecessors.

Medical devices are embodied forms of technology which can only be liberated by the human touch, with all its fallibility and variability. Consequently, the assessment of the health outcomes of medical devices cannot be performed in isolation of the health personnel responsible for its delivery. Other medical technologies present the same problem, but with medical devices there seems to be less awareness of the key role that manpower plays in correct utilization and maintenance.

As with other technologies in different sectors of society, the physical nature of medical devices demands a spacial organization and concentration, which is well represented by the hospital with its supportive physical plant, including electricity, building, supplies, air conditioning, and so on. This is similarly true with regard to health personnel. The role of infrastructure in supporting the correct utilization of many medical devices is not frequently appreciated. Because of this dependence of personnel and infrastructure, effectiveness results are often difficult to translate from one setting to another, and this is a serious drawback to one-shot evaluations of medical devices. Alternatives to counteract this limitation will be discussed later.

The last influence of the physical nature of medical devices to be considered is one of confounding. Because of the inadequate definitions and classification schemes, a large number of supportive, non-health related devices are combined into the same category as diagnostic and therapeutic devices. Unfortunately this leads to the collective treatment of all kinds of devices for the purpose of management, regulation, and assessment of financial costs. For the purposes of evaluating the health benefits of devices, it is obvious that some distinctions need to be established and this approach is adopted in the following sections.

PERSPECTIVES FOR EVALUATION

Before the possibilities for evaluation of medical devices are considered, it is important to standardize some concepts that are frequently the object of widely different definitions in the literature (*11*). More than a matter of preference, differences among authors reflect the complexity of expressing "health" in objective terms and establishing its quantitative relation to specific medical technologies.

The health outcome of a medical device is the benefit it provides to patients in any of the multiple dimensions of health: physiological (mortality/morbidity), psychological, or social. In most instances this benefit can be equated to a positive change in the quality of life of individuals or populations.

For any given technology, benefits will depend on the health problem involved, population affected, and the conditions of use (*12*). The definition of efficacy proposed by the Office of Technology Assessment covers these three aspects (*13*): "Efficacy is the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use." Because ideal conditions of use are not usually present, a more useful concept is that of effectiveness, which reflects the benefits derived from a technology under average conditions of use.

When compared using objective units of measurement (e.g., length of survival), effectiveness will always be inferior to efficacy. The main reason for this is the degrading effects of infrastructure and changes in the experience, motivation, and skills of health personnel when one moves from ideal to average conditions of use. The failure of classical efforts of "technology transfer" (i.e., sale/donation of equipment) from the northern to the southern hemisphere is demonstrated by the substantially lower level of effectiveness of technology applied in the southern hemisphere, although similar efficacy figures are not impossible. Again, the explanation for the average low benefit is to be found mainly in the lack of infrastructure and adequate manpower. However, with endogenous or appropriate technologies, efficacy might be much lower than with more complex solutions but a higher effectiveness may be achieved (Figure 1).

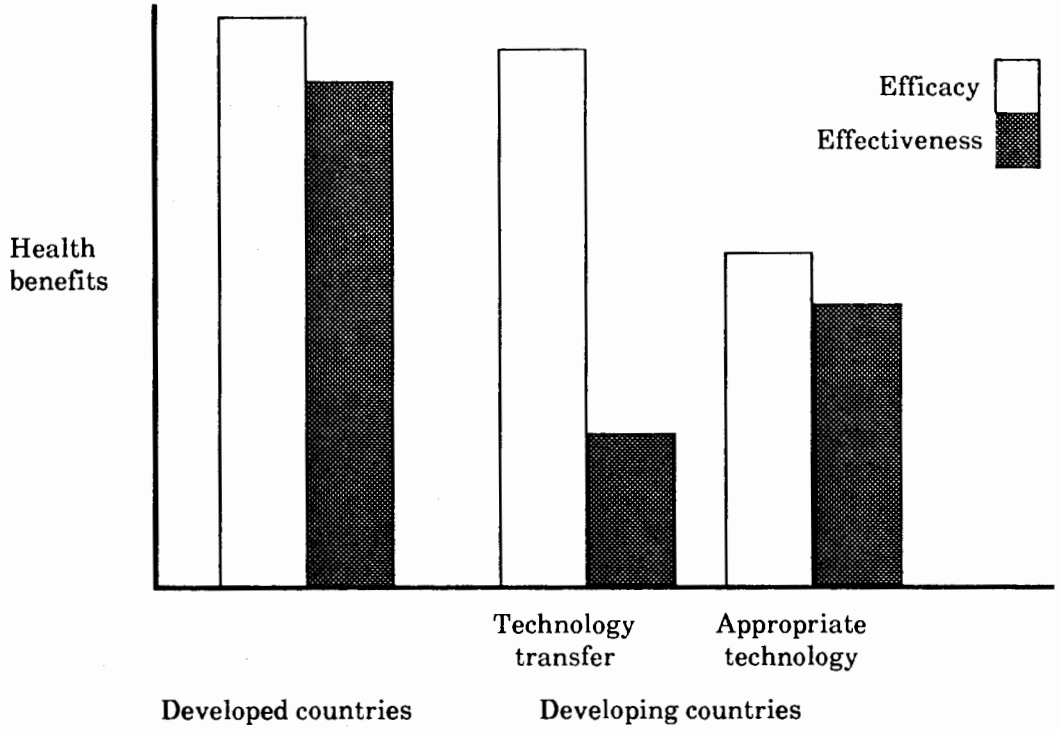

Figure 1. Effect of conditions on the health benefit derived from medical devices

Besides infrastructure and manpower, a third factor usually comes into play to reduce effectiveness even further. At the stage of innovation or premarket trial, a device or other technology is usually tested in very specific groups of patients who, because of the rigid selection criteria, are likely to benefit from the procedure. As the technology

goes into the marketplace and diffuses, indications for its application become loose, involving patients who do not present the original conditions. Instead of receiving any benefits, these patients are exposed to unnecessary risks. The use of ultrasound in obstetrics is a classical example of this distorted utilization that results in a considerable reduction in net effectiveness.

According to the above concepts, the use of efficacy and effectiveness to measure the health outcome of medical devices allows the identification of the intrinsic value of the device (efficacy) as well as the reductions in benefit to be expected under local conditions of use (effectiveness). However, the possibility of estimating these parameters with some accuracy depends on the health problem involved and the type of medical device under analysis: a large number of devices are purely supportive (beds, gloves, operating room stools) and therefore have no possibility of influencing outcome in terms of health. Other kinds of devices could be classified as therapeutic/rehabilitative, preventive, diagnostic/monitoring, and coordinative/administrative. Clearly, it is easier to measure the effectiveness of therapeutic devices, such as the artificial heart, than of preventive ones, such as circuit fault detectors.

For the simpler case of therapeutic or rehabilitative devices, evaluation methodologies are well developed and have been the object of numerous papers in the literature (*3,12,13*). Ideally, the technology under study would be compared with other alternatives (including no-treatment) in a randomized controlled trial (RCT), which minimizes the influence of all other variables that might affect outcome, including factors unknown at the time of the study. One drawback of device testing when compared to drugs is the greater difficulty of performing blind (single or double) studies because of the practical and ethical problems involved. Although RCTs represent the most effective tool for the estimation of effectiveness, their cost, duration, and level of organization required preclude their wider utilization (*12*). Many situations do exist, however, in which conclusions can be drawn from simpler designs such as historical controls, case studies, and epidemiological surveys (*13*).

For health problems with an associated significant risk of death, the effectiveness of therapeutic devices usually has been expressed by the duration of survival after intervention. This parameter does not take into account the quality of life following intervention, prompting Weinstein and Stason (*14*) to propose the use of "quality adjusted life years" (QALY) as a better indicator of health outcome. Other indicators proposed, which might be more adequate in conditions not involving an immediate risk of death, are health status indexes (*15*) such as the sickness impact profile (*16*).

The use of well-established methodologies such as RCTs and case-control studies, together with some of the indicators of outcome mentioned above, forms an analytic framework that make feasible the estimation of efficacy/effectiveness figures for therapeutic and rehabilitative technologies. Unfortunately, the number of devices of this type that have been subjected to comprehensive and well-designed studies is extremely small when compared to the universe of medical devices.

Two factors explain why most therapeutic devices do not have their impact on health outcome routinely evaluated. First, many devices have capital costs that are not substantial compared to other technologies, and consequently receive a low priority for evaluation. Typical examples of this group of devices are breast pumps and nebulizers. Although the purchase price of this group of devices is not high, their use can lead to very significant indirect and induced costs which should justify greater concern about their evaluation. Secondly, many therapeutic or rehabilitative devices contribute only partially to a health outcome. This is the case with incubators in neonatal care and

respirators in anesthesia and surgery. Theoretically, the health benefits of devices in this group could be assessed by an RCT. In practice however, such studies have not been undertaken because of their own cost-benefit considerations or because physicians have already accepted the device to the point where they are self-assured of their need and the definite benefit.

Therapeutic devices that cannot be directly and uniquely associated with some health effect constitute a group of great interest, because all other kinds of devices (diagnostic, preventive, coordinative/administrative) are in a similar position. Accordingly, diagnostic technologies can only benefit the patient if used jointly with some form of therapy, including changes in life style. In some cases, some diagnostic/monitoring devices that are intensively used or extremely expensive have been the object of RCT (*17*). In most cases however, this group of technologies is evaluated only by their diagnostic precision (sensitivity/specificity), which, in general, cannot be directly related to health outcomes. This limitation is unfortunate because of the large number of complex and costly diagnostic devices that have been launched in the marketplace in the recent past, and whose real contribution in terms of health outcome is a great puzzle.

Diagnostic and monitoring devices, along with preventive, coordinative/administrative, and those therapeutic devices that are only partial determinants of outcome, all have the common characteristic of participating in technological interactions which will dictate the resulting effectiveness. One alternative for the evaluation of these devices has been the assessment of a complete technological package that constitutes a well defined procedure, such as neonatal care or coronary bypass surgery. This approach represents the natural interest of different medical specialties and health authorities in evaluating medical practices.

In relation to the management of medical devices, the global evaluation of entire procedures presents serious limitations. In the first place, many devices, like monitoring equipment in surgery, are used in many procedures and their aggregate contribution is never evaluated. Second, the technological content of many procedures has been growing rapidly and haphazardly. Even if evaluations have been performed from time to time, it has not been possible to relate improved health to specific pieces of technology. Neonatal care is the perfect example of this swelling in technology accompanied by a general ignorance of the benefits attributable to individual devices. In most cases some key devices can be identified and their role, as an essential part of the process, cannot be questioned. This is the case with the operating table and light in a surgical theater. However, comparing a modern surgery room with its counterpart of 20 years ago, one wonders about the contribution of new and complex technology, especially in light of the small gains in outcome observed from most surgical innovations (*18*).

The result of the current practice of evaluating complete medical procedures, thereby avoiding the problems of technological interactions, reflects more what we can do, rather than what we should do. The ignorance about the contribution of specific devices is disastrous, mainly for developing countries that need to make much harder decisions involving the allocation of scarce resources. Whether one considers bone-marrow transplants, coronary intensive care, or thoracic surgery, the model becomes the complete package of modern resources as assembled and evaluated in a developed country. When poorer countries incorporate these new technologies, the tendency is the uncritical importation of the complete package, including items and accessories that are totally perfunctory in the new scenario. What can be observed then, is that the major cost of medical technology is not exactly what we are paying, but is the cost of ignorance, of not knowing exactly what we are buying (*2,8*).

PERSPECTIVES FOR PROGRESS

At this point it is clear that, with the exception of supportive devices, which do not present potential health benefits, and a small number of therapeutic/rehabilitative devices, which can be evaluated by classical methods, all other medical devices are in the category of interactive technologies, for which evaluation of their effects on health presents a considerable challenge. Several other health technologies are exactly in the same category. If any progress is going to be made in the coming years on the rational management of medical technologies, it is imperative that we attack the problem of technological interaction with the development of new methodologies and data gathering efforts.

At the present stage only a timid effort has been made to advance technology assessment in order to deal with the complex problems posed by the interdependence of health technologies. However, several methodologies already tested in other fields of knowledge show a good potential to help throw some light on this problem.

One area that has received a fair amount of attention is that of diagnostic methods in connection with decision analysis and event trees (*19-21*). Figure 2 presents a simple example of this approach.

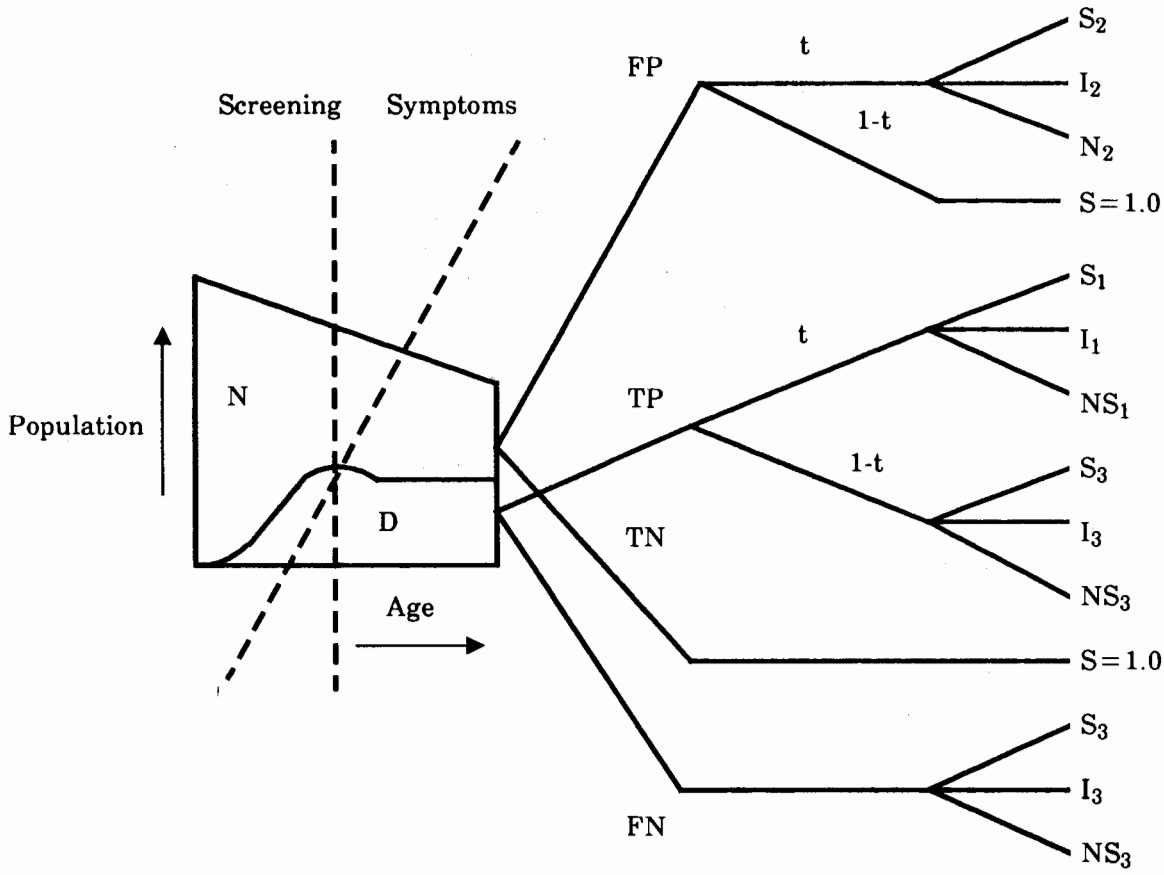

Figure 2. Decision analysis and event tree model

Assume that a diagnostic device can detect a condition or disease D in a population with prevalence P = D/(N+D). N reflects the number of healthy individuals (normals) and D the number of persons who carry the disease. The precision of the diagnostic test determines the number of true-positive (TP) cases detected, as well as true-negatives (TN), false-positives (FP), and false-negatives (FN). For simplicity, the outcome of therapy or the natural history of disease are characterized by three outcomes: survival (S), impairment or lession (I), and non-survival or death (NS). The incidence of these outcomes will differ in each case receiving different indices S_1, I_1, NS_1. When a positive test is detected (either TP or FP), in general not all patients receive treatment for economic, safety, or other reasons. Therefore, it is assumed that the clinical decision is to treat a fraction t of the patients with a positive test, while the complementary fraction 1-t will not receive treatment. It follows that all true-negative patients, i.e. those without the disease (n), and a fraction 1-t of the false-positive patients will survive as expressed by S=1.0 Patients with the disease who are not treated, and false-negatives, will follow the natural history of disease and result in outcomes S_3, I_3, and NS_3. True-positive patients which are treated fall into outcomes S_1, I_1, and NS_1. If the treatment is effective, it can be expected that $SD_1 > S_3$ and $I_1 < I_3$. The third group of outcomes, S_2, I_2, and NS_2 represent the result of unnecessary treatment of the FP group, and in this case I_2 and NS_2 reflect the iatrogenic effect of therapy.

In the absence of the diagnostic and therapeutic technologies, all individuals with the disease (D) would not receive treatment, resulting in a mortality $D \cdot NS_3$ and a number of impaired people, expressed by $D \cdot I_3$. However, treating a fraction t of all positive cases detected, it is possible to calculate the fractional mortality averted (F_a), by:

$$F_a = \frac{survivors\ due\ to\ therapy\ -\ deaths\ due\ to\ unnecessary\ treatment}{D \times NS_{33}}$$

The survivors due to therapy consist of the fraction t of individuals in group TP which have outcome S_1 or I_1 while the deaths due to unnecessary treatment is the additional mortality imposed by outcome NS_2 in group FP.

To calculate the above quantities it is useful to resort to the concepts of sensitivity (S_e) and specificity (S_p) of a diagnostic test expressed by:

$$S_p = \frac{TN}{TN+FP} = \frac{TN}{N}$$

$$S_e = \frac{TP}{TP+FN} = \frac{TP}{D}$$

The number of survivors due to therapy is expressed by $TP \times t\ (S_1 + I_1 - S_3 - I_3)$ or $TP \times t(NS_3 - NS_1)$ since $S_i + I_i + NS_i = 1.0$.

The number of deaths due to unnecessary treatment is simply given by $FP \times t \times NS_2$. Substituting these expressions in equation *1* results:

$$F_a = \frac{TP \times t(NS_3 - NS_1) - FP \times t \times NS_2}{D \times NS_3}$$

which can be simplified to:

$$F_a = \left(\frac{S_e(NS_3 - NS_1) - [(1-P)/P] \times (1-S_p)NS_2}{NS} \right) t$$

The above equation shows how this simplistic model of technological interaction allows the evaluation of partial improvements in the devices involved on the overall health benefit, expressed here as the percent reduction in mortality. Note that this approach involves other factors such as the risks involved (NS_2) and the prevalence P of the condition in the population.

More than anything else, the example in Figure 2 shows existing limitations in dealing with the phenomenon of technological interaction, given the fact that real life problems are much more complex, rarely involving only one diagnostic/therapeutic combination. From a theoretical standpoint, more complex problems can be dealt with by the decision analysis and event-tree approach. In practice, the problem becomes intractable because of the size of the event tree and the amount of data required.

Detailed data, which is necessary to attack the problem of technological interaction but which is absent in many cases, is a severe limitation, especially for developing countries that do not have a good tradition in the organization of data collection systems, both at hospital and public health levels. A radical alternative is to use methods of expert opinion, which attempt to organize the knowledge about the benefits of a technology based on the experience of specialists (*22*). Although methods such as the Delphi technique (*23*) are prone to biases, and have inherent limitations in accuracy, they have a large potential to be a first step towards an improvement in the present chaos of information about the health effects of individual devices.

Another line of work would be the meta-analysis of large numbers of individual studies covering a specific technology or device (*13*). The advantage of this alternative is its immediate applicability without the need to set up long-term prospective investigations. However, severe limitations also exist here because of the variable quality of the medical literature and the difficulty of standardizing indicators of outcome. In addition, the basic problem of interaction among technologies is not generally solved. Nevertheless, a small number of cases might exist in which carefully conducted meta-analyses might throw some light onto the health benefits of certain devices.

Other possibilities for determining the health effects of medical devices that share their contribution with other devices/technologies will necessarily require concentrated efforts towards the development of data bases with appropriate information. In this area there is a clear mismatch between our present dedication and the possibilities presented by modern information handling technologies. Assuming that future developments in this direction will take place, it is possible to foresee the usefulness of some specific methodologies.

With large data bases available, the first requirement will be a judicious selection of the information that is pertinent to solving the interdependence problem among technologies. Some techniques for this purpose have already been developed for application in health systems analysis, biological modeling, and automated diagnosis (*24*). With a parsimonious selection of variables and data, multivariate analysis can be brought used to determine clusters of devices that should always be considered as a package, and the share of improvement in health outcome that can be attributed to specific devices or minimum-packages. The feasibility of this approach ultimately will be determined by the data set, which can be flawed by a high degree of multicolinearity.

As more data becomes available, the assessment of medical devices and the problem of interdependence is open to the incorporation of new developments that are taking place in systems analysis and the information sciences, such as pattern recognition and other techniques belonging to the new field of artificial intelligence.

The possibilities discussed above suggest that, although the contribution of too many devices to the overall improvement of public health is clouded by their interaction and shared benefits, the problem is not unsolvable considering that an array of techniques already exists and is only waiting for the correct data to be collected. The question that lingers though is--what will we do with the information about the health benefits of devices when we finally unravel it?

THE REGULATION OF EFFECTIVENESS

The main objective of the regulation of medical devices is to contribute to the well being of society by enforcing some minimum standards of performance and safety in health care. This protection of patients and health providers is necessary throughout the spectrum of health care models, going from a strong and active private sector in one extreme to a monopolistic public sector in the other. The search for some health benefit is the very reason for incorporating devices or any other technology into health care. Consequently, patients, health providers, and society as a whole should also be protected against the misuse of technology in the form of devices that are of doubtful benefit and, many times, harmful, because they lead to the use of unnecessary and risky procedures (*25*). Furthermore, in many countries the promotion of some technologies must be done necessarily in detriment of others. This critical situation implies that the uncontrolled incorporation of technology can be extremely harmful to collective health.

Hitherto, regulations in developed countries have concentrated on the safety of devices, their design, manufacturing practices, and performance. Unfortunately, the word "effectiveness" has been used by the FDA and other authors (*3,11,12*) not in terms of health outcome, as adopted here, but in terms of satisfactory operation of the device according to the specifications and intended objectives of the manufacturer. In this context, the statement that a device is "effective" is misleading and cause for worry because it can be regarded by health providers as the final blessing for the uncritical adoption of another innovation.

The lack of government involvement in the regulation and control of the effectiveness (i.e., health benefit) of medical devices in most countries has left the decisions concerning the incorporation and utilization of medical technologies in the hands of health providers. Very poor results with either the containment of costs or the rationalization of medical procedures have been obtained with this form of control (*26,27*). The failure of this mandate for self-regulatory control of the influx of technology follows from its contradiction to the physician's commitment to the individual patient, as well as economic and professional interests. Moreover, the ideology of "quality care" gives room for incorporating technologies not only on the basis of benefits to health, but also on the basis of the demand caused by structure and process, which poses requirements that cannot be objectively determined. This pattern of lax control, combined with a literature of varying quality, leads to a very conservative attitude towards the condemnation of ineffective devices. The sudden abandonment of gastric freezing is a rare exception; more representative examples are the continuing use of devices (*28*), drugs (*29*), and surgeries (*30*) for a long time after they are shown to lack any health benefits.

Even assuming that better information, and more conclusive studies, become available, it is not possible to expect that judicious control of medical devices will occur if physicians are left to their own accord. Depending on systems of payment, hospitals might be more careful in the use of resources, but control requires the cooperation of all health personnel in charge. Therefore, the only alternative left is the involvement of

governments in an attempt to change the present situation. Contrary to safety regulations though, the regulation of devices to promote effectiveness is not a matter of yes/no licensing of devices, but the stimulus for more rational allocation and utilization of medical technologies.

By not restricting the commercialization of devices that are otherwise safe, regulations concerned with effectiveness should not be regarded as damaging to innovation. Out of several possible alternatives, it seems reasonable to propose, as a starting point, that medical devices be classified for effectiveness in a number of well-defined categories, reflecting our current knowledge about their health benefit. In each case, devices classified as "effective" or in similar categories would require additional information describing precisely under which conditions they were shown to be efficacious and the degree of effectiveness that can be expected. By leaving the burden of evidence to be presented by manufacturers, this classification would create a stimulus for the R & D of more effective technologies and for evaluative efforts. The classification of a device as "supportive" or of "unproved effectiveness" should give health administrators, physicians, and health insurers second thoughts about its incorporation and utilization.

The classification of medical devices according to the existing knowledge about their effectiveness should be seen as just a small component of a much larger effort that is essentially educational. Here, the World Health Organization has a large role to play by diffusing whatever information we will have in the future to all levels of government, the health professions, and the population at large. To some extent, our problems with palliative medical technologies are a consequence of our limited knowledge of biological processes (*31*). More and better basic research should certainly help to replace most devices that today are perfunctory, and maybe one day all devices will become almost as good as gold. For their wise utilization, and the health benefits we derive from them however, we can only expect significant improvements if we transmute ourselves, our perception of health, and our attitude towards life and death.

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IIE7. FORECASTING AND LONG TERM PLANNING

C. O. Pannenborg

Dr. Pannenborg spoke on the issues of strategic planning and long term forecasting. He stressed the need to consider regulation of medical devices not only with regard to the development of medical devices over the last three decades and its research and development today, but to take into account future accelerating technological changes that would affect the very concept of a medical device and thereby the whole fabric of its present day and envisaged national and international regulation.

Dr. Pannenborg described extensively the ever faster pace of technological change and provided examples of future health technologies that would be difficult to classify as a device, drug, procedure or other subdefinition of health technology. Illustrating his point for the need to look ahead, to anticipate future "possible" and "probable" health technologies, he briefly described a major project on future health care technologies that at present is being undertaken by the Netherlands goverment, WHO, and other national and international organizations. The project, headed by Dr. Banta and Mrs. Gelyns, set up a so-called "early warning system" and has already identified approximately 400 future health technologies with varying probabilities of introduction. Dr. Pannenborg stressed the importance of the project as a good example of a "look-ahead institution," the first of its kind in the health field so far. Of special importance for the strategic regulation of devices is the fact that such a project not only should identify future devices, but specifically should analyze the various consequences that might realistically flow from their introduction into health care.

Assessing the possibilities of future devices in terms of social, economic, legal, cultural, financial, and medical consequences (including consequences for policy) will, according to Dr. Pannenborg, become more and more an absolute strategic necessity, as the process of technological change accelerates and aggravates the ever larger complexity of problems from new and future medical devices.

In order to have regulation take such future oriented approaches into account, Dr. Pannenborg pointed to the need to bridge the gap between the "two cultures" of H. G. Wells, which still very much exist in the field under consideration. On the one hand industry, scientists, universities and health care providers involved in the innovation of medical devices; on the other hand goverment regulators, health insurance structures, and the health care professionals concerned with safety, effectiveness, and the issues of resources and effective utilizations of technology. Dr. Pannenborg pleaded for the explicit introduction of "needs" as distinct from demands. In the case of devices, utilization often is driven by supply. Technological development should be driven equally or more so by need - health need. Overemphasis on new devices, which are mainly developed according to technological possibility and expediency, combined with medical professional "interest" (in both senses of the word), will increasingly result in faulty investments. By combining specific "needs" for new devices with the existing system of R & D, regulation will be able to function from a much more consistent base in terms of looking after the health needs of the population, while at the same time not hampering innovation but actually including and supporting R & D in health technology. The bridging of the existing dichotomy in this field will be a difficult and hazardous task, which can only be brought about by open, honest, and genuine commitment to communicate, by the members of the "two cultures" - the innovators and the regulators - on the ultimate objective of regulation and medical device technology innovation.

Dr. Pannenborg concluded that conferences like this one are an essential first step in such communication and should be encouraged. In the future not only regulating agencies and international organizations like FDA, WHO, and World Bank should be involved, but also representatives of all the parties involved in medical device R & D.

Dr. Pannenborg ended by arguing that such activities in essence concern prospective medical technology assessment and as such should possibly become an integral part of the emerging international structure of health technology assessment.

IIE8. EQUIPMENT MANAGEMENT

D. Potter

INTRODUCTION

The purpose of an equipment management system in a health-care establisment is to ensure that suitable medical equipment is available when required, that it is safe and serviceable and is purchased at a reasonable, if not minimum, price. Such a system will:

1. decide that equipment is needed,
2. define requirements or specifications,
3. select equipment,
4. purchase,
5. perform acceptance testing,
6. provide for training of users and maintenance staff,
7. provide for servicing or maintenance, and
8. provide for replacement.

The general principles of an equipment management system will apply in any health-care establishment, whether it is a small clinic or a large regional or national center; it is only the complexity of each step and the overall management structure that will depend on the particular nature of the establishment. Thus, the equipment management system outlined in this paper will need to be tailored to suit a particular health-care establishment.

The result of not implementing an adequate equipment management system may be very serious, the death of a patient being the extreme consequence. Investigation of incidences over a number of years in which patients died in UK hospitals has revealed deficiences in equipment management with respect to:

1. equipment specification (i.e., equipment did not comply with the appropriate British standard),
2. inappropriate choice of equipment,
3. inadequate user training,
4. unapproved local equipment modification, or
5. inadequate maintenance.

In 1982 the Department of Health and Social Security (DHSS) published advice to the National Health Service (NHS) in the form of Health Equipment Information No. 98, entitled Management of Equipment. Copies of HEI 98 may be obtained from DHSS (Leaflets), P.O. Box 21, Stanmore, Middlesex, HA7 1AY.

NEED

It is worth noting that the establishment of need is the first step in an equipment management system. The health-care authority should ensure that decisions relating to the need for medical equipment are made by management and medical staff at the

appropriate level. Cognizance should be taken of any local, regional, or national plans for the delivery of health-care in the relevant medical speciality.

REQUIREMENTS

The user, probably in conjunction with colleagues, should specify the requirements to be met and the service to be provided by the equipment. The functional requirement should be defined precisely, making selection easier and user satisfaction more likely. Care must be taken not to specify a perfomance level higher than that needed because equipment that is more complex or sophisticated may be needlessly expensive, more difficult to use, and more costly to maintain.

SELECTION

The use of medical equipment that does not conform to a recognized standard or is of an inappropriate type has led to serious or fatal incidents in the UK, so it is crucial to make the correct choice.

An advisory group comprised of medical, technical engineering, supply services specialists, and users should be formed to provide a comprehensive advisory service that will help users make informed and objective decisions when choosing equipment. The fields of investigation that might be pursued in the selection procedure include determining the user requirements, identifying available models that appear to satisfy the functional requirements, assessing manufacturers' specifications, studying relevant evaluation reports, examining compatibility with equipment already in use, and investigating safety, servicing/maintenance arrangements, installation and overall costs.

The DHSS assists the NHS in several ways.

1. It sponsors the comparative evaluation of a wide range of medical equipment and provides the NHS with the results by way of Evaluation Issues of Health Equipment Information and Scientific and Technical Branch Reports.

2. It provides the NHS with a list of manufacturers registered as complying with an appropriate quality assurance system.

3. It provides a standard questionnaire to medical and laboratory equipment manufacturers. Answers to the questionnaire help the NHS secure product information from suppliers prior to purchase. This questionnaire deals with compliance with standards, quality assurance, sterilization, service, consumables and spares.

PURCHASE

Purchase orders should be drafted to clearly define equipment to be supplied, standards to be met, installation/commissioning work to be carried out, acceptance procedures, price details and delivery schedule. Many of these points may be covered easily by reference to the prepurchase standard questionnaire that has been completed and signed by the supplier.

ACCEPTANCE PROCEDURE

The governing authority of a health-care establishment should determine responsibility for ensuring that the appropriate acceptance procedures are initiated, co-ordinated, and implemented.

A formal acceptance procedure is needed to ensure that entry of all equipment into service is properly controlled. This procedure will include an initial inspection and test to verify safety and proper function, and inclusion of the equipment in an inventory list and incorporation into the equipment management system. There have been incidents in which equipment has failed during its first use, the users having presumed that new equipment would function correctly, whereas in reality, poor quality assurance, transit damage, or supply of wrong items rendered the equipment defective.

The DHSS has published two guides on acceptance testing: HEI 95 for medical equipment and HEI 140 for hospital laboratory equipment. The main elements in acceptance testing are:

1. general inspection to verify packaging is intact, equipment is undamaged, equipment is of correct type, appropriate accessories are included, and documentation is complete;

2. inspection of basic electrical components (eg. cables, plugs, fuses, voltage setting);

3. electrical measurements relating to earth continuity insulation resistance and leakage current; and

4. installation and functional check.

Having successfully passed the acceptance test, equipment is then allocated an identifying code number and included in an equipment inventory. It should then be arranged for the supplier to demonstrate to appropriate users the operation and user servicing of the equipment. Technical literature supplied with the equipment must be safeguarded and controlled. Lastly, an equipment log should be maintained to record brief datails of all inspections, routine service procedures performed, repairs, modifications, and faults.

TRAINING

User training is certainly one of the most important aspects of equipment management because evidence suggests that many incidents reported to the DHSS are caused by inadequate training of the user or service personnel.

No medical equipment should be allowed to enter service until potential users have had adequate training in its use, routine servicing, and emergency actions to take in the event of its malfunction. New or replacement staff unfamiliar with equipment should be forbidden to operate it unless supervised or until considered competent to operate and use the equipment. Staff who service or repair equipment must have undergone a recognized course of training.

Many manufacturers offer suitable technical training courses, and equipment appreciation courses on medical equipment maintenance are available to NHS staff at a Hospital Engineering Centre.

SERVICING/MAINTENANCE

Experience in the UK indicates that servicing of equipment probably rates equally with user training in importance. There have been several serious incidents which were the result of either inadequate or no maintenance.

If equipment is to remain safe, serviceable, and reliable throughout its working life, a formal system of maintenance is essential to ensure that regular inspections and routine servicing are carried out on a planned and controlled basis. Such a system may be organized in three tiers:

1. user servicing (user care or maintenance),
2. scheduled servicing (planned preventative maintenance), and
3. unscheduled servicing (emergency repairs).

Where appropriate, health-care establishments should nominate a "supervisor of technical servicing" to be responsible for the overall technical management of scheduled servicing, and "departmental equipment controllers" to be responsible for day to day supervision of user servicing.

The supervisor of technical servicing is a responsible post; the main duties should include the following:

1. provision of expert advice on servicing, repair, and modification of equipment, the suitability of contractors, the capability of "in-house" facilities and technical content of maintenance contracts;
2. establishment and operation of a scheduled servicing system;
3. supervision of scheduled servicing whether carried out by in-house NHS staff or the contractor;
4. in-house servicing, which includes authorizing staff, maintaining availability of service schedules and circuits diagrams, arranging technical training, authorizing and controlling work, maintaining quality assurance and safety, prescribing functional and safety checks; and
5. ensuring that the interests of the user are always safeguarded.

Day to day user servicing, managed by the departmental equipment controller, may include cleaning and sterilizing, inspecting such items as leads and ancillary devices), calibrating equipment, performing safety checks, making adjustments, lubricating equuipment, replacing parts, and performing functional checks.

The object of Scheduled Servicing is to ensure that equipment will continue to work satisfactorily at least until the next scheduled service. It should involve performing comprehensive inspections, replacing certain parts, thoroughly lubricating moving parts,

calibrating equipment, testing equipment performance, performing safety checks, and performing the final functional check.

Three additional points relating to servicing need mentioning.

First, a procedure should exist to ensure that random failures of equipment are dealt with expeditiously, and the supervisor of technical servicing should decide whether the necessary unscheduled servicing or repair can be handled in-house or whether a contractor should be called in.

Second, uncontrolled modification is dangerous and should be forbidden. If an equipment modification is considered justified, the modification should be properly controlled and documented by formal authorization from both the user and competent technical adviser.

And finally, a system should be established to warn users of newly serviced, repaired, or modified equipment that is about to be used for the first time following such work. One such system involves the signing of a "serviceability certificate" by the service technician prior to handing the equipment back to the user and the placing of a warning on the equipment that work has recently been performed.

REPLACEMENT

The last step in an equipment management system is a planned replacement policy.

The management team should avoid hurried and unstructured purchases of equipment to replace that which may be worn out or damaged beyond repair, unreliable, clinically or technically obsolete, or unserviceable due to the unavailability or high cost of spare parts. With timely decisions on replacement, all interested parties are then in a position to work through the equipment management system once again from the beginning.

IIE9. EFFECTIVE UTILIZATION

H. D. Banta

Effective utilization of health technology is an important issue. The question that requires attention is whether medical devices are effectively utilized (especially by physicians), and if not, what can government policies do to improve the situation.

In this paper, efficacy may be defined as the health benefit accruing to a particular population arising from the use of a medical device for treatment of a certain disease, under perfect conditions of use. Efficacy is tested under ideal or experimental conditions, and the randomized clinical trial is the method that we think of as most rigorous for this purpose. Effectiveness has a similar definition, but refers to performance under average or regular conditions of use at the community level. In this session we are concerned with the benefits from device utilization at the level of community and hospital practice.

PROBLEMS WITH UTILIZATION

Whether medical devices are used optimally to produce a health benefit for people cannot be answered directly, but there are many indications that devices are not well used, either in developed or developing countries. The best evidence comes from developed countries. There has been a considerable amount of work in both North America and Europe documenting rather remarkable variations in device use between countries, between regions within a country, and even between small areas within a country. This evidence is now being assembled and analyzed in a coordinating center in Copenhagen. Details can be obtained from Dr. Johannes Vang with the World Health Organization's Regional Office for Europe in Copenhagen.

Some of the devices that have been studied are cardiac pacemakers; cosmetic implants; artificial joints; intrauterine devices; insulin infusion pumps for home use; and monitoring, intensive care, ultrasound, diagnostic X-ray, computed tomography (CT) scanning, magnetic resonance imaging, clinical laboratory testing, and renal dialysis, equipment.

One clear-cut example is routine use of ultrasound equipment for monitoring the progress of labor. Policies in such countries as Belgium and France encourage up to four or five examinations during pregnancy, although this practice has not been shown to be of benefit and may be harmful. Other countries in Europe do not do require routine ultrasound examination. The National Institutes of Health Consensus Development Program statement on this subject said that routine screening was not advisable until this practice was shown to be beneficial.

Another clear-cut example is the use of diagnostic devices for intensive care of patients who have received serious head injuries. Comparisons between San Francisco and Glasgow have shown diagnostic devices are used 10 times more frequently in San Francisco with no improvement in patient outcome.

These large variations in use certainly reflect in part a lack of knowledge about the benefits to be expected under differing conditions. In many cases, such use may be presumed to be excessive; in other cases, low rates of use probably are inappropriate. In most cases, an optimal level of use cannot be defined using available evidence.

Much less is known about the situation in developing countries. Of course, in many cases, a country or region of the country may have no device, or a poor population group may have no access to the device; in these cases, utilization is zero. In other cases, devices are not in service because of problems with maintenance or spare parts. Devices may be underused or overused because of lack of appropriate training for those using the device, including physicians. There are also suspicions, if not data, that certain devices are overused in the private and social security services of developing countries, such as those of Latin America. For example, a Brazilian commission stated that there was enormous overuse and inappropriate use of x rays and laboratory services in the private hospitals of that country.

EXISTING POLICIES TOWARD MEDICAL DEVICE UTILIZATION

Policies toward medical devices can be related to the diffusion curve, characteristic for all medical technologies. Diffusion is made up of two parts: adoption of the device, and use of the device. Devices are introduced into the market and gradually spread into use. Adoption has been the subject of much more study than use, and policies are also focused on the adoption stage.

Thus, a program such as the Food and Drug Administration's program to regulate efficacy and safety of medical devices is aimed at influencing adoption. The device cannot be marketed until it is found to be effective and safe, in a technical sense. Adoption is zero until the FDA approves the device. However, after the device is approved for marketing, and physicians and hospitals buy it, FDA has little influence on how it is used.

A program often found in developing countries regulates imports of devices. Again, such a program prevents adoption of the device until importation is allowed. After the device is imported, the program has little influence on its use.

Other approaches to controlling adoption of devices involve regulation of their placement through health planning (licensing or certificate-of-need) or through withholding payment for services on the device unless its purchase has been approved in advance by the government or another policy maker, such as a council of insurance funds.

Few policies have been aimed at explicitly controlling or influencing use, although such policies are beginning to receive more attention. Why is this so? It seems obvious that we should be concerned about appropriate use of devices. In part, it must be because of the reluctance to regulate physician practice. Physicians are still powerful professionals in most countries, and policy makers try to avoid confronting them directly. Another reason is the enormous volume of services that would have to be monitored and controlled. It is one thing to regulate the placement of a multichannel blood chemistry analyzer; it is quite another to regulate the hundreds of tests that will be done by that analyzer.

POSSIBLE POLICY APPROACHES TO UTILIZATION OF MEDICAL DEVICES

There are two approaches to effective utilization that have so far been seldom tried. One involves explicit use of the payment system; the other, use of an informational or educational approach.

The payment system is certainly known to influence patterns of device use. Any payment system has incentives built into it, and physicians and other providers respond to such incentives. If the reward for using a particular device is large, it is used more. If there is no reward to the provider for using the device, it is used less. Generally, public systems of care do not reward the provider financially for using a specific device. However, private and insurance systems are still largely based on methods of payment that do reward increased use, such as fee-for-service payment to physicians. A particular problem is that the payment for services that require use of medical devices is often quite high. For example, physician payment for endoscopy examinations is very high in both the United States and the Netherlands.

Industrialized countries, which generally have rather complete coverage for health services for their populations, have strong financial tools to use in controlling the use of technology. One method that is increasing in popularity is to put hospitals on a global budget, which removes incentives for using high technology. It is also possible to have one national budget for health care, which constrains overall use of devices, as is the case in Canada, Britain, and Italy. These budgets do not necessarily promote effective utilization, however.

The situation is more difficult for developing countries, in which many segments of the population generally do not have complete access to health services. Still, in every country the method of payment for services is a powerful determinant of device use. Each country can examine payment policies and find methods of providing incentives for more appropriate use.

The other major tool is to develop information concerning effective utilization of devices. Such information can be in the form of guidelines and recommendations or it can be in the form of review articles or professional consensus statements.

A rapidly growing method for developing information on effective use of technology, including medical devices, is consensus development. Consensus development began at the U.S. National Institutes of Health almost 10 years ago. Now consensus development conferences have been held in a number of countries, including Sweden, Denmark, The Netherlands, and Britain.

A recent example is a consensus development meeting in Sweden on hip joint replacement. In this case, the conclusion was that the device was effective and cost-effective and should be used more widely in Sweden.

Denmark had a recent consensus development program on prevention and treatment of dental caries which dealt with a number of dental devices.

A well-known consensus development statement from the National Institutes of Health concerned electronic fetal monitoring. The conclusion was that electronic fetal monitoring had not been shown to be more effective than monitoring by auscultation with a fetoscope (stethoscope). In this case, as in so many others, the device was being widely used without proof of benefit.

Technology assessment programs in a number of countries are now maturing and better able to assess medical technologies, including devices. In many cases, results of such programs will include conclusions concerning effective device utilization.

There are several problems with technology assessment at the moment. Perhaps the most serious is the lack of studies of efficacy and safety on which to base decisions. Devices are generally well-examined technically, but their contribution in the clinical setting to improved health for the patient is not frequently studied. Studies that are done are often uncontrolled or have inappropriate controls. Most programs of technology assessment, including consensus development, depend on synthesizing or examining evidence. That evidence is often lacking. Nonetheless, the situation is rapidly improving. There is now an International Journal for Technology Assessment in Health Care and an international society. The International Society for Technology Assessment had its second meeting in Washington last week with 200 participants. Johannes Vang is Vice-President of the society and questions can be addressed to him. The President of the society, Dr. Seymour Perry, is also a participant in this meeting.

One particularly interesting model program in information development is the National Perinatal Epidemiology Unit in Oxford, England. The Unit does clinical trials on important perinatal topics, collects data, and prepares synthesis reports. The World Health Organization has supported the Unit's effort to develop a complete registry of all well-designed clinical trials in the perinatal area. The data from these trials is also computerized, and an electronic journal to improve access to the data is being developed. The Unit is now summarizing information known on most of the devices used in perinatal care.

A number of professional societies have also become actively involved in issues of appropriate use. Naturally, policymakers need to keep the concerns of the medical profession in mind, and active involvement of medical professionals in these kinds of information development efforts is highly desirable. One excellent program is run by the American College of Physicians in the United States. The College is the major professional body for internists. The college's program examines the efficacy and safety of medical technologies, including devices, of interest to its membership. The statements produced are published in the Annals of Internal Medicine.

While much remains to be done, these developments in the use of the payment system, along with informational approaches, promise to significantly improve future utilization of medical devices.

SUMMARY AND CONCLUSIONS

To contribute to health care, medical devices must be appropriately used. It is not enough to assure the electrical safety or technical performance of a device, although that is certainly important. We need to know much more about appropriate utilization. Obviously, devices make a large contribution to human health. But many devices are greatly overused. Such overuse is particularly important in developing countries, with their limited resources for health care.

While utilization has historically not been subject to much examination, and policies have not dealt effectively with it, that situation is now beginning to change. The major tools now being considered for use in most countries are the development of better information on benefits and cost-effectiveness of medical technology and use the payment system to try to assure appropriate use. It is also possible to combine these two approaches, for example, by setting levels of payment following a cost-effectiveness analysis of a particular device.

IIE10. PRODUCTION AND DISTRIBUTION OF MEDICAL EQUIPMENT: PROBLEMS OF TECHNOLOGY TRANSFER TO PUBLIC HEALTH

B. I. Leonov and I. M. Arefjev

More than 300 enterprises in the Soviet Union produce technology used in medical applications. They develop different items for health care according to their area of specialization. Plastic processing enterprises produce items made of polymers; electronic technique factories, electronic medical equipment; optical enterprises, endoscopes, spectacles; etc.

Computers are used in all spheres of activity, and medical technology is not an exception. This causes, on the one hand, a significant modification of diagnostic and therapeutic technical devices, and on the other hand, an increase in the cost of medical technology. All these factors are taken into account in the development of plans for the purchase and distribution of new medical technology to the health care institutions in our country.

Most medical technology in our country is produced on demand; that is, each public health institution orders the equipment it needs and transmits the order to the united commercial organization "Sojuzmedtechnika" which executes the entire order, transmitting it to industrial enterprises manufacturing medical technology. Medical technology in the Soviet Union is purchased according to this unique process.

Most medical equipment is provided to newly-built health-care institutions. Provision is made for the planned replacement of obsolete equipment and the acquisition of new technology. The resources for acquisition of medical technology are provided within the budgets of health care facilities.

The All-Union organization "Sojuzmedtechnika" has its own trading network throughout the country including all republics and regions. "Sojuzmedtechnika" has its own service support organization that provides service and medical equipment maintenance.

The problem of medical equipment maintenance in medical-preventive institutions in our country, as probably in the other countries, is connected with the shortage of highly skilled technical specialists who not only help physicians in modern equipment maintenance, but train them to correctly use the medical equipment. With the increasing use of expensive high-efficiency medical equipment that is supplied with computers, microprocessors, x-ray computerized tomographs, laboratory biochemistry automatic machines, ultrasonic tomographs, and NMR equipment, the shortage of technical specialists has become acute.

This problem is alleviated by training physicians to manage complex medical equipment and recruiting technicians for positions in medical institutions.

IIE11. MEDICAL EQUIPMENT FOR PUBLIC HEALTH WITH DUE REGARD FOR U.S.S.R. SPECIFICITY

B. I. Leonov and I. M. Arefjev

DIAGNOSTIC MEDICAL ENGINEERING ITEMS

In the Soviet Union primary attention has been paid to the development of facilities that permit a physician to obtain the most objective diagnostic information. Introscopic techniques are used for the visualization of the body's internal structures, and provide objective diagnostic information to the physician. Technology for examination and imaging of internal body structures includes endoscopic units based on fiberoptics, x-ray units with computerized tomography, ultrasound imaging devices NMR equipment, and thermographic devices.

ENDOSCOPES

Technology provides a large range of fiberoptic-based endoscopic devices. These include: fiber gastroscopes, sigmoidocolonoscopes, gastroduodenoscopes (for children), universal colonoscopes, universal gastroduodenoscopes with fiber tip optics, gastroscopes with fiber light conductors, radiation cystoscopes, etc. At present, the optical and functional features are being improved. Endoscopes with ultrasonic scanners and laser radiation sources are being developed.

X-RAY TECHNIQUE

Over the last 5 years, technology was modernized by: computerized tomographic scanning devices, which produce high quality images of internal structures; by panoramic tomographs which permit detailed x-ray images of various parts of the skull; and by modern x-ray diagnostic complexes, pediatric x-ray units, mammography units, etc. These developments enhance the ability of health care facilities to obtain essential diagnostic information.

Considerable attention is paid to dose reduction during x-ray examination and to improved imaging through the use of image-intensifying screens, electronic intensifiers, and various x-ray image transducers.

Portable units with high-technology, yet economical features have been developed. The portable x-ray units for surgical wards are being improved by built-in memory image modules, by pulsed function provisions, and by reduction of mass and size. Our designers have created x-ray units with on-line subtraction image processing, fluorographs with x-ray image intensifiers, powerful tubes up to 100-150 kW and more. We have developed facilities for computerized image processing, and improved computerized tomography, in which we employ an original system of information processing to produce reconstructed images.

RADIOLOGICAL UNITS

More recently, we have begun manufacturing gamma cameras in increasing numbers. We developed a transverse computerized gamma tomograph for imaging the brain. With

the help of a computer, it monitors radionuclide distribution in transverse sections of the brain.

We have also designed systems for automated radiological information processing, scintillation gamma cameras, movable gamma cameras for cardiological wards and intensive care units, special devices for radioisotopic investigation, investigation of thyroid gland function, and radioimmunological investigation, and movable chronoscopes for functional investigation of the internal organs.

ULTRASONIC DIAGNOSTIC TECHNIQUE

Ultrasonic diagnostic technique and technology has been successfully developed in the U.S.S.R. This includes versatile modern echocardioscopes and doppler devices.

EQUIPMENT FOR FUNCTIONAL DIAGNOSTICS

Recently there has been substantial development of various devices for processing of biopotentials from heart, stomach, skull, and other organs; units for respiration, blood circulation investigation. All modern equipment of this kind is based on microprocessor technology that facilitates the acquisition of diagnostic information.

INDUSTRIAL HEALTH CARE SYSTEMS

In the U.S.S.R. special automated diagnostic systems for cardiology, oncology, ophthalmology, gynecology, and other fields of medicine have been developed based on modern medical diagnostic technology. Specialized dispensaries and approaches have been developed for the diagnosis and treatment of occupational disease. These are also designed to avoid overexamination of workers and to identify persons who should visit a physician for the more complete examination and treatment.

Special attention is paid to the delivery of health care to workers and employees at industrial enterprises. This provides an opportunity to combine disease prevention and therapy for disease. Attention is also paid to trauma and to high quality post trauma management of injury and to rehabilitative medicine. Workers are divided into groups according to age, sex, profession, length of service, and unhealthy conditions of work. Monitoring includes the primary examination of the groups due to risk factors, and conduct of follow-up examinations for persons in specified risk categories.

MEDICAL EQUIPMENT FOR MANAGEMENT

Last year, the automated complex for nuclear-radiated therapy "Microtron-M" was designed. The introduction of this equipment into medical practice provided additional therapy options for the management of malignant tumors by more effective methods including static irradiation/hard radiation, and accelerating electrons beams with an energy of 22 MeV.

Ultrasound units are employed in accordance with their design purposes and equipped with special emitters; the units for intravascular surgical operations, for ophthalmological microsurgery, urological equipment for stones distruction in ureters, the units for bone tissue connection and cutting for all types of biological tissues. Their

application decreases blood loss, operation time is shortened, post-surgical complications are decreased, and healing processes are accelerated.

Various kinds of lasers for treatment and surgery have been designed, and widely applied the various myo- and neuro-stimulators (heart, stomach, bladder, intestines, etc.).

Devices for stimulation myography and audiometry also have been developed. The units for reflexotherapy and electroneurostimulation through skin have been further improved upon.

The clinics of the country are provided with modern surgical techniques, instruments, staplers, artificial lung ventilation facilities, inhalation narcosis units, modern units for surgery—electronic laser scalpels, plasma scalpels, and other techniques.

IIF1. INFORMATION EXCHANGE

INTRODUCTION

Dr. J. McHardy chaired Session VI. Mr. J. Arcarese and Dr. C. Gamboa served as rapporteurs. The Chairman welcomed the delegates to Session VI of the conference. He indicated that the conference had provided ample evidence of the intense interest and activity in the field of medical devices, and stated that much has been done and much remains to be done. Dr. McHardy commented on the previous sessions on Approaches to the National Management of Medical Devices - focusing on the spectrum of regulatory approaches employed by national authorities - and on Medical Devices and Government policy - which examined issues of national policy raised by the accelerating pace of innovation and activity in health technology. He introduced the topic of Session VI, Information Exchange, a central focus of the conference and an area of interest fundamental to international collaboration in this complex field. Dr. McHardy then introduced the speakers for the session, who made their presentation.

IIF2. NATIONAL INFORMATION EXCHANGE: THE FDA EXPERIENCE

M. H. Barnett

The purpose of this paper is to share with government officials from the many nations represented at this conference our experience in the U.S. Food and Drug Administration in communicating information about medical devices to a variety of audiences, including health professionals of various specialties, and the general public. Although we realize that the needs and communications systems in various countries differ considerably, we believe that some of the communications lessons we have learned may be broadly applicable.

The importance of disseminating accurate, adequate, and prompt information about medical devices is underpinned by several basic assumptions. The first is that the way a medical device is used, as opposed to its design or manufacture, is often the key to a safety problem. When an anesthesia mishap occurs, for example, the cause is often a failure of the user to perform adequately, or a faulty interaction between the user and the machine. With the increased use of devices in the home and in extended care facilities - locations where expert, specialized personnel are often not available - the opportunity for user-originated mishaps is increased.

The second basic assumption is that to correct such problems, behavior change on the part of the user is often necessary. In the case of a heart valve that is especially prone to failure, the change in behavior may consist of an increased alertness on the part of physicians in monitoring patients. In the case of a home-use pregnancy test, the change may be in the care with which the woman reads and carries out the instructions for use.

The third assumption is that information dissemination is a primary vehicle through which we can stimulate this behavioral change. This assumes, of course, that the recipient of the information is motivated to change his or her actions. In the majority of instances, in which the outcome of the behavioral change is immediately apparent, there is more than enough motivation to do the job. In the two examples above, the anesthesia machine user wants to decrease the likelihood of patient injury and the women using the pregnancy kit want the results to be accurate. But in those instances in which the results of improved behavior may be subtle or delayed - for example, the presumed reduction in long term cancer risk as a result of reducing patient radiation dose during an x-ray procedure - providing sufficient incentive and motivation may be an additional and difficult problem.

Given that these assumptions are valid, success in reaching health professionals and the public depends in large measure on several essential elements.

First, the information must be targeted at the specific audience that needs it. When a cardiac defibrillator fails, the target audience is emergency medical personnel; and when a serious problem arises with infant apnea monitors, this information must be focused on pediatricians, pediatric departments, and special parent groups whose children use these devices. To aim these messages in broad-brush fashion at the medical and public communities at large would be wasteful of time and resources.

Second, given that the personnel and funding of any government agency is limited, multiplier groups must be used to help spread the message. We have successfully recruited as multipliers medical specialty organizations, state and city health agencies,

local public school authorities, organizations of patients with particular medical conditions, and, perhaps the most potent multiplier of all, the news media.

Third, to ensure the cooperation of health professional organizations in acting as multipliers to disseminate the information, and to further ensure that the information, after it is received, will be accepted and acted upon by physicians and others, it is essential to solicit the approval and agreement of professional organizations as to the content of the message during its early development. "Co-ownership" of the message, in other words, is of vital importance.

Fourth, redundancy is essential to ensure that the message is received by a wide audience of health professionals, and that it is absorbed and utilized. No matter how effective the dissemination process, we cannot force recipients to notice the information and act upon it. For this reason, the message must be repeated over time, and must be delivered through a wide variety of mechanisms.

I would now like to describe three of the Food and Drug Administration's primary vehicles for transmitting information, and how we in the Center for Devices and Radiological Health have used these vehicles to inform health professionals and consumers about device problems.

The FDA Drug Bulletin is a publication on drugs and medical devices. It is directed at health professionals, is published several times each year, and is received by approximately 1.5 million persons, including physicians, dentists, pharmacists, and nurses. It warns of safety problems, familiarizes readers with pertinent regulations, notifies them of changes in recommendations, and informs them about newly-approved products. Recent issues of the Drug Bulletin have included medical device- and radiation-related articles, such as ones discussing the possible association between extended wear contact lenses and corneal ulcers; minimizing radiation exposure of the embryo during nuclear medicine procedures; preventing electrical accidents with apnea monitors; procedures to protect the female breast against excessive radiation exposure during scoliosis radiography; the approval of the lithotripter, a new device to disintegrate urinary stones; complications with convexo-concave heart valves; safety hazards with certain models of cordless phones; and a possible association between toxic shock syndrome and the contraceptive sponge.

The FDA Consumer is a monthly magazine for the general public. This publication often includes articles on medical devices and covers new products, safety precautions, etc. The articles from this magazine are frequently reprinted by FDA and distributed as individual brochures. Recent issues of the FDA Consumer have included medical device- and radiation-related articles on the FDA's medical device regulations; electroconvulsive therapy devices; home testing products; fraudulent medical devices; the use of x-ray contrast media; teleradiology; the care of contact lenses; devices used to diagnose and to treat scoliosis; and nuclear magnetic imaging.

FDA Talk Papers are brief background sheets, prepared as needed, to cover a particular issue or problem. Their basic function is to serve as resource materials that FDA personnel at headquarters and in field offices throughout the U.S. can use in answering questions from health professionals, the public and the news media.

In addition to these FDA-wide vehicles for disseminating information, the Center for Devices and Radiological Health uses several additional mechanisms. One of these is the Alert Letter, used to quickly warn health professionals about life-threatening problems. In the past few years, such letters have been sent when several children had been

crushed by electrically powered hospital beds; when a series of accidental disconnects occurred in breathing systems; when injuries were sustained by infants in a particular type of pediatric crib; when batteries used to power cardiac defibrillators failed prematurally and unexpectedly; and when several infants received electrical injuries, from apnea monitors.

When the need for a warning is rapid but the target audience is smaller - for example, when only a small number of medical facilities are involved, or a single subspecialty medical group is the audience - then a "Dear Doctor" letter can be used.

In a recent example, FDA used a "Dear Doctor" letter to communicate with U.S. renal dialysis centers about "first-use syndrome."

For more routine communications, the Center publishes two bulletins - one on medical devices, the other on radiological health matters - that are sent regularly to a list of approximately 5000 subscribers, mainly health professionals and industrial firms. The bulletins are intended to familiarize readers with pertinent Center programs, warnings, recently discovered problems, regulations, etc.

CDRH Technical Reports, which are issued at a rate of approximately 30 per year, are scientific reports summarizing the Center's research or providing recommendations and guidance about specific device usage problems. They are particularly important in instances in which, because of length or subject matter, the open scientific literature is not appropriate as a communication mechanism. The Center has performed significant research over the the past decade on ways for clinicians to improve the quality of diagnostic images during medical x-ray procedures while at the same time maintaining radiation doses to the patient as low as possible. This research has resulted in practical guidance in the area of radiographic quality assurance, including such areas as film processor maintenance. The guidance has been issued and widely disseminated through the Technical Report mechanism.

Finally, the Center maintains a television studio which prepares instructional videotapes on device use. The tapes are used to train FDA's field staff, and are loaned to health professionals, professional schools, industrial firms, etc. The Center now has approximately 100 titles, which are loaned at a rate of approximately 3000 tapes per year; an estimated 40 thousand persons view one or more of these tapes annually.

It should be apparent from this description of FDA's activities in disseminating information about medical devices that there is a considerable amount of redundancy in the process. A physician may learn of a device problem through the FDA Drug Bulletin; through a notice in a professional journal placed by FDA; through an FDA Alert Letter or "Dear Doctor" letter; through the news media, which in turn are informed by FDA; or through his patients, who may have learned of the problem through an FDA-initiated information campaign. This redundancy is both intentional and essential. Along with proper targeting of the audience, the effective use of multiplier groups, and the approval of professional organizations, it helps to ensure that FDA's messages about the safe use of medical devices are received and acted upon.

IIF3. PAHO APPROACH TO REGIONAL INFORMATION EXCHANGE

M. A. Bobenrieth

The lack of accessible scientific and technical information that is both validated and timely is a serious problem that has not yet been resolved in the Americas.

How is this problem approached by the Pan American Health Organization and the Region of the Americas of the World Health Organization? What is the policy of the Organization? How does it view its own role? How does it operate today, and what strategies does the Organization envision for the near future?

The Region of the Americas is in an unusual situation. Its 35 independent countries are a mixture of North and South America and possess geographical, cultural, historical, and other ties that permit the collective handling of problems. But there are also important differences in terms of social and economic development. This presentation refers mainly but not exclusively to what happens in the countries south of the Rio Grande.

The countries of the Region of the Americas face a growing scarcity of accessible scientific and technical information, and this makes it difficult for them to achieve goals in the development of programs and activities necessary to improve the health of their peoples. This scarcity of scientific and technical information has been aggravated in recent years by the increasing deterioration of libraries, of health and biomedical information and documentation centers, and other institutions in the Latin American and Caribbean countries. Indeed, PAHO is faced with reduced funds for subscriptions to scientific journals, for bibliographical material on primary and secondary sources, for reference material, and for access to the numerous and, some of them, excellent and complete data banks from other countries - not only in the health sector but also in the education and often in the industrial sectors. This situation has been aggravated in recent years by the current economic recession, whose solution is not in the hands of our countries. The dissemination of knowledge and experience in the vast fields of health and technology in Latin America and the Caribbean requires substantial improvement in order to meet the urgent need for scientific and technological information by government workers who make policy decisions, institutions that develop programs, professionals, technicians, and millions of auxiliary workers who are today at the forefront of health care. In addition, the public needs to participate and to be informed if PAHO is to fulfill its goal of health for all by the year 2000.

Each community should assume, in some way, responsibility for its own health and participate actively in its achievement. This is especially important in developing Third World countries, where often there are almost insurmountable obstacles to the effective transfer of health and biomedical information.

One of the most important missions of PAHO and WHO is what PAHO's current director calls the "management of knowledge." This management of knowledge involves the promotion, collection, analysis, classification, and dissemination of scientific and technical information in health and biomedicine to be of significant help in the prevention, diagnosis, and solution of local, national, and regional problems. These problems are multifaceted. Therefore, this improvement can only be achieved through a close relationship between the activities of the Organization and the institutions responsible for resolving priority health problems of the countries.

The Organization should not have goals separate from those of the countries that comprise it. Within this context, the role of the Organization each day takes on more importance for the member goverments, especially for those that make decisions related to health and its individual and social consequences. We must address the needs of the scientific community in the Region of the Americas, of the educational institutions in the hemisphere, the staff who work devotedly and selflessly in the health services, other international agencies whose tasks bear a direct or indirect relation to the health field, and a public that is informed and genuinely interested in its own well-being. As a result, one of the strategies for technical cooperation is to assist PAHO member countries to fulfill, in some way, their urgent need for scientific and technical information. This encompasses perception of the timeliness of this information, the availability of the informative material, and the strengthening of the capacity for production of information and national publications. Within this frame of reference, the Organization's policy on scientific and technical information constitutes a set of guidelines that set forth program objectives and the strategies for reaching these scientific, technological, and administrative objectives. We should not forget, moreover, that no program of technical, scientific, or social action is better than the administrative instrument that makes it possible. As a result, PAHO's policy on scientific and technical information takes into account the input, processes, products, expected impact, and evaluation according to the results achieved, in order to modify programs and, if necessary, the Organization's policy itself based on this feedback.

From the program perspective, a program of scientific and technical health information has been set up in the Organization as the unit responsible for cooperating on technical matters with Organization countries to collect, process, and disseminate scientific and technical information. The program works in close collaboration with other technical programs of the Organization in order to significantly improve health conditions. We at PAHO believe that information is essential for efficient and effective action. We also believe that inaccessibility of information is the cause of poor quality in planning, administration, research, and practice in the health-care sector, thus impairing and lowering the quality of life itself. There is a direct relationship between the triad of information-documentation-publication and the quality of decisions that are made. This is not the only factor, there are others that are also important, but this has been perhaps the weakest and most often overlooked link in a long chain of situations.

Recent studies on the need for bibliographical information on biomedicine and public health for Latin America and the Caribbean reaffirm that this information is and will continue to be a factor of critical importance for the development of preventive and curative health care. The same is true of information on research and education. The Organization began to work on research and education 20 years ago. In 1965, PAHO already recognized the need to improve Latin American and Caribbean access to scientific information on health and the biomedical sciences, and established the Regional Library of Medicine, now the Latin American Center on Health Sciences Information. The library was established under the general auspices of the federal government of Brazil, the Sao Paulo School of Medicine, and the State of Sao Paulo. This initiative, which began as a focal point, was then transformed into a national network for Brazil and an international health and biomedical network for Latin America. Subsequently, important technical improvements were introduced, and, through a program cosponsored by the United Nations Development Program, additional financing was obtained and a network has been formed which is adjusting to the growing needs of Organization countries. Although these actions have been productive, the system has not been adequate to meet the growing demand for, and surprisingly the supply of, scientific and technical information.

PAHO is faced with a paradoxical situation. Never in the history of mankind has there been so much production, publication, and supply of scientific and technical information. At the same time, never in the history of the Third World has it been so difficult to gain access to this information on a selective, and therefore useful, basis. The role of PAHO is as promoter, facilitator, coordinator, articulator, and catalyst. The Organization cannot assume a different or lesser role. It also has a production strategy for its own publications: the Organization looks for information gaps and unmet needs for printed matter in vernacular languages. PAHO has an active publications program that is supplementary to the efforts of member countries and groups that publish within the Region of the Americas. PAHO collaborates in disseminating information to member countries to help them formulate their health policies, in order to narrow the gap between a locality that has a particular health problem and the information needed to solve the problem, and those thousands of other localities that have the same problem but do not have the needed information. In addition, the role of PAHO is to identify what is happening in a country: what is being published; what is being developed; and what, for various reasons, will never be published.

The countries of the Third World are developing a fair amount of research, but little of what is researched is documented, and the little that is documented is not published. PAHO's strategy is to support scientific research, writing, and publication. This includes the design of collaborative projects for research and development of scientific and technological information, the exchange and use of information and technology evaluation, the formulation of cooperative strategies for regional integration, and the setting up, on a voluntary basis, of a Pan American network for scientific and technical information. In this regard, PAHO has the task of sensitizing the people who make the decisions; of linking institutions, sometimes within the same country; and of bringing together countries with other networks that are rich in information. The Organization also needs to think about strategies for internal coordination within the United Nations and WHO family, and about important external coordination that should go beyond the health sector. The health sector is often confused with the health-care sector. Genetic, environmental, and behavioral variables have a greater effect on human health than does direct care alone.

It is also appropriate to point out the strategies of organization and operation, for example, the strengthening of basic collections in the national information center and the preparation of catalogs and development of the human resources that can handle the processing of technological information. It also will be very important to develop evaluation strategies in cooperation with member countries, because it is indispensable to have a criterion for selection, with decisions shared by all the interested groups.

Finally, PAHO must think about information for the decision-making process: politically, at the highest national level; concerning the production of technology; concerning the importation of technology, with appropriate adaptations when needed; concerning technological options, which increase daily; and involving how to evaluate how feedback makes it possible to improve health with increasingly limited resources. The Organization thinks that its countries today and in the future face conflicts and unavoidable dilemmas in which governments and authorities must make decisions and in which information plays a key role. PAHO needs information to help resolve the dilemma of dividing resources between the needs of individuals and the needs of the group; to choose between what people want and need; to decide on investment in health care versus investment in health sciences education at different levels; to decide on investment in current pressing needs and, in the midst of this pressure, how much can be reserved for the future and how much can be devoted to research.

All these considerations have an inherent and unavoidable cost, leading to the following conclusion: Organization countries will either pay for valid and timely information or they will pay for the lack of information with resulting technological decisions that are inefficient, ineffective, and generally high in cost. Moreover, this disinformation will take its toll in human suffering and loss of life.

IIF4. THE TRIPARTITE EXPERIENCE

A. K. Das Gupta

Medical device technology, in spite of its numerous successes, suffers from an abundance of problems, coupled with a paucity of experts to resolve them.

Most problems are worldwide and it is imperative that regulatory authorites from all nations cooperate to maximize the utilization of available talent, avoid duplication of effort, achieve consensus on priorities and health standards, exchange data and intelligence at the working level, and conduct joint investigations.

The need for such interaction in the health field was keenly felt in 1969 when the U.S. FDA took action to ban the use of cyclamates. Neither the U.K. nor Canada had prior information on this far-reaching decision and had to act without ready access to full scientific information. To avoid recurrence of similar incidents, it was decided that the Chief Medical Officer in the U.K., the Commissioner of the Food and Drug Administration in the U.S.A., and the Head of the then Food and Drugs Directorate in Canada would meet informally and frequently to discuss areas of common concern. The tripartite meetings are held in the U.K., U.S.A., and Canada, in turn. Initially the meetings took place more than once per year; they are now an annual event. It is of interest to note that these meetings are characterized by the absence of minutes, formal decisions and media publicity. The participants are therefore free to talk openly and are not committed to any resolutions.

Items are placed on the agenda at the request of any of the three participating countries. This process and the subsequent tripartite interaction not only facilitate information exchange but frequently lead to collaborative activities at the working level.

A session devoted to medical devices was first introduced in 1975 in keeping with the advent of formal regulatory programs in both the U.S.A. and Canada. It soon became obvious that there was need for in-depth discussions to establish consensus and coordinated approaches on topics of common interest such as: sterility of devices, recognition of mutual inspections, device standards, use of artificial blood, clinical trials, reuse of disposables, hazards of medical plastics, etc. This could best be achieved by meetings of senior officials at the working level along with technical experts on different topics. The first such meeting was held in the fall of 1983 in Ottawa. It was designated as a Subcommittee of the Tripartite Main Committee which deals mainly with policy matters.

Among the topics discussed were warning letters (such as the DHSS Hazard Report, the Canadian Medical Devices Alerts, and various U.S.A. publications), the role of WHO in medical devices, adverse reaction reporting systems and problem definition studies, establishment of priorities, coordination of educational programs, and specific device classes to cover such items as anesthesia machines, incubators, etc.

The 1984 Subcommittee meeting in Washington led to the formation of a number of working groups to develop consensus on specific device problem areas such as anesthesia system disconnects, particulate contamination of medical devices, home-use devices, pacemaker leads, and biotoxicology.

It is encouraging to note that significant progress has been made by several of these task forces. Their outputs have already resulted in improvement in the device classes involved and in the recognition of the problem by the user community.

One of the first examples of collaboration by the Tripartite Subcommittee was the study of conical connectors for anesthesia and ventilation breathing systems. These connectors are simple cone and socket fittings designed to join easily with a push and twist and to separate with a pull. Most connectors have no locking or latching mechanism, and are notoriously prone to accidental separation. Several coroners' inquests into patient deaths due to accidental disconnections prompted the Canadian and U.S. members of the Tripartite Subcommittee to undertake a joint study of the problem in 1983. This included two complementary contract surveys of U.S. and Canadian anesthetists and respiratory care specialists to identify the nature and causes of disconnections. Through the auspices of the U.K. members, an opinion survey of U.K. anesthetists was conducted in January 1984. These surveys helped to publicize the importance of the problem among anesthetists and to marshall their support for a solution to the problem. Canada and the U.K. carried out tests of disconnection forces and studied numerous connectors to ascertain the degree to which they complied with existing voluntary standards. These studies showed that compliance as well as performance was poor. Canada has now proposed the establishment of a regulation requiring locking connectors for anesthesia and ventilation connectors.

Other areas of concern and continued study by the Tripartite Subcommittee include alarms and monitors for breathing systems (areas of vital concern for patient safety), the problem of particulate contamination in certain devices, and the development of consensus standards. The first meeting on this topic was held in Ottawa in 1986.

Sale of medical devices to the general public is one of the fastest-growing sectors of the medical devices industry. Several concerns have arisen over the safety and effectiveness of these devices. A meeting was held in Ottawa in November 1985 to discuss the issues. Invited participants included representatives from both the U.K. and U.S.A. Several recommendations were made and are currently being circulated among the various agencies in their respective governments.

It can be seen from the above that international cooperation can yield impressive results by pooling expertise.

IIF5. WHO MECHANISMS FOR INTERNATIONAL DISSEMINATION OF INFORMATION

B. Sankaran

An important aspect of WHO's coordinating function is the generation and international transfer of valid information on health matters. The Organization thus serves as a neutral clearinghouse for absorbing, distilling, synthesizing, and disseminating information that has practical value to countries attempting to solve their health problems. Recently, in an effort to develop and improve this function, five broad target groups were identified: general policy makers, health policy makers, health service providers, health service consumers, and opinion makers.

In the short time available, it is impossible to cover all the mechanisms employed by WHO to disseminate information and, on reflection, perhaps the title of this presentation should have been more precise. For instance, through the mass media (press, radio, television, and films) WHO tries to inform the public not only about the Organization's activities, but also about the nature of the health problems with which it is concerned and the ways countries are coping with those problems. Clearly, this is no small task and a separate presentation would be required to do justice to this particular area of operation.

On this occasion it would seem more appropriate to concentrate on a few of the "technical" publications issued by the Organization. These publications make available the results of scientific work supported or promoted by WHO; the advice of international groups of experts; WHO-supported studies of subjects of public health importance; and information obtained from member states, which is tabulated, extracted or summarized by WHO (e.g., health legislation, health statistics). A second category, "official" documents, which includes the records of the World Health Assembly and the Executive Board, is not covered in this presentation.

Sample copies of all WHO publications are distributed free of charge to the member states, who are offered special terms if they wish to purchase bulk quantities. Prices are low by commercial standards. A glance through the catalogs of WHO publications gives some indication of the wide range of subjects covered. This is not surprising when you consider that, since 1948, WHO has been the publisher of books and periodicals conveying the collective thinking, expertise, and recommendations of world leaders in public health and the biomedical sciences.

NON-PERIODICAL PUBLICATIONS

First I will deal with the *Technical Report Series* not because I consider this Series in any way superior to other publications but simply because it is the one with which I have been most directly involved. The first report in this series, on the Unification of Pharmacopeias, was published in 1950; we have now reached number 734. Distribution varies according to the subject of the report but, in general, a total of more than 20,000 copies is printed in English, French, Spanish, and Arabic; some reports are also printed in Russian and Chinese.

These reports contain the recommendations of various groups of experts who attend meetings in a personal capacity and not as representatives of any government. Over the years these reports have covered practically all the technical and scientific operations of the Organization. The invited experts thoroughly review and discuss the issues put

before them and then determine the form and content of recommendations for solutions to health and related scientific problems. Their findings and recommendations are intended to assist national administrations and international health organizations in formulating their health policies and establishing standards.

For instance, one of the functions of the Expert Committee on Biological Standardization is to formulate Requirements for Biological Substances. These Requirements are not intended to be the ultimate criteria for acceptability of a biological product but rather they represent an international consensus on what is essential, particularly with regard to potency and safety of vaccines. Although the Requirements are not legally binding they are generally accepted by most national authorities.

The *Health for All* Series is published in Arabic, Chinese, English, French, Russian, and Spanish. It serves as a way to publish fundamental texts on policies, strategies, and processes that will assist countries in planning, implementing, and evaluating their own programs for attaining health for all by the year 2000. Included in the series are the report of the International Conference on Primary Health Care held in Alma-Ata in 1975 and the Executive Board document on formulating strategies for health for all (1979).

The *Environmental Health Criteria* series provides an authoritative assessment of data about the effects of chemical substances and a number of physical factors on human health and on the quality of the environment. It furnishes scientific information on which national health and other authorities can base suitable control measures if they are needed, and the series gives guidelines for setting exposure limits consistent with the protection of human health in the general environment and in the workplace. If a report discusses a substance that occurs in nature (such as lead and titanium), the natural exposure is taken into account. Inevitably, however, the emphasis is on exposure to such substances during and after manufacture, as wastes, and as constituents of man-made products (chemicals for industrial use, pesticides, lasers, etc.).

Each volume deals with a single substance or group of substances, selected from a list of substances that has been internationally prioritized. Drafts are prepared by individual experts or national institutions and are then subject to extensive revision by one or more international groups of experts in order to ensure that the documents are as accurate and comprehensive as possible. The volumes that deal with chemical substances are, for the most part, the outcome of work performed by the International Programme on Chemical Safety, which is a joint venture of the United Nations Environmental Programme, the International Labour Organization, and the World Health Organization. Publications that concern sources of nonionizing radiation are prepared jointly by the International Radiation Protection Association and the World Health Organization, with funding from the United Nations Environment Programme.

The series also comprises a number of volumes describing the principles and methods that are applied in environmental investigation; those published so far cover toxicity testing, the conduct of studies in environmental epidemiology, and exposure monitoring in relation to pregnancy.

The volumes that deal with chemical substances are, for the most part, the outcome of work performed by the International Program on Chemical Safety, which is a joint venture of the United Nations Environment Program, the International Labor Organization, and the World Health Organization. Those that concern sources of nonionizing radiation are prepared jointly by the International Radiation Protection Association and

the World Health Organization, with funding from the United Nations Environment Program.

Publications in the *Environmental Health Criteria* series deal with the effects on human health and the environment of exposure to individual chemical compounds or groups of compounds. The series also includes a number of publications dealing with the methodology of data interpretation and risk assessment.

In addition to the usual distribution to ministries of health of member states, copies are made available, free of charge, to anyone connected with government and official institutions such as universities and teaching colleges. The series appears in English and French.

Education for Health, a newsletter in support of health for all, came into being in 1984. It is issued by WHO in collaboration with the John J. Sparkman Centre for International Public Health Education (SCIPHE) and is addressed to all who use the educational approach and can influence health through their actions and decisions. The newsletter encourages a lively dialogue between readers on innovative ways to promote individual, family and community self-reliance in health. Its aim is to help accelerate the exchange of experiences on the most sensitive and appropriate ways to achieve the goal of health for all through primary health care. There are English, French, and Spanish versions of the newsletter, which now has a total circulation of more than 10,000.

Many other newsletters exist, principally of a restricted nature in view of their dedication to specific topics, as explained below.

PERIODICALS

The *Bulletin*, published six times per year, is the principal scientific journal of WHO and contains original papers by research workers in medicine and related sciences. This bilingual English/French publication, with complete Arabic and Russian translations, has a total circulation of more than 11,000. Specially commissioned articles keep readers informed of the latest progress in selected fields of biomedical science and public health. There is also a mechanism for groups of experts participating in WHO meetings to make authoritative pronouncements on scientific matters relating to the Organization's work. Occasionally, summaries are made of current biomedical nomenclature and terminology as well as review articles describing overall progress in various fields.

The *World Health Forum* is an international journal of health development that is published quarterly and directed principally at those responsible for health policy, health planners, economists, and teaching staff in schools of public health. It has a circulation of 40,000 in six languages - Arabic, Chinese, English, French, Russian, and Spanish. An Italian version is also available. It is not restricted to work in which WHO has been involved and is essentially a practical journal with a bias towards articles evaluating the results of projects and discussing the reasons for success or failure. It also encourages debate on controversial topics through the correspondence column. The Forum is an important means of promoting technical cooperation among developing countries.

The *WHO Chronicle*, which appears six times per year, provides a continuing record of the Organization's activities and of the principal health work being carried out in various countries and regions with WHO's support and collaboration. Produced for the medical and public health professional with an interest in international health work, the WHO Chronicle publishes articles describing the Organization's policies and programs

and summarizes the proceedings of important administrative and scientific meetings. Shorter features on meetings and workshops draw attention to important unpublished documents and provide general news about the Organization. Each issue includes an account of recent WHO publications. The Chronicle appears in six languages - Arabic, Chinese, English, French, Russian, and Spanish, with a total circulation of 33,000.

The *International Digest of Health Legislation*, of more direct interest to this assembly, appears quarterly in separate English and French editions, and seeks to provide systematic coverage of significant national and international legislation on all aspects of health. Designed primarily for health administrators and policymakers, it is also widely read and used in schools of public health and law faculties, in the pharmaceutical, food, and chemical industries, as well as by public health professionals concerned with legislative policies in their specific areas of interest. Material in the Digest is organized into 22 subject categories covering such topics as health manpower, family health, care of the elderly, food safety, and national pharmaceutical policies. Approximately 250 books per year on health law and allied topics are reviewed and concise reports are provided on noteworthy events. Review articles on current issues in health legislation, mostly commissioned from acknowledged experts, also appear from time to time. The total circulation is approximately 4000.

World Health is an illustrated magazine designed to present WHO's policies and activities to the general public. Its target audience includes opinion leaders, decision-makers, journalists, and broadcasters. Serious in content, it is couched in popular language in order to generate support in the media for WHO programs. Most of the articles are specially commissioned. Most issues deal with a single main theme, but the magazine also has regular features dealing with such issues as health-for-all strategies, primary health care, publications, and news items. World Health is published 10 times a year in English, French, Portuguese, Russian, and Spanish and 4 times per year in Arabic. A German version is also available. The circulation is approximately 130,000 and the readership is estimated at more than 1 million.

The *Weekly Epidemiological Record* provides a rapid means for disseminating to health administrators information on recent communicable and noncommunicable diseases and health hazards. Topics include cholera, plague, and yellow fever, which are subject to the International Health Regulations, and a wide range of other conditions such as viral influenza, malaria, paralytic poliomyelitis, AIDS, and food-borne disease. It is concerned with all aspects of these diseases, including their epidemiology and the nature of the public health problem they pose to national health administrations, and it also attempts to put into perspective the influence of travel and trade on the spread of disease. The Record is an important medium for health administrations; through it they can obtain information on disease control and on preventive programs such as the Expanded Programme on Immunization and the Diarrheal Diseases Control Programme. The Record has a circulation of approximately 7500 and is published every Friday morning in a dual English/French version; it is sent by airmail to every national health administration.

The *World Health Statistics Quarterly* publishes articles and reviews that assess the health situation throughout the world and make projections of future trends. A single issue covers not only specific diseases and causes of death, but also statistics on health manpower, resource utilization, health promotion programs, and socioeconomic factors affecting health. To gather this information, authors use techniques from the fields of biostatistics, demography, epidemiology, and health data processing. A notable feature of the publication is that it provides comparisons of data from different countries over various periods of time, with analysis and interpretation. Particular emphasis is given

to the application of data analysis to the planning, implementation, and evaluation of health policy. The Quarterly appears in a bilingual English/French edition and in Russian, with a total circulation of more than 5000.

The *International Classification of Diseases*, which has an interesting history, is a basic tool for recording, processing, and analyzing of health information. In 1946 the Interim Commission of the World Health Organization was entrusted with the responsibility of undertaking preparatory work for the revision of the International Lists of Causes of Death (adopted in the original form in 1893 at a meeting of the International Statistical Institute in Chicago); and for the establishment of International Lists of Causes of Morbidity. At the Sixth Revision, the classification was extended to cover nonfatal conditions. In its present form, the ICD is useful for the purpose of hospital indexing, for use in medical audit systems, and in statistics for evaluation of medical care.

The books published by WHO are too numerous to mention, but range from topics such as *Chemotherapy of Malaria* (WHO Monograph Series, No. 27), to practical training and reference material, as contained is the *Manual of Basic Techniques for a Health Laboratory*.

These, then, are some of the mechanisms already available within the Organization. But the setting up of a more specific international system to exchange information on medical devices could undoubtedly contribute towards the reduction of costly duplication of effort. Experience has shown that such systems can be effective given the necessary commitment and collective will to establish common standards and methods of approach. The designation of national information officers also has proved successful and has introduced a degree of flexibility and informality into the channels of communication.

Having said all this, and without seeking to minimize the importance of the written word (especially emanating from WHO), I firmly believe that a great deal can be achieved through gatherings such as this in which information is exchanged, problems are discussed, our thought processes are stimulated and, if we are fortunate, we arrive at workable recommendations for solutions.

As a result of a similar International Conference of Drug Regulatory Authorities in 1980, again a joint FDA/WHO initiative, there has been an improvement in information transfer and in collaboration between regulatory agencies. There is every reason to be optimistic that this conference will have an equally positive impact.

IIF6. WHO: THE ROLE OF COLLABORATING CENTERS, THE RADIOLOGICAL HEALTH EXPERIENCE

G. P. Hanson

INTRODUCTION

Radiological health is defined as the broad scope of activities involving the health aspects of radiation. This includes the use of radiation for diagnosis and therapy, and the various radiation protection activities related to the use of radiation in medicine, industry, and research. Near the end of the 19th century, soon after the discovery of x rays, radiation became a valuable diagnostic and therapeutic modality. Even now, new methods of using both ionizing and nonionizing radiation for medical purposes are being developed continuously, and at an extremely rapid rate.

Considering the ubiquitous nature of the human activities involving radiation, and the large body of knowledge and expertise required to utilize it effectively, it is obvious that a small cadre of medical doctors and scientists at the World Health Organization or at the Pan American Health Organization could not provide all the expertise required. Hence the imperative need to identify and enter into collaboration with competent and highly motivated institutions or groups that have an interest in sharing their expertise with the world community through WHO.

As defined by WHO, a collaborating center is an institution designated by the Director-General to form part of an international collaborative network carrying out activities in support of the Organization's program at all levels. Institutions that have already achieved international prominence, as well as those that are demonstrating a developing ability to carry out a necessary function related to WHO's programs, may be designated as collaborating centers. Designation does not signify that financial support will be provided, although grants are occasionally provided to conduct specific tasks in support of WHO programs.

ORIGIN OF THE WHO COLLABORATING CENTERS IN RADIOLOGICAL HEALTH

In April 1968, at a meeting on Dosimetric Requirements in Radiotherapy Centers, organized by the International Atomic Energy Agency (IAEA), in Caracas, Venezuela, in which WHO and PAHO participated, three items were urgently recommended:

1. the preparation of a basic manual of dosimetry,
2. the organization of regional training courses in radiotherapy physics, and
3. the creation of regional dosimetry facilities (*1*).

Collaborating with staff and consultants of IAEA, PAHO, and WHO, Dr. John B. Massey began working on the dosimetry manual immediately following the Caracas meeting, and in 1970, the Manual of Dosimetry in Radiotherapy was published (*2*). The first of several regional training courses in radiotherapy physics was conducted at the Puerto Rico Nuclear Center from 1969 to 1970, and the first WHO Collaborating Centers for Secondary Standard Radiation Dosimetry were established in Buenos Aires, Argentina (1968), and Bucharest, Romania (1969).

These WHO Collaborating Centers were established to fill a serious technological gap that existed in the radiotherapy dosimetry area. For decades, following the discovery of x rays by William Conrad Roentgen in 1895, radiation had been employed as a therapeutic agent for cancer treatment. Gradually, during the development of radiotherapy as a medical science, methods of quantifying the amount of radiation dose had been worked out, and national primary dosimetric laboratories had been established in most of the developed countries. These laboratories exchanged information, and compared their dose meters through a system organized by the Bureau International des Poids et Messures (BIPM) in France.

Yet, in 1968, few radiotherapy departments in most developing countries owned a dose meter, and even if they owned one they seldom were able to send it to a primary dosimetric laboratory for calibration. Thus, it was not uncommon to observe that even if a radiotherapy center had a dose meter, it had not been recalibrated in 10 to 20 years, and often, never.

Radiation dose prescription and measurement in many radiotherapy centers was analagous to a situation in which a physician prescribing pharmaceuticals would instruct the patient to "Take a few red pills, some green ones, and a tad of yellows every once in a while." An unfortunate complication was that, frequently, the content of the red, green, and yellow pills was not known.

EXPANSION OF THE WHO COLLABORATING CENTERS FOR SECONDARY STANDARD RADIATION DOSIMETRY

Following the establishment of the first WHO Collaborating Centers for Secondary Standard Radiation Dosimetry in Argentina and Romania, others were established in Mexico (1970), Singapore (1970), Iran (1973), Thailand (1973), Nigeria (1975), Brazil (1976), and India (1976).

Later, in collaboration with IAEA, these first WHO Collaborating Centers became the backbone of a worldwide network of Secondary Standard Radiation Dosimetry Laboratories (SSDL). Currently, this network consists of 50 laboratories, of which 36 are in developing countries (3). The resources, abilities, and quality are variable. Some of the laboratories are capable of working independently, while others have not progressed beyond the organizational stage and still are highly dependent upon support from the central IAEA laboratory in Vienna. However, the beginning of order in radiation dosimetry is emerging from the chaos that existed prior to 1968.

Typical terms of reference for a Secondary Standard Radiation Dosimetry Laboratory are shown below. Other examples are given at the end of this paper.

Typical Terms of Reference (SSDL)

1. Maintain secondary standard instruments in adequate agreement with the international measurement system, including periodic recalibration in accordance with the procedures of the IAEA/WHO Network.

2. Perform calibration of appropriate radiation measurement equipment to an accuracy specified by the IAEA/WHO Network and issue calibration certificates with all necessary information.

3. Participate in measurement comparisons within the IAEA/WHO Network, and with other appropriate laboratories.

4. Organize, for its country or region, dose comparison services.

5. Cooperate with the IAEA/WHO Network and with other metrological laboratories in exchange of information and improvement of measurement instruments and techniques as necessary.

6. Document and record all procedures and calibrations in a manner specified by the IAEA/WHO Network; preserve all records for a time specified by the Network.

7. Keep informed on progress in radiation measurement so as to improve calibration techniques as necessary and to better meet the needs of the users of radiation.

8. Provide training in techniques of radiation measurement and calibration, and use and maintenance of relevant instrumentation, appropriate to the users of radiation served by the SSDL.

One of the most important quality assurance activities conducted by the SSDLs is the Postal Dose Intercomparison Study for Radiotherapy Centers. This study uses small thermoluminescent dose meters (TLDs) consisting of a thermoluminescent material, lithium fluoride, which can be sent to participating radiotherapy centers through the mail. Following a standard protocol, the dose meters are given a radiation dose that is calculated and administered by the participating radiotherapy center. Then, the dose meters are returned to the SSDL for measurement and evaluation. The resulting information, which consists of a comparison of the calculated dose versus the actual measured dose, is provided to the participating radiotheapy center along with observations and advice concerning possible sources of any discrepancies and suggestions for improvement.

In some countries with more developed SSDLs, the entire dosimetric intercomparison, e.g., preparation of the TLD, calibration, measurement, and evaluation, is conducted entirely by the national SSDL. In countries with lesser-developed SSDLs, the TLD and the scientific support are provided by IAEA and WHO; the SSDL provides collaboration with the national organization and coordination of the dosimetric intercomparison study.

Results of more than 1200 measurements in some 300 radiotherapy centers in the six regions of WHO are summarized in Table 1.

Table 1. Results by region of PAHO-IAEA-WHO Dosimetric Intercomparison Study for radiotherapy centers
(Values shown are percentage of participating centers, rounded to whole numbers)

% Deviation (Plus or minus)	Africa	Americas	Eastern Med	Europe	Southeast Asia	Western Pacific
0 - 5	53	63	66	67	63	72
5 - 10	18	20	15	28	23	13
10 - 20	12	13	16	2	10	10
+ 20	18	4	3	3	3	5

The dosimetric results should be evaluated in conjunction with the concensus of scientific opinion concerning radiotherapeutic dosage for curative cancer treatment, which is that for the treatment to be effective, the radiation dose to the tumor should be accurate within approximately 7 percent.

In some countries, groups collaborating in clinical radiotherapy protocols have established criteria for acceptable factors as shown below in Table 2 (*4*).

Table 2. Criteria for accuracy of prescribed dose in radiotherapy clinical trials

Status	Prescribed dose
Fully acceptable	within ± 5%
Minor variation	± 6% to ± 10%
Major variation	± 11% to ± 15%
Unacceptable variation	Greater than ± 16%

For the dose to the tumor to be accurate within 7 to 10 percent, it is generally accepted that the deviation between the dose calculated to have been given to a dose meter and the actual measured value must be within at least 5 percent; and, preferably, this deviation should be on the order of 2 to 3 percent.

In the Americas Region of WHO, the radiotherapy dose intercomparison system using TLD was analyzed and evaluated at a meeting hosted by the University of Texas System Cancer Center in Houston, Texas, (M.D. Anderson Hospital) in April 1982 (5). The Directors of the WHO Collaborating Centers in Argentina, Brazil, and Mexico participated actively and the unanimous decision was reached that "...for quality assurance purposes the measurement of dose at a certain depth in a phantom was the single most useful test that could be made in terms of economy and potential impact."

EXTENSION OF THE WHO COLLABORATING CENTER CONCEPT TO OTHER AREAS OF RADIOLOGICAL HEALTH

Since the establishment of the WHO Collaborating Centers for radiation dosimetry in 1968-69, other collaborating centers for specific radiological health activities have been established in the following areas: Basic Radiology, Environmental Radioactivity, Nuclear Medicine, Protection and Standards for Nonionizing Radiation, Radiation Pathology, Radiation Emergency Assistance, and Training and General Tasks in Radiation Medicine.

Basic Radiology

At the University of Lund in Sweden, under the direction of Dr. Thure Holm of the Lund University Clinics, a collaborating center was established in 1980, to serve as a focal point for development of the WHO Basic Radiological System (BRS). During the period 1975-80 the concept of the WHO Basic Radiological System was developed and "Technical Specifications for the X-Ray Apparatus to be Used in a Basic Radiological System" were prepared through the cooperative efforts of WHO, PAHO, and radiological experts throughout the world (*6-13*).

The BRS x-ray apparatus consists of a high quality x-ray generator and x-ray tube, together with a high-quality focused grid, and a unique tube-stand; all of which are linked together in a sophisticated manner to produce an optimum (and deceptively simple) x-ray system. The BRS also includes three training manuals that are an integral part of the system: Manual of Radiographic Technique, Manual of Darkroom Technique, and Manual of Radiographic Interpretation for General Practicioners.

During the development of the BRS, the need became apparent for a laboratory to test prototype x-ray equipment, as well as for an expert group that could provide an unbiased technical opinion regarding the compliance of equipment with the WHO specifications for the BRS, and its performance.

The logical choice for a Collaborating Center for Basic Radiology was the Lund University Clinics, which already had extensive experience in testing x-ray equipment, and which had played an important role in development of the specifications for the BRS x-ray apparatus.

Regarding the evaluation of image quality produced by one manufacturer's BRS-type x-ray machine, Dr. Thure Holm stated "I have seen many university centers with the same image quality, but none with better image quality than we have with these WHO-BRS machines."

Environmental Radioactivity

In the area of environmental radioactivity measurements, the WHO Collaborating Center established within the Ministry of Health of France at Le Vesinet, under the direction of Professor Pierre Pellerin, serves as a focal point for collecting, analyzing, and disseminating information concerning levels of radioactivity in the environment.

Another center of this type also has been established within the Radiological Protection Bureau of the Department of Health and Welfare of Canada, under the direction of Dr. Ernest G. le'Tourneau.

Nuclear Medicine

The first WHO Collaborating Center for Nuclear Medicine was established in 1970 within the Center for Devices and Radiological Health of the U.S. Food and Drug Administration. This center, under the direction of Dr. Peter Paras, has played a key role in various workshops on quality assurance in several Regions of WHO and in the preparation and dissemination of information on quality assurance, including a WHO publication on that subject, the Spanish version of which was published by PAHO in 1984 (*14,15*).

Another Collaborating Center under the direction of Dr. Nilo Herrera of the Danbury Hospital in Connecticut is making a significant contribution to the improvement of diagnostic imaging in nuclear medicine by using specially designed test objects or "phantoms." These phantoms, which have been made to simulate human organs such as the brain and the liver, have been sent to nuclear medicine centers in 20 countries of Europe and Latin America as part of studies of imaging quality organized by WHO and PAHO. In the participating nuclear medicine centers, the local nuclear medicine specialist subjects the "phantom" to an imaging study using a common protocol. The specialist then reports his findings concerning simulated lesions or tumors. The reported

findings are analyzed by the Collaborating Center and the participating laboratory is advised of its diagnostic accuracy and provided with observations and suggestions for improving techniques.

Other WHO Collaborating Centers in Moscow, U.S.S.R, and Mexico City, Mexico, have concentrated on both national and international training and have made valuable contributions in preparing specialists in nuclear medicine.

Protection and Standards for Nonionizing Radiation

A Collaborating Center on Nonionizing Radiation was established in 1970 under the direction of Dr. Moris L. Shore at the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration. Currently this collaborating center is under the direction of Mr. John C. Villforth, the Director of CDRH. Numerous publications concerning the properties and biological effects of nonionizing radiation, which includes ultrasound, microwaves, lasers, and radiofrequency radiation, have been prepared by CDRH and have been made available to scientists and health workers throughout the world through WHO and PAHO. The Center has played a key role in the development of the WHO Environmental Criteria documents on microwaves, lasers, and ultraviolet and radiofrequency radiation (*16,17*). Additionally the collaborating center has often served as a valuable reference resource for consultation or responding to inquiries concerning specific problems or issues from WHO member governments.

Radiation Pathology and Radiation Emergency Assistance

Under the direction of Dr. Henri Jammett of the French Atomic Energy Commission, the WHO Collaborating Center on Radiation Pathology was established in 1980 at Fontenay aux Roses. The Terms of Reference include the provision of information and assistance for the treatment of persons accidentally exposed to large doses of radiation, as well as assistance for training of national health workers for emergency response to radiation accidents.

This Center has collaborated in the treatment of victims of radiation accidents in several countries of the European Region of WHO and has provided information and training assistance to various WHO Regions.

In 1980, the Radiation Emergency Assistance Center and Training Site (REAC/TS) of the Oak Ridge Associated Universities in Oak Ridge, Tennessee, was designated as a WHO Collaborating Center with Terms of Reference similar to the Center at Fontenay aux Roses, and currently is under the direction of Dr. William W. Burr. This Center provided valuable assistance in response to the cobalt-60 accident in Juarez, Mexico, in 1983, and in response to a 1984 incident in another country in which the contamination of a public hospital by radium was suspected. Both of the radiation emergency assistance centers were alerted by WHO following the recent nuclear reactor accident at Chernobyl in the U.S.S.R, and their staffs were ready to respond if requested.

A noteworthy example of the manner in which the various WHO Collaborating Centers can function together was provided during the "Regional Seminar on General Procedures to Manage Persons Receiving Whole or Partial Body Irradiation", which was coorganized by the Ministry of Health and the National Nuclear Energy Commission of Brazil and the Pan American Health Organization. This seminar was attended by 42 physicians and scientists from Argentina, Bolivia, Brazil, Chile, Mexico, and Venezuela who met at Itaipava, Brazil, in December 1981. The participants met for theoretical

and practical sessions under the guidance of a faculty composed of the staff of three WHO Collaborating Centers (Secondary Standard Radiation Dosimetry, C.N.E.N., of Brazil; Radiation Pathology of Fountenay aux Roses; REAC/TS of Oak Ridge), plus staff from WHO Headquarters and the Pan American Health Organization.

Training and General Tasks in Radiation Medicine

One of the most important functions of a WHO Collaborating Center is that of the production and dissemination of information. Under the direction of Mr. Joseph S. Arcarese, the Collaborating Center for Training and General Tasks in Radiation Medicine, which was established at FDA's Center for Devices and Radiological Health in 1977, has collaborated most admirably in this respect. This Center is the third WHO collaborating center now established within CDRH, all of which have provided excellent support, both in quantity and quality, for the WHO and PAHO radiological health programs.

For more than two decades, CDRH, formerly the Bureau of Radiological Health, under the overall guidance of its Director Mr. John C. Villforth, has generously shared its knowledge and expertise with the world. The mailing list of the Center includes some 700 institutions in 70 countries. Many health professionals and scientists have received training at the Center for periods ranging from a few weeks to a year. On many occasions the expert staff of the Center has been made available through WHO for seminars, training courses, and special consultative assignments in all parts of the world and has played important roles in preparing numerous WHO Technical Reports (*16-20*).

Two valuable CDRH informational activities, which are made available to the world through WHO, are the Problem Reporting Program for Radiation Therapy Devices and the Medical Device Reports, which provide alerts concerning potential safety hazards involving medical equipment, including x-ray machines.

The visiting scientist program of the Center has enabled outstanding research scientists from various countries to spend up to 1 year at the Center working in collaboration with the Center's staff on specific research projects. In addition, through an agreement with PAHO, the Center has loaned modern, well-calibrated and maintained radiation measuring instruments to PAHO for use in training and research programs.

RESUME OF THE EXPERIENCE WITH THE WHO COLLABORATING CENTERS IN RADIOLOGICAL HEALTH

During nearly two decades since the establishment in Buenos Aires, Argentina, of the first WHO Collaborating Center in the radiological health area, experience has shown that a complex subject requiring high levels of specialization can be differentiated into manageable components; in various parts of the world institutions or groups with specific expertise and motivation can be identified; and through a coordinating mechanism, such as the WHO Collaborating Centers, the best of the world's resources can be enlisted to cooperate in the solution of national problems.

Of the WHO Collaborating Centers in the radiological health area, approximately half are established in institutions outside of the Ministries of Health. The result is that valuable resources that otherwise would not be available are mobilized, through WHO, to help improve health conditions.

FUTURE NEEDS FOR COLLABORATION

Considering health needs in the radiological area, diagnostic imaging is one of the most important areas for future collaboration. The new imaging modalities such as ultrasound, computed tomography, and magnetic resonance imaging are raising many issues in developing countries. The collaboration of institutions that have special expertise in the planning of services and facilities, training, quality assurance, and evaluation of images and results will be invaluable. A related area, in which collaboration among centers in developing countries may be more important than among developed countries, involves the rationalization and optimization of the mixture of diagnostic imaging modalities. Within almost any health care system, there is a spectrum of imaging requirements ranging from the most essential, such as the WHO-BRS, to the currently most complex, such as computed tomography or magnetic resonance imaging. Health authorities will need to optimize this mixture of diagnostic imaging modalities within a health care system.

Another discipline in the radiological health area that the tragic accident at Chernobyl has shown needs reinforcement is that of the measurement of radiation levels in the environment. The WHO Collaborating Centers for Secondary Standard Radiation Dosimetry can perform the basic function of assuring the credibility of radiation instruments; however, in many cases these centers do not have resources for conducting environmental radioactivity measurement programs. Hence the need to strengthen the centers and/or to identify and enlist the collaboration of other institutions.

From the viewpoint of the existing WHO Collaborating Centers, the greatest problem is the lack of resources. When the first centers were established nearly two decades ago, it was possible for WHO to provide a modest grant for equipment. Much of the existing equipment, even that which was purchased subsequently with national funds, has become obsolete or needs repair. Consequently, resources to continue operating are urgently needed and need to be obtained either through some form of international support, or through recognition by national authorities of the precious scientific and technological capability that these centers represent.

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ATTACHMENT: TYPICAL TERMS OF REFERENCE

WHO COLLABORATING CENTER FOR ENVIRONMENTAL RADIOACTIVITY

The terms of reference of the Center will be:

1. Assist WHO in generating internationally comparable data on levels and trends of environmental radioactivity

2. Provide advice to WHO in preparing technical guidelines for public health assessment of actual and potential radioactive releases into the environment, their monitoring, and the evaluation of measures for controlling such releases

3. Aid WHO in gathering information on research progress in the field of environmental radiation, and in planning and coordinating such research as agreed upon.

WHO COLLABORATING CENTER FOR TRAINING AND GENERAL TASKS IN RADIATION MEDICINE

1. Assist WHO in the collection and distribution of information and teaching aids for the training of medical radiological technicians, radiological engineering technicians, medical physicists, and physicians in all branches of radiation medicine

2. Prepare and issue such material for use in the different WHO regions and country projects

3. Formulate, in collaboration with WHO, recommendations and guidelines for training in the medical applications of radiation.

WHO COLLABORATING CENTER FOR PROTECTION AND STANDARDS FOR NONIONIZING RADIATION

The Center will perform the following functions according to needs and requests and depending on the capacity of the Center:

1. Assist WHO in estimating present levels and trends of human exposure to nonionizing radiation

2. Promote the establishment of calibration and reference services

3. Promote and assist WHO in establishing internationally acceptable:

   3.1 Nomenclature

   3.2 Definitions of quantities and terms

   3.3 Comparable methodology of dosimetry

   3.4 Comparable processing of the results

   3.5 Definition of parameters to be measured and recorded

4. Provide facilities and assist WHO in training public health personnel

5. Assist WHO in promoting and achieving comparable and reproducible measurements

6 Assist WHO in alerting public health personnel of the need for control programs

7. Assist WHO in stimulating international research on:

   7.1 Experimental radiation bioeffects and epidemiologic research

   7.2 Development of suitable measuring instrumentation.

WHO COLLABORATING CENTER FOR NUCLEAR MEDICINE

To assist in the promotion and improvement of nuclear medicine by:

1. Collecting information aimed at outlining the situation in nuclear medicine services and their efficiency and quality of work

2. Collecting and providing information on the optimized use of equipment and application of technique; selection of the most adequate radiopharmaceuticals and their quality control; radiation doses delivered; adverse effects of different radiopharmaceuticals, including those effects ocurring because of long storage time or inadequate storage procedures

3. Promoting quality control and quality assurance principles and methods in nuclear medicine at the national and international level

4. Cooperating with countries in the planning and establishment of nuclear medicine services in the framework of other radiation medicine services

5. Issuing and distributing, through WHO, recommendations, manuals or codes of practice and giving advice, at the request of individual institutions concerning the organization of nuclear medicine facilities and the proper use of equipment and procedures

6. Promoting education and training in nuclear medicine, including the selection and development of appropriate training programs and organizing training courses on selected topics as required and requested

7. Establishing and maintaining contacts and working relations with national and international nongovernmental organizations involved in nuclear medicine tasks, other WHO Collaborating Centers, and other institutions as requested.

WHO COLLABORATING CENTER FOR RADIATION EMERGENCY ASSISTANCE

The function of this collaborating center is to:

1. Assist in the establishment of emergency plans to be used in the event of a large-scale radiation accident

2. Serve as a focal point for advice and possible health care in cases of human radiation injuries

3. Develop and carry out coordinated studies on human radiopathology and epidemiological studies that may be appropriate

4. Facilitate the progressive establishment of a network of equipment and specialized staff for radiation accident response and human radiopathology

5. Assist in the preparation of relevant documents and guidelines

6. Provide, in the case of an actual radiation accident, the following as necessary:

   6.1 A team for on-site emergency treatment

   6.2 A survey team for rapid external radiation and/or contamination surveys with appropriate equipment

   6.3 Transportation of patients

   6.4 Facilities for medical investigation and treatment including: bio-assay services, whole-body monitors, radiochemical analysis of samples, specialized staff and hospital facilities for treatment of radiation injury

   6.5 Followup medical supervision and treatment.

WHO COLLABORATING CENTER FOR TRAINING AND GENERAL TASKS IN RADIATION PROTECTION

The collaboration proposed refers exclusively to ionizing radiation used in medicine, industry, research and nuclear fuel cycle (uranium mining and milling, fuel element fabrication, conversion, enrichment and nuclear reactors).

The Center shall perform the following tasks according to mutual agreement in order to establish the priorities:

1. Assist in estimating present levels and trends of human exposure to ionizing radiation by:

   1.1 Maintaining an inventory system of sources of ionizing radiation used in industry, medicine, research, and the nuclear fuel cycle

   1.2 Developing guidelines on estimating human exposure from the data bank of the personal monitoring system (film badge, TLD, albedo, bioassay analysis and whole body counter)

   1.3 Analyzing and interpreting the data to estimate human exposure and trends.

2. Promote and assist in the establishment and use of internationally accepted standards, quantities, and methodology for data assessment

3. Provide facilities and assist WHO in training public health personnel and professional users of radiation sources concerning radiation protection and dosimetry

4. Assist WHO in informing public health personnel of the need for control programs, through workshops, seminars, technical reports, and recommendations

5. Advise WHO on trends and progress in the following areas:

5.1 Protection programs to reduce unnecessary radiation exposures

5.2 Development of standards

5.3 Development of adequate measuring techniques and instruments

5.4 Research on bioeffects and human health effects of ionizing radiation

6. Assist WHO in stimulating international research on:

6.1 Bioeffects and epidemiological research in human populations, especially radiation workers

6.2 Development of adequate measuring instrumentation.

IIF7. MEDICAL DEVICE DATA BASES: NOMENCLATURE AND CLASSIFICATION

G. A. Coe

INTRODUCTION

In an era that is quickly becoming known as the Information Age, information about medical devices is often hard to obtain, difficult to analyze and compare, and virtually impossible to cross-reference from one data base to another. There is no compatibility between data bases even in the same country and, at times, in the same institution. An international nomenclature has not been developed that provides systematic procedures for indexing and searching data in an information storage and retrieval system.

Information storage and retrieval systems are of critical importance in industrialized countries. The information industry is now the most rapidly growing sector of the U.S. economy, representing more than 65 percent of the total labor force. In several member countries of the Organization for Economic Cooperation and Development (OECD), the information labor force represented one-third of the total force and increased in size in the mid-70s. In effect, this means that more people are managing and manipulating information than are manufacturing goods, growing food, or providing services. The Information Age is, therefore, an era in which the exchange of information is as critical a function of economic development as the production of goods.

In 1597, Sir Francis Bacon wrote that knowledge is power. Years later, Peter Drucker, consultant in business management, wrote: "The productivity of knowledge has already become the key to productivity, competitive strength, and economic achievement. Knowledge has already become the primary industry, the industry that supplies the economy with the essential and central resources of production."

Approximately 6000 to 7000 scientific articles are published each day. Scientific and technical information doubles every 5.5 years, an increase of approximately 13 percent per year.

Many scientists are overwhelmed with technical data, but starving for knowledge. The critical importance of information systems, or on-line data bases, in helping to bring order out of chaos and providing for careful selection of available information cannot be overemphasized. The emphasis shifts from developing information to selecting it and using it effectively.

DECISION MAKERS AND THEIR NEED FOR INFORMATION

The need for information on medical devices is widespread. It includes the researcher developing a new prototype, the physician selecting the best treatment, the pregnant woman confronting the decision of an ultrasound examination, and the policy-maker developing priorities for rural health services.

In general, there are three large groups of decision makers who need information on medical devices: 1. Decision makers concerned with the supply of medical devices, 2. decision makers concerned with the demand and use of medical devices, and 3. policy makers concerned with the regulation of medical devices.

Decision makers concerned with the supply of medical devices - are involved in research and development, production, quality control, good manufacturing practices, marketing, export, import, and similar activities. They need information to define feasibility

projects in research and development, to identify patent and copyright agreements, to determine margins for profit sharing or for joint ventures, to develop viable production capacity, and to select appropriate mechanisms to capture national and foreign markets. In developing countries, some ministries of health are designing, financing, and providing technical expertise to produce more appropriate health care technology. In Brazil, for instance, the Dental Unit of the Ministry of Health designed portable dental units, assisted in providing financial and technical resources, and worked as a guarantor for developing several cottage industries. The Ministry of Health of Mexico is also developing prototypes of medical equipment, assisting in identifying manufacturers, and working with industry to identify potential markets.

Decision makers concerned with the demand and use of medical devices - include purchasing agents, clinicians, bioengineers, and managers.

A purchasing agent, particularly in a developing country, needs information to facilitate selecting and importing technology that is socially and culturally acceptable, economically feasible, and technically effective. In addition, he must know whether the equipment will easily corrode in hot humid climates, if it will operate efficiently with changes in voltage, if manufacturers will provide maintenance and parts, and the degree of specialization and training needed by operators who will use the device.

Clinicians must be aware of the importance of technology widely used in medical practice to diagnose illness, treat disorders, monitor treatment, and prevent disease. Clinician/decision makers must be able to assess the efficacy, risks, costs, and health impact of medical technology. The widespread use of technology in medical practice to diagnose illness, treat disorders, monitor treatment, and prevent disease has led to an increased awareness of the need to assess its efficacy, risks, costs, and health impact. Although some of the industrialized countries have agencies to assess health care technologies, the information is often difficult to retrieve from data bases such as the Medline system of the National Library of Medicine. Even at current levels of research funding, however, information on the clinical value of technologies is insufficient for the need. And technologies developed in semi-industrialized and developing countries are not being assessed. Information on the recall of medical devices using new technologies is difficult to obtain in developing countries because of lack of communication.

Bioengineers find it difficult to obtain information specifying maintenance, repair, and performance monitoring of medical devices. This difficulty is the most frequently discussed problem in developing countries. Problems related to maintenance and repair often begin when the device is being selected. The control by the physician of the selection process has been well documented in industrialized and developing countries. The absence of information to assist in careful analysis of products and manufacturers is of concern worldwide but particularly in developing countries that face heavy demands to cut costs and improve efficiency.

Managers are concerned with the financial strain on health care budgets and with demands from large population groups, both rich and poor, for increased access to health care. Comprehensive and detailed information on procedures is needed to equitably manage health care technology, to allocate resources, to improve coverage and access, and to regionalize medical devices. Decisions of importance at the national and institutional levels concern: 1. managing cost while maintaining quality of care, 2. providing new services locally or in satellite areas, 3. determining operational and maintenance costs, and 4. evaluating future needs and developing plans to meet these needs.

It is possible that the most important information needed by developing countries concerns the software and management systems which must be provided in health facilities to assure optimal operation and maintenance of the medical device.

Policy makers concerned with the regulation of medical devices - at the national level need information from both the supply and demand sectors. In addition, they need to consider the impact of technology on the social, cultural, and economic fabric of society, its impact on health conditions of different subgroups and geographic areas, and the disease profiles of different socio-economic and cultural groups.

Decisions by policy makers are made within the framework of the social, cultural, economic, and political objectives of each country. They relate to a broad range of policy concerns in such areas as: economic growth; international trade and substitution of imports; environment; labor; social policies; health care of public institutions, social security or health maintenance organizations; national industrial development; technological self-sufficiency; and appropriate technology.

In many countries, particularly Canada, the United States, and in the nations of Western Europe, consumer groups are beginning to influence health policies on medical devices. People are reclaiming from the medical practitioner personal control over life, death, and childbirth. Particularly in the area of childbirth, changes are being made towards the use of low and soft technology, such as increased use of midwives, birthing centers, and natural childbirth.

INFORMATION DATA BASES FOR MEDICAL DEVICES

Australia, Canada, England, France, Hungary, Italy, Japan, the Netherlands, Sweden, and the United States have or are developing national data bases for medical devices. These vary from a general listing of manufacturers and medical devices produced within a country to more complex systems that incorporate information on safety, efficacy, maintenance, cost, and other relevant information. The attachment to this paper includes a brief description of medical device data bases that have been identified.

The nomenclature used to index the information for storage and retrieval appears to be developed either by the institution, as is the case of SPRI in Sweden and ORKI in Hungary; to be a modification of the FDA nomenclature as is the case with the Medical Device Registry; or is an implementation of the ECRI nomenclature.

The FDA classification and nomenclature systems were designed to meet the requirements of the Medical Device Amendments of 1976. Under this act, FDA developed a device classification and nomenclature system based on Classification Panels whose responsibility was to identify broad categories of types of devices that would need premarket approval. This nomenclature, broad and general in nature, has been adopted by different organizations such as MDR, PRODEX, and some foreign governments. So that specific instruments and devices can be identified within these broad categories, MDR and others have added additional detail and specificity to the FDA nomenclature. These procedures have not been coordinated by any agency.

The ECRI nomenclature, on the other hand, was developed by using specifying descriptors for each generic type of medical device. Unlike the FDA system, instruments were consistently classified by the same generic name whether used in two or more branches of medicine. ECRI nomenclature is presently being translated into French, Dutch, German, and Turkish; Spanish and Italian translations are planned for the near future. ECRI also has developed a partial cross reference to the FDA nomenclature.

A limitation of both the FDA and ECRI nomenclature systems is that products commonly used and manufactured in many semi-industrialized and developing countries are not included. Frequently omitted are technologies used in parasitic diseases, respiratory infections, and diarrheal diseases.

To date, the medical device data bases do not have a standardized nomenclature. A system to cross reference different information storage and retrieval data bases is needed and is being discussed but has not yet been developed.

NATIONAL AND INTERNATIONAL INFORMATION NETWORK

National data bases on medical devices will provide the essential link between national policies and institutional management, and will provide the informational resource for international exchange of information.

The development of national data bases on medical devices depends upon many factors, such as the managerial and administrative infrastructures of the health care system and its ability to systematically produce and process the information.

A national data base could be initiated in a single hospital in which communication problems are minimal. Gradually the network can be developed to include other hospitals or health centers until it becomes integrated into a national and regional network.

Components of national data bases should be developed to meet the needs of different sectors. Among those which appear to be the most important are a registry of medical devices, a clearinghouse on assessed technologies, and information on production and international trade.

A registry of medical devices is a central component of a national data base system. This registry is an instrument of public policy that supports regulatory decision making for market approval. Such a registry could be established using a common international nomenclature with appropriate descriptors for each device. The registry should include information on products approved, rejected, and recalled in the other countries.

A clearinghouse of assessed health technologies could include information on safety and efficacy of medical devices, cost, coverage, and social implications. The amount of information resulting from clinical trials and broader evaluations of social impacts is growing. Not all of this information is easily available and that which is available is difficult to retrieve from such systems as Index Medicus or Medlars.

Information on production and international trade is needed to support industrial development, local production, and trade projects. These data refer mainly to producers, products, prices, services, and commercialization and are needed by various sectors. National data bases containing information described above are needed to support both purchasing and investment.

The need for an international nomenclature is important for trade and customs purposes. In Latin America, ALADI is reviewing the actual classification of medical devices that have only a limited number of codes and is too broad to facilitate the analyses of data. Other regions use different nomenclatures. The exchange of information in this area is important for improving the negotiating capacity, particularly of the developing countries.

Information on medical devices is important to all managers, whether they work in supply, demand, or policy making.

Networks exist to foster self-help, to increase productivity, to organize ideas and strategies, to facilitate decision making, and to share resources. Beyond sharing ideas and information, networks can create knowledge. In the Information Age, the whole is greater than the sum of its parts.

With the availability of new telecommunication systems for data transmission, new possibilities have been developed for rapid development of international data networks. For example, satellite technology facilitates transfer of information to a large number of subscribers at a relatively low cost.

In essence, networking promotes the interchange of information between people involved in common activities. Networking may involve individuals in the same institution working on a project or individuals in many different areas working, for example, to assess the safety and efficacy of health technology. Networking implies that communication is transferred horizontally as well as vertically, that both parties benefit, that the communication is in both directions. Networking is a product of the Information Age. The effective use of information is the development of networks that contribute and use information.

In the field of medical devices, it is envisioned that networking could be developed between national institutions involved in promoting the efficacy and safety of medical devices, as well as among units involved in such activities as importing, selecting, or maintaining medical devices. Argentina, Brazil, Mexico, and other countries have taken initial steps to solve common problems related to import and production of medical devices.

For the semi-industrialized and developing countries the benefits of networking are many. There is no doubt that an international information network would make them more self-reliant and efficient and better negotiators in purchasing imported technology, would facilitate the rational selection and use of medical devices, and would improve their capacity to maintain and operate medical devices.

The organizers of this Conference hope that we develop here the strategies and mechanisms to first, select or develop an international nomenclature for medical devices and second, establish national and international information networks on medical devices that will assist in developing policies and collaborating programs for the management of medical devices.

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ATTACHMENT: LIST OF INTERNATIONAL DATA BASES

The following is a compilation of medical device/health technology data bases worldwide that may be useful to authorities charged with the responsibility of managing medical device regulatory programs, and officials responsible for the evaluation and procurement of medical devices.

A number of these data bases are maintained by public health authorities charged with the responsibility for managing medical devices, or evaluating the safety and effectiveness of these technologies. Many of these health authorities will provide information on these databases without charge. Other data bases are maintained by various nonprofit organizations that may make them available at cost. In some cases it may be possible that access to the data base is available only to institutions that subscribe to a service provided by the manager of the data base. The listing below provides information that will facilitate contact with managers of these data bases.

AUSTRALIA

Medical Devices and Dental Products Branch
Department of Health
240 Langridge Street
Abbotsford, VIC 3067
Australia
Tel. (03) 428-4131
Telex AA151696
Fax (03) 429-8585

This data base presents information on supplies, product name, classification, description, details of accessories, contents of kit, whether the device is intended for single use or reuse, sterility, power source, use with drugs, marketing details, and status. The data base uses ECRI nomenclature and the 1985 codes of therapeutic devices. It provides sensitive and confidential information that is used by the Department, and the data base itself is used principally by the state and federal departments of health, hospitals, and medical device manufacturers and distributors. In addition, other data bases are available on request. The data base is in the formative stage and publications are not yet available.

CANADA

1. Health and Welfare Canada
   Health Protection Branch
   Evaluation and Notification Division
   Bureau of Radiation and Medical Devices
   Tunney & Pasture
   Ottawa, Ontario

Notification Section. By law, manufacturers are required to supply to the Bureau information concerning all new medical devices within 10 days of their first sale. The information received is recorded via the Notification Computer System. Various reports are produced and distributed within the Bureau's other sections. The Notification Section data base captures most of the basic manufacturer, distributor, and medical device information. Because this section is the Bureau's f cal point for this common information, requests for additional information are frequently received from the other

sections within the Bureau and from Field Operations Directorate. Notifications received from manufacturers of medical devices that are manufactured or sold in Canada are in the form of a submission containing all relevant device, manufacturer, and distributor information. The submission also includes the name and address of the authorized person designated by the company to deal with all communications/legalities, etc.. The information received may concern a new medical device or changes to an existing device.

Premarket Review Section. All manufacturers of new implantable medical devices must apply for and receive a Notice of Compliance letter prior to general marketing. Information supplied by the manufacturer concerning the device is received in the form of a submission document. If the initial information that is received is not complete the evaluator will send the manufacturer a form letter requesting additional information. The submission is evaluated and assessed by the Pre-Market Review Section of the Bureau. Information in the data base includes: name and address of manufacturer, submission number, submission date, model number, purpose of device, description of device, status, and status date

Clinical Trials Section. New medical devices and devices that are considered new technology are required to undergo clinical trials prior to general distribution. The Clinical Trial Section receives information concerning the clinical trial testing of new medical devices and technology. This information is obtained from the manufacturer on a voluntary basis. In addition, information is obtained from a variety of other sources. These sources include medical associations, trade literature, and other interested sources. If insufficient trial information is available for the indicated device or technology, additional information will be requested from the manufacturer.

Evaluation Section. When a problem occurs with a medical device while in use in Canada, information may be provided to the Bureau of Medical Devices in the form of a problem report. Problem reports are either forwarded to the Bureau of Medical Devices or to the Field Operations Directorate. Sources of problem information include hospital personnel, health care professionals outside hospitals, general public, manufacturers, medical association or society members, and staff within the Bureau of Medical Devices. The computerized information is analyzed and distributed, in the form of reports, as required within the Bureau of Medical Devices. Some of the computer reports produced are summary of minutes report, problem reports divided into medical speciality and device class, and daily statistics report.

Field Operations Directorate. The Field Operations Directorate investigates problem reports in many areas across the country. The Directorate enforces and monitors compliance with the required actions. Sometimes problems are initiated within the Directorate and sometimes the problems are referred to the Directorate from the Evaluation Section for followup. When problems are referred to the Directorate from the Evaluation Section, the Evaluation Section will still monitor the progress of the followup actions. The Directorate also is responsible for ensuring compliance and enforcement with all other regulatory requirements of the Food and Drugs Act and the Medical Device Regulations.

2. CANADIAN HOSPITAL DIRECTORY
   17 York Street, Suite 10
   Ottawa, Ontario K1N 9J6
   Canada
   (613) 238-8005

The directory is published as a service by the Canadian Hospital Association. The first section contains the names, addresses, services, bed distribution, and other data provided by the member hospitals of the Canadian Hospital Association. The second section contains a complete listing of manufacturers and distributors in Canada and an alphabetical directory of equipment, supplies, building materials, services and specialties with names of suppliers. The Canadian Hospital Association has a formal affiliation with ECRI and will employ the ECRI standard nomenclature and coding system.

FRANCE

1. CNEH
   3 Avenue du Centre
   78182 Saint Quentirien Yve Lines
   (1) 3043-1754

This data base includes information on the manufacturers, products, models, main specifications, and approval status. It is used by hospitals, general buyers, and users. Plans are being developed for paper and informatic terminal output. This data base uses nomenclature developed by CNEH, the National Nomenclature for Hospital Equipment.

2. PHARMAT
   Centre d'Etudes Sur la Pharmacie Hospitaliere
   Hotel Dieu
   Rue Viguerie
   31052 Toulouse Cedex

This data base includes information on the manufacturers, products, models, main specifications, and approval status for disposable devices. It is used by hospitals, general buyers, and users. Plans are being developed for paper and informatic terminal output. This data base uses nomenclature developed by Pharmat, the national nomenclature for disposable devices.

HUNGARY

ORKI
National Institute for Hospital
and Medical Engineering
Budapest, 1125, Di˜s{rok Vt. 3

The data base includes information on the manufacturer; the medical device, including name, type, model; data on the user, year of purchase, cost and other relevant information. It is used by the ministry of health, hospitals, health councils, and the national institute for hospital and medical engineering (ORKI). The data base uses nomenclature developed by ORKI.

ITALY

Instituto Superiore de Sanita
Viale Regina Elena 299
I-00161 Roma-Nomentano

This data base has been, up to now, only for biomedical instrumentation and is maintained on software running on a personal computer. The information that has already been coded in the data system includes the following:

1. A data base with name, address, and other information on manufacturers and suppliers of biomedical instrumentation available on the Italian market (relevant foreign ones plus Italian ones). This includes approximately 1790 items as of February 28, 1986.

2. A data base with names of instruments and a brief, but as complete as possible, description of the instruments themselves. This data base includes approximately 500 items as of February 28, 1986.

3. A data base with safety and standards information (either international or national standards) concerning the instruments included in the data base.

Data bases on purchasing, legal regulations, and on technical evaluation reports related to the instruments defined in 2, above, are presently under development. A data base for an automatic maintenance system in a hospital environment, such as data base for warnings, alerts, and recall is under investigation or evaluation.

All items are connected in a single "linking" data base. Its items are defined as a sum of codes of information as described in the above data bases. The code is three alphanumeric characters for the manufacturer and for every instrument, two for the model, three for the safety documents, and so on. The Institute is now studying the possibility of connecting its data base to the ECRI data base and employing ECRI nomenclature and coding.

JAPAN

1. Office of Medical Devices
   2nd Evaluation and Registration
   Division Pharmaceutical Affairs Bureau
   Ministry of Health and Welfare
   1-2-2 Kasumigaseki Chiyoda-ku
   Tokyo 100
   081-3-503-1711 Ext. 2745

The data base contains registration data on medical devices including the generic name, computer code, approval number, approval date, and manufacturer's name. In addition the importer's name and address is included along with other relevant information. The information can be accessed by telephone or by obtaining the published material and is used primarily by government. The nomenclature and computer code were developed by the Ministry of Health and Welfare. It is cross-referenced to the Dynamic Statistics of Production of Pharmaceutical and Related Products data base.

2. Economic Division
   Pharmaceutical Affairs Bureau
   Ministry of Health and Welfare
   1-2-2 Kasumigaseki Chiyoda-ku
   Tokyo 100
   081-3-503-1711

The data base named the "Dynamic Statistics of Production of Pharmaceutical and Related Products" contains manufacture and import statistics data such as the generic name, code, amount, cost, and additional information on the manufacturer and import statistics. The information is published and used primarily by manufacturers and importers. The nomenclature is cross-referenced to the data base of the Office of Medical Devices previously presented.

3. Statistics and Information Department
   Ministry of Health and Welfare
   1-2-2 Kasumigaseki Chiyoda-ku
   Tokyo 100
   081-503-1711

The data base contains survey data on medical facilities. Information includes a complete description of medical devices available in each Prefecture. The information is published and used for local planning.

NETHERLANDS

Netherlands Organization for
Applied Scientific Research (TNO)
Medical Technology Unit
P.O. Box 188
2300 Ad Leiden

This data base contains information on medical devices, including at this moment:

- approximately 1000 makes, with about 4000 models, of commercially-available medical devices representing approximately 250 types of medical devices;
- Approximately 450 test reports and market surveys (from 8 countries) concerning about 200 types of medical devices;
- approximately 450 hazard reports (from 4 countries) concerning approximately 150 types of medical devices.
- approximately 450 national (9 countries) and international standards concerning approximately 200 types of medical devices;
- approximately 40 market surveys with product information concerning about 1700 device models that are commercially available in the Netherlands;
- approximately 100 national and international congresses, exhibitions, etc.

Output from the data base can be arranged:

1. by device, to show test reports, market surveys, hazard reports, standards, etc.;
2. by make and type, to show test reports, market surveys, hazard reports, etc.; and

3. by report, to show title, report code, name of testing facility, aspects investigated, makes and types of devices involved, standards used as evaluation criteria, etc.

The data base can output purchase information, design and facilities, and specifications for approximately 1700 devices. The data base system incorporates two nomenclatures:

1. Product names, in English, as published in the Health Devices Source Book by ECRI, and
2. Product names, in Dutch, as mentioned in a Dutch hospital inventory system.

Further information, if needed, is available on request.

SWEDEN

SPRI
Box 27310
S-10254 Stockholm

The SPRI data base consists mainly of a listing of different categories of devices. It is used primarily by health care providers. The nomenclature is a standardized code, called SPRI-Code, for medical devices, which includes equipment and supplies.

USA

1. American College of Physicians
   Clinical Efficacy Assessment Project
   4200 Pine Street
   Philadelphia, PA 19101
   (215) 243-1200
   (800) 523-1546

The American College of Physicians (ACP's) Clinical Efficacy Assessment Project (CEAP) evaluates the safety and efficacy of medical tests, procedures, and therapies and makes recommendations on their appropriate uses. All recommendations are approved by the ACP Board of Regents or its Executive Committee. The program is intended to help physicians practice high quality, more efficient, and cost-effective medicine. The program was begun in 1976 as the Medical Necessity Project. Early in 1981 it was renamed the Clinical Efficacy Assessment Project and expanded with the assistance of a 3-year grant from The John A. Hartford Foundation. The project now is a fully supported activity of the College. An alphabetical index and summaries of all recommendations separated into diagnostic and therapeutic categories are presented. Asterisks following the year of approval indicate that detailed statements and in some cases, statements and background papers are available upon request.

2. Center for Devices and Radiological Health
   U.S. Food and Drug Administration
   5600 Fishers Lane
   Rockville, MD 20857
   (301) 443-4690

The Center for Devices and Radiological Health maintains a number of data bases in support of voluntary and mandatory programs for devices that are in commercial distribution. A brief description of each data base follows.

Voluntary Programs

Medical Device and Laboratory Product Problem Reporting Program (PRP). The PRP is promoted for use primarily by health care professionals, although it is also used by lay persons, to report problems with medical devices and radiological health products. The program is conducted through a contract with the United States Pharmacopeia Convention and involves the mailing of reporting forms to hospitals and members of the 35 health care professional associations that sponsor the program. The PRP was started in 1971 and has received more than 20,000 reports to date. The data base includes: name and address of reporter (for internal FDA use, not released), product information, and description of the problem. Data is used by FDA to identify problems and where necessary to protect the public health. Data is available to the public through Freedom of Information Act (FOI) requests.

Government Wide Quality Assurance Program (GWQAP). This program is conducted with the Department of Defense and involves the submission of medical device problem reports that occur within the DOD and Veterans Administration Hospital Systems. The data base includes: name and address of reporter (for internal FDA use not released), product information, and description of the problem. Data is available to public under FOI.

Mandatory Programs

Medical Device Reporting (MDR) Data Base. Manufacturers and importers of medical devices are required to notify FDA whenever they receive information that one of their devices may have caused or contributed to a death or serious injury. In addition, they are required to submit a report of any malfunction that, if it were to recur, would be likely to cause or contribute to a death or serious injury. This reporting is required by the Medical Device Reporting (MDR) Regulation which became effective in December 1985. To date, firms have submitted more than 21,000 reports. These reports:

1. identify the device, including its brand name and common or usual name and, to the extent known, the model, catalog, or other identification number or code of the device, and the manufacturing lot or serial number of the device.

2. identify the manufacturer or, in the case of an imported device, identify the importer and the foreign manufacturer;

3. identify, by name, address, and telephone number, the individual making the report to FDA;

4. describe, to the extent known, the event giving rise to the information received by the manufacturer or importer, including (i) whether any deaths or serious injuries have occurred and (ii) the number of persons who died or were seriously injured;

5. identify, by name and address, the person submitting the information to the manufacturer or importer;

6. state whether the manufacturer or importer intends to submit additional information, and, if so, when such information will be submitted; and

7. state whether the reported event has occurred or is occurring more frequently or with greater severity than is stated in the labeling for the device or, if there is not any pertinent statement in the labeling, than is usual for the device, if such information is available.

FDA uses the above data to identify defective devices and patterns of user error and to provide information to support plant inspections, device classification and other FDA activities that could prevent death, serious injury, and malfunction that could result in death or serious injury. Reports are available under FOI (except for patient and institution identification, or trade secret information.)

DEN Data Base. Some devices must receive premarket approval before they can be commercially distributed. The manufacturers of devices that have approved PMAs are required to submit certain types of reports as a condition of approval. The reports usually involve unusual adverse incidents or events that are occurring more frequently or with more severity than noted during the clinical trials. All of the aforementioned data is stored in a automated information system - The Device Experience Network or DEN. DEN is used by the Center to evaluate incoming reports and to monitor devices and firms for trends. This data is available under FOI.

Registration and Listing Data Base. Section 510 of the Food, Drug, and Cosmetic Act (FD&C) requires manufacturers and other specified processors of devices to register their establishments with FDA and to list their devices. The form for registration is FDA-2891 and the form for listing is FDA-2892. Manufacturers are required to renew registration each year through a process called "reregistration" and they must register each establishment that is involved in the manufacture of medical devices. Listing is required within 30 days after the receipt of listing material from CDRH. Listing material is sent to each owner/operator of a newly registered establishment. Listing must be updated twice a year during the months that changes, as described in the regulation, occur.

Principal information included in this data base is: name and address of establishment; name and address of owner/operator if different from first item; identification of official correspondent; and type of establishment such as initial distributor of imported devices, manufacturer, repackager and/or relabeler, contract sterilizer, specification developer, contract manufacturer, intermittent manufacturer, or rebuilder-refurbisher. The data base also includes information on the generic class of device locations where device activities take place, including: specification developer, foreign owner/operator, initial distributor listing on behalf of foreign owner/operator, domestic owner/operator, manufacturer of device to own specifications for labeling for other owner/operators who act as private label distributors, and repackager or relabeler. The information in this data base is used to support inspectional activities required by Section 510 of the FD&C Act. Data is available under FOI.

Premarket Notification (510k) Data Base. FDA requires that firms notify FDA 90 days before they commercially distribute a device. This notification, known as a 510k submission is required when firms are: (1) introducing a device into the marketplace for

the first time; (2) introducing a new device or product line for the first time, even though the device may already be marketed by another firm; or (3) introducing or reintroducing a device for which there is to be a significant change or modification which could affect the safety or effectiveness of the device. The FDA will review the submission and determine if the device is "substantially equivalent" to a device that was on the market prior to enactment of the Medical Device Amendments of May 1976. If the device is equivalent, the firm will receive approval to market the device. If the device is determined not to be equivalent, premarket approval, relabeling, or additional data may be required before the device can be marketed. The data base includes: name and address of submitter, name of the product, generic device class, and FDA decision: substantially equivalent, not substantially equivalent, withdrawn, other. Information from this data base is available under FOI.

3. ECRI medical device data bases
   5200 Butler Pike
   Plymouth Meeting, PA 19462
   (215) 825-6000
   (800) 523-1546

ECRI produces the following data bases on medical devices. Some are for internal research or management use only. Others are published, made available as electronic data bases, or are available as custom data base searches on request. Still other databases are in development. All the internal and external data bases uniformly employ a standard ECRI developed medical device nomenclature and coding system, which has been broadly accepted and implemented internationally. ECRI is a nongovernmental nonprofit research institute that makes its publications, data bases, and services available at cost. Certain ECRI databases, those designated with an asterisk, are available electronically from Biomedical Engineering Decision Support System (BMEDSS) which is supported via Compuserve and can be accessed via local terminals and modems.

Health Devices Alerts*. This data base features government and manufacturer's product recall data; abstracts in English; engineering, medical, and legal literature on medical device problems; evaluations, hazards, and health care technology assessment studies. There are approximately 2500 abstracts added annually to this 8-year-old data base. HDA is issued as a bimonthly print product and available electronically via custom data base searches. A special key word system facilitates efficient data base searches. Weekly publication and extension of the abstracting base to non-English-language sources is planned.

Health Devices Alerts Action Items*. This selective data base, drawn from Health Devices Alerts, deals with medical device recalls and problems about which hospitals and health professionals can and should take immediate action to protect patients and staff from injury and death, or to protect equipment and environment from damage. Information is published weekly in hard copy and available electronically.

User Experience Network™. This umbrella data base encompasses information from ECRI's international medical device hazard reporting network, problem reporting network, and medical equipment user experience derived from questionnaires, interviews, and other reporting mechanisms. Information from this data base is incorporated in various ECRI print and electronic information products and is available via custom data base searches.

Device Experience Network (DEN)*. ECRI's DEN database consists of short reports replicating the DEN data base in which all reports have been assigned an ECRI, coded, and reformatted to facilitate data base searches. This data base is available electronically or via custom data base searches. Almost 30,000 reports are on file.

Mandatory Device Reporting (MDR)*. This is an ECRI data base derived from the FDA's Mandatory Device Reporting System. It has been reorganized and reformatted with ECRI nomenclature and codes assigned to facilitate searching. Almost 2000 citations are added per month, a significant number of which convey information on injuries or deaths. Information from this data base is incorporated in various ECRI print and electronic information products and is available via custom data base searches.

Product Comparison System. ECRI produces the Product Comparison System on behalf of McGraw-Hill. It provides information on a broad variety of clinical, laboratory, radiology, imaging, and general hospital equipment. Each product comparison examines competing devices within a single category (e.g., three-channel electrocardiographs or CAT scanners), explains the technology, the state-of-the-art, principles of operation, problems and hazards associated with that technology, lists all manufacturing sources, and examines detailed features and characteristics in easy-to-use comparative charts showing one manufacturer's specifications compared to all others. This material is distributed by McGraw-Hill as a print product, with specialized versions for different hospital departments, as well as an overall hospital product comparison system. It is not available electronically at present.

Best Price Data Base. This data base lists prices paid by U.S. hospitals for a wide variety of brands and models of medical equipment. It is based on examination of invoice data from hundreds of institutions and thousands of purchasers. It is used internally to produce SELECT™, VHA Equip+, and similar specialized custom consulting reports for hospitals and to prepare life-cycle cost studies, which compare the relative economic advantages of one brand and model of medical equipment over others. It is not available electronically, as a print product, or via custom database searches, except on a selective basis for specific client institutions.

Health Devices Sourcebook. This data base lists all types of medical devices produced throughout the world, all North American manufacturers, their product lines, in which specialties devices are used, and provides manufacturer's addresses and toll-free and standard telephone numbers. Meticulously organized and cross-referenced, with a broadly standard nomenclature and coding system, it is published annually as Health Devices Sourcebook and is available in print and electronically.

Medical Device Manufacturers Data Base. This data base lists basic business information concerning each North American medical device manufacturer. The information is used to make judgments about the economic stability and developmental capabilities of companies. It is employed primarily as an internal database to support custom consulting reports such as SELECT™ or VHA Equip+.

Indexing Database. ECRI produces 36 publications, the combined index for which will be available electronically in late 1986.

4. Medical Device Register
   51 Bank Street
   Stamford, Connecticut 06901
   (203) 348-6319

Medical Device Register: Volume I. Volume 1 covers more than 8000 U.S. and Canadian manufacturers, with complete data on company size, ownership, key executives, financial data, distribution method, and complete product line. Products are organized into 6000 FDA-standard categories, and prices and specifications are compared among competing products. Definitions and product descriptions are also given for product categories. More than 13,000 local dealers are identified. The 1986 edition is a 2280-page hard-cover book, which includes product and company information on manufacturers and distributors of medical equipment and supplies in the U.S. and Canada.

Medical Device Register: Volume II (International). This volume presents information on medical supplies and equipment produced and distributed by companies located outside the U.S. and Canada.

Distributor Profiles. This is a new publication from the Medical Device Register, which highlights the leading distributors world-wide, and contains a profile of each. Distributor profiles cover the major distributors geographically and alphabetically with indexes by type of distribution.

Public Company Profiles. This new publication from the Register provides overview information for the 500 publicly owned companies covered in the Register, including income statements for 5 years, number of employees, medical products sales volume, names of key executives, and listings of subsidiaries in the medical business.

Product SOS. Situation Occurrence Service was first published in 1985 to present informaton on FDA product problem reports. The first edition of Product SOS covered only reports made by device users to FDA through DEN. The 1985 Product SOS organized the reports into a 1300-page hard-cover book for easy analysis, included extensive indices, and covered reports from December 31, 1980 through December 31, 1984. The new edition, 1986 Product SOS, covers all serious problem reports in addition to DEN. All Mandatory Device Reports (MDR) from November, 1984 through early 1986 are included. With these new features, Product SOS has become a key resource in evaluating medical products and identifying product safety problems. Because all the reports are based on actual user experience with the devices, it provides critical feedback that cannot be obtained from testing devices in a controlled laboratory environment. However, the key to the success of Product SOS has been its organization and indexing.

Catalog Library Service. A new publication from the Medical Device Register, these are complete catalogs on microfiche for the top 2000 medical product manufacturers.

Supplier Hotlist. A new service in 1986, the Hotlist provides bimonthly updates to the annual editions of the Medical Device Register. All new companies added to the Register data base during the previous 2-month period are profiled, and their products are organized by category. This regular updating service is valuable for identifying new ventures and new products as they are launched. It is also a great source of sales leads for distributors, OEM suppliers, and recruiters.

5. National Institutes of Health
   Consensus Development Program
   Office for Medical Applications of Research
   Building 1, Room 216
   Bethesda, Maryland 20205
   (301) 496-2351

The National Institutes of Health initiated the Consensus Development Program in September 1977 to improve the process of transferring technology from the laboratory to the health care system, while concomitantly providing a mechanism for evaluating medical devices, drugs, and procedures. The Office for Medical Applications of Research (OMAR) was then created in the Office of the Director to serve not only as the organization to coordinate, facilitate, monitor, and evaluate the program, but also to act as the focal point for technology assessment at NIH.

The Consensus Development Program has three primary objectives: (1) to provide a setting for the evaluation and review of the scientific soundness of a health or health-related technology, with emphasis on safety and efficacy; (2) to aid in the diffusion of knowledge of advances in biomedical technology, through dissemination of the findings from the Consensus Development process to physicians and consumers; and (3) to facilitate the diffusion, adoption, and appropriate use of technologies found to be sound.

The program provides a forum in which the public can assess information on a technology's safety and efficacy, as determined by scientific evaluation of these new or existing technologies. The vehicle for assessment is the Consensus Conference -- a 2½-day open meeting to which members of the public and the medical community are invited.

At a Consensus Conference, a broadly based panel, which includes consumers and members of medical and nonmedical disciplines, addresses a set of predetermined questions regarding the technology under review. During the course of the conference, the Consensus Panel develops answers to the questions in a draft consensus statement that blends the expert opinions expressed by conference speakers with the comments and assessments provided by the audience. This document is read to the audience on the morning of the third day and is modified and sharpened as a consequence of the interplay between Panel and audience.

The final statement thus reflects a consensus formulated by expert investigators, users of the technology, and consumers, all of whom form part of the audience. It is clearly of great importance that Panel members be capable of weighing the evidence and be able to find the proper balance between the various judgments expressed at the conference.

After the consensus statement is approved by the Panel, the document is published by the Government Printing Office and widely disseminated to physicians, the public, the media, and medical periodicals. To date nearly 30 statements on topics ranging from the treatment of breast cancer to the removal of third molars have been distributed throughout the United States and to nations in Europe, Africa, Asia, and South America.

6. Office of Technology Assessment
   Congress of the United States
   Washington, D.C. 20510
   (202) 226-2070

The Office of Technology Assessment (OTA) was created in 1972 as an analytical arm of Congress. OTA's basic function is to help legislative policymakers anticipate and plan for the consequences of technological changes and to examine the many ways, expected and unexpected, in which technology affects people's lives. The assessment of technology calls for exploration of the physical, biological, economic, social, and political impacts that can result from applications of scientific knowledge. OTA provides Congress with independent and timely information about the potential effects - both beneficial and harmful - of technological applications.

Requests for studies are made by chairmen of standing committees of the House of Representatives or Senate; by the Technology Assessment Board, the governing body of OTA; or by the Director of OTA in consultation with the Board. The Technology Assessment Board is composed of six members of the House, six members of the Senate, and the OTA Director, who is a non-voting member.

OTA currently has studies underway in 11 general areas: energy, international security and commerce, materials, food and renewable resources, health, biological applications, communication and information technologies, oceans and environment, space, transportation, and innovation.

7. Medical Prodex
   American Medical Communications Center
   145 Prospect Street
   Ridgewood, New Jersey 07450
   (201) 670-9000
   (800) 624-0048

The Medical Prodex is an annual encyclopedic reference text prepared for primary care providers. It consists of lists of products, devices, equipment, and supplies cross-indexed by company and by product type or category. All manufacturers and suppliers are included in alphabetical sequence with a write-up of 15 or more paragraphs for each primary product, brand or line.

Revisions, corrections, and additions are published during the year for inclusion in the text. Each hard-cover, bound annual edition will be printed and distributed in March of the title year. The overall intention for Medical Prodex is to provide immediate, handy access to critical information for the safe and effective use of a product. The product presentations in this book should approximate a "full disclosure" statement by the manufacturer.

8. U.S. Department of Commerce
   Office of Trade Information Services
   P.O. Box 14207
   Washington, D.C. 20044
   (202) 377-2432

Export Statistics Profiles. Export Statistics Profiles (ESP) provide the latest available trade statistics for the medical equipment industry in one convenient reference. It

presents past and recent trends for each product and country, and the best prospects for the future. ESPs, derived from U.S. Census and U.N. Market Share data, are arranged in a series of easy-to-read, 5-Year tables. In addition to export and import figures, many tables show prior 5-year growth rates and some show 1985 forecasts based on linear projections of 5-year historical trends. New market share tables provide valuable percentage comparisons among competitor countries. Also included is an Export Market Brief, which gives a concise industry analysis that quickly highlights the fastest growing markets, leading export products, products with the fastest growing sales, leading foreign competitor countries, best prospect countries, and much more.

Market Research Reports. These reports are comprehensive, professional documents that examine medical equipment and services industries in many key overseas markets.

Four types of reports are available:

1. International Market Research reports, which provide a complete, in-depth industry picture in a single market or country, offer the detailed findings of in-country analysts. Along with a full range of statistics and analysis, these studies also contain lists of key buyers, potential agents, trade associations and local publications suitable for advertising products. IMRs range in price from $50 to $250 each.

2. Country Market Surveys highlight only the market essentials in a 10- to 15- page summary of the information found in the studies above on a country-by-country basis, including specific information on market size, trends and prospects for U.S. exports. The cost of each CMS is $10 with a 10 percent discount if six or more are purchased.

3. International Market Information are special situation reports written by commercial officers in U.S. embassies abroad on selected industries and countries. Of varying lengths, these reports focus on unique market situations, new foreign trade opportunities, trade initiatives and recent economic developments of interest of U.S. exporters. IMI prices range from $15 to $100 each.

4. Annual Worldwide Industry Reviews are multi-country views for the year, which focus on a particular U.S. industry's export prospects in a number of promising countries. They combine in one convenient document a worldwide profile of U.S. Export Trends for an industry, country-by-country market assessments for the industry as reported annually by U.S. Commercial Service Officers, and statistical tables showing U.S. exports of the industry's products to each country over the latest 5 years. Each AWIR costs $200.

III. ANALYSIS AND CONCLUSIONS
IIIA. REPORT OF WORKING GROUPS AND SUMMARY OF DISCUSSION

IIIA1. INTRODUCTION

For Session VII, the participants of the conference were divided into six working groups. Each working group, led by a Chair and two Rapporteurs, was charged with the responsibility of conducting in-depth discussions on specific topics which were assigned. Reports of the working groups were to be prepared by the Chairs and Rapporteurs for presentation to Plenary Session IX. The working groups and assigned topics are indicated below.

Group 1 - Production and Purchase of Medical Devices

Chair:	Dr. F. J. de Ranitz
Rapporteurs:	Dr. P. Msaki
	Dr. H. U. Nino

Group 2 - Effective Utilization of Medical Devices by Health Professionals

Chair:	Dr. P. Nanasatit
Reporters:	Dr. R. Magalhaes
	Dr. N. Saranummi

Group 3 - Methods to Ensure the Effectiveness and Safety of Medical Devices

Chair:	Mme. C. Sanchez
Rapporteurs:	Dr. M. Rovere
	Dr. K. G. Gurzu-Hazarli

Group 4 - Problems Related to the Recycling of Disposable Medical Devices

Chair:	Dr. S. Perry
Rapporteurs:	Dr. L. B. Saenz
	Dr. M. Shani

Group 5 - Medical Devices at Different Levels of Health Care

Chair:	Dr. B. Azmeh
Rapporteurs:	Dr. M. Torrealba
	Dr. B. Sankaran

Group 6 - International Communication and Exchange of Information

Chair:	Dr. W.J. Rudowski
Rapporteurs:	Dr. M. Guerrero
	Ms. N. Singer

Prior to the meeting of the working groups, Dr. R. Hapsara, Chair of Session VII, introduced the topic, pointing out the descriptive, informative, and analytical nature of the conference, and encouraged the participants to exchange information in each group to the highest degree possible.

After giving some precise directives for the operation of the groups, he referred briefly to the specific theme of each of the working groups, calling attention to the abstracts of the working group meetings presented in the following section of the proceedings, which described the focus of the discussions for each of the working groups and listed specific discussion points for the guidance of the working groups.

The conclusions of each of the working groups were communicated to Plenary Session IX on Friday, June 5. Session IX was chaired by Dr. C. Migues Baron who, prior to the presentation of each group, took special note of their accomplishment: summing up in necessarily brief reports the broad spectrum of situations that are experienced in a heterogeneous world, relating to the production, acquisition, utilization, safety, and efficiency of medical devices. He stated that the communications of the individual working groups provide the best indicator of the success of the conference and the degree to which the proposed objectives of the conference have been attained. The Chairman introduced the speakers (Chairs or Rapporteurs of working groups) who presented their reports.

ABSTRACTS - DISCUSSION POINTS FOR WORKING GROUP MEETINGS

INTRODUCTION

The overall approach of the conference sessions is descriptive. Emphasis should be on exchanging information about what is occurring around the world in relation to medical devices. It is important that this experiential, empirical approach be carried into the deliberations of the working groups. The abstracts, discussion points, ICMDRA presentations, and personal and national experience of the participants, should provide a basis for the discussion of the working groups.

The topics of the six working groups are:

1. Production and Procurement of Medical Devices
2. Effective Medical Device Utilization by Physicians and Health Care Professionals
3. Approaches to Assurance of Safety and Effectiveness of Medical Devices
4. Problems Related to Reuse of Single Use Medical Devices
5. Medical Devices at Different Levels of Health Care
6. International Communication and Information Exchange

WORKING GROUP 1 - Production and Procurement of Medical Devices

The focus of this discussion is on the techniques, processes, and technical knowledge necessary to produce or procure medical devices of acceptable quality and reliability. On the production side, this can be addressed through the concept of manufacturing quality assurance or "good manufacturing practice" (GMP) techniques. On the procurement side, ways of looking at device parameters and describing them in procurement documents can be examined. Difficulties generated when GMPs are included as part of procurement parameters and approaches to effective execution of such procurements may also be considered by this working group.

Discussion points:

- Production and Procurement of Medical Devices
- Comparisons of GMP's for devices from those nations that have them
- Sources of information on quality assurance systems
- Definition of procurement requirements based on performance versus specifications
- Mechanisms for obtaining GMP status
- New frontiers in device production

WORKING GROUP 2 - Effective Medical Device Utilization by Physicians and Health Care Professionals

The focus of this discussion is on ways of mobilizing physicians and other health care professionals towards the improvement of the safe and effective utilization of medical devices. No matter how well designed or reliably manufactured, a device cannot be safe

and effective if the practitioner does not know how to use it properly in the correct disease state, or if it is used for a disease state for which it is not effective. Dissemination of information about technology is not the sole purview of government or industry. Experience in some cases has shown that broader and more rapid communication may be achieved cost effectively through cooperation with professional organizations.

Discussion points:

- Identification of relevant national and international professional associations
- Role of health professional associations in dissemination of technical information
- Medical education for device utilization
- Education and information on maintenance and repair
- Access to modern electronic media aimed at the health care community

WORKING GROUP 3 - Approaches to Assurance of Safety and Effectiveness of Medical Devices

The focus of discussion for this working group is on the examination of the various approaches taken by national governments to assure that medical devices are, in fact, safe and effective. One of the approaches that can be examined is the process used to establish the safety and effectiveness of devices prior to their entry into the marketplace. Critical to this process is the definition of the type and quantity of data which must be provided to support premarket submissions. Differences in types of developmental testing should be examined. For example, the possibility, in specific instances, of including bench-engineering testing as a substitute for multi-year followup clinical trials might be examined. Postmarketing surveillance of device safety and effectiveness may also be addressed.

Discussion points:

- Existing mechanisms in various countries for assurance of safety and effectiveness of medical devices
- Comparisons of standards of "proof" of safety and effectiveness
- Protection of proprietary information in submissions for review
- Approaches to developmental testing
- Clinical trials of medical devices
- Informed consent and human protection in clinical trials
- Postmarket surveillance
- Collaborative research

WORKING GROUP 4 - Problems Related to Reuse of Single Use Medical Devices

The focus in this discussion is on the problems associated with the reuse of medical devices that have been designed, manufactured, and intended for single use and disposal. In the past when many medical devices were intended for repeated use, cleaning techniques were well developed, and materials were used which could withstand effective steam sterilization. Because cleaning and sterilizing processes were subject to human error and labor costs were rising, the presterilized disposable product became not only safer but more cost effective, at least in many countries. The economics of this situation have reversed in the last few years. It has become more attractive to attempt to clean and reuse plastic devices in both developed and developing countries. The materials used in these devices, however, are no longer compatible with steam

sterilization, and the techniques that must be used are susceptible to a complex variety of technical problems as well as human error. Dealing with these complexities at the user site can create a number of health problems.

Discussion points:

- Resterilization and reconditioning
- High tech reuse (for example, dialysis) versus low tech reuse (for example, syringes)

WORKING GROUP 5 -Medical Devices at Different Levels of Health Care

This working group is focusing on the complex issues of local and institutional decision-making for matching technology to defined health care needs. Medical device technology is rapidly advancing. A range of devices of varying sophistication is currently being developed for most medical applications. What factors (for example, operating requirements, maintenance, and training) can be identified that should be considered in the selection of devices to assure that their technological base is compatible with the level of care? Processes for identifying local, institutional, and national needs for devices will be discussed. Mechanisms will be explored for the exchange of information concerning devices to meet needs at all levels of health care. The working group is requested to use WHO definitions of levels of care as working definitions for the purpose of this discussion.

Discussion points:

- Availability of multiple technological generations of devices in the marketplace
- Compatibility of level of health care and technologies
- Comparison of different national selection processes
- Translation of needs of health care at various levels into the adaptation and availability of appropriate devices

WORKING GROUP 6 - International Communication and Information Exchange

The focus of this working group is on a review of information exchange mechanisms and technologies. This can be done with a view toward the usefulness of information exchange regarding medical devices both on an ongoing basis and related to specific items of information.

Discussion points:

- Identification of appropriate contacts including national officials and organizations charged with the responsibility for medical devices
- Establishment of ongoing communications network
- Crises communication mechanisms
- National and international (including bilateral, regional and multilateral) experience
- WHO Collaborating Centers
- Medical device nomenclature, data base, and classification

IIIA2. WORKING GROUP 1: PRODUCTION AND PROCUREMENT OF MEDICAL DEVICES

I. PROBLEMS AND CONCERNS

The quality of health care depends to some extent on the safety and effectiveness of medical devices. Some manufacturing countries have regulations for medical devices, others have voluntary agreements, and others have none. In many cases, applicable regulations designed to protect safety and effectiveness are not legally enforced.

Few countries that primarily import medical devices, particularly developing countries, have regulations for purchasing and distributing medical devices.

Many countries have inadequate regulations that apply to exported medical devices, and they generally do not apply existing regulations to their exported products.

Medical devices imported by developing countries are not always designed to meet the needs of these countries. In most cases, developing countries are not fully aware of how to translate their needs into requirements for medical devices.

A severe problem in developing countries is the inadequate maintenance and repair of medical devices. The main reasons are: the large variety and complexity of medical devices; the lack of adequate supply of spare parts; and the limited availability of service personnel, lack of service information and limited budgets.

More attention must be given to the medical device interactions to promote safety and effectiveness in the use of medical devices.

There is insufficient exchange of information about the adequate or inadequate performance of medical devices for all countries.

II. TASKS

To establish a "Good Purchasing Practice" code for medical devices to be used by industrialized and developing countries.

To prepare guidelines for the preventive maintenance and servimedical devices directed to partially developed and developing countries.

To establish regional training facilities in developing countries for the testing, use, maintenance and repair of medical devices.

To establish communications and information centers for dissemination of performance data of medical devices.

To encourage a wide application of Good Manufacturing Practices by all manufacturers of medical devices.

Under WHO sponsorship to establish programs with the participation of professionals, industry, and users of medical devices to assist manufacturers in the development of appropriate medical devices for developing and partially developed countries.

III. POINTS TO CONSIDER

To what extent the existing regulations for drugs can be modified and adopted to be suitable for medical devices in those countries that have no regulation for devices yet.

More emphasis must be given to the training and updating of users of medical devices, including technical, medical, and administrative personnel.

Increased attention must be given to local, national, and regional quality assurance and proficiency testing programs in the use of medical devices particularly for developing countries.

To investigate the possibility of regional service and refurbishing facilities for medical devices, particularly for developing countries.

To plan, under WHO sponsorship, follow-up conferences on medical devices with the active participation of professionals, government representatives, manufacturers, and users of medical devices.

F.J. De Ranitz, Chairman
P. Msaki, Rapporteur
H. V. Nino, Rapporteur

IIIA3. WORKING GROUP 2: EFFECTIVE MEDICAL DEVICE UTILIZATION BY PHYSICIANS AND HEALTH CARE PROFESSIONALS

INTRODUCTION

Working Group 2 discussed a number of relevant topics, including effective utilization, of medical device technology difficulties experienced by the developing and developed countries, user requirements, manufacturers, management policies, ongoing collaborative activities, needs, and possible solutions.

EFFECTIVE UTILIZATION

Effective utilization requires:

1. information on how to use a certain device, comprising clinical indications and contraindications for use, the limitations of this device (or procedure), knowledge and availability of operational principles and skills required for effective use of the devices; and

2. that the device be in good working condition.

To ensure effective utilization, a policy on medical device management and a supportive infrastucture is required. Device management is a system in which, for proper functioning, the following elements must be present:

1. users must be adequately trained;

2. users must be adequately motivated to make use of their training;

3. adequate operational and maintenance information must be made available by the manufacturer as part of the purchasing process;

4. there must be adequate support from the manufacturer after purchase; and

5. there must be an adequate regulatory environment (both at the local and national level) to assure safe and effective use of medical devices.

An effective device management system is equally applicable to developing and developed countries. The relative importance of the various elements of the system may vary, depending on the developmental state of a country.

DIFFICULTIES EXPERIENCED BY THE DEVELOPING AND DEVELOPED COUNTRIES

Different approaches are necessary for developing and developed countries. For developing countries, whose access to medical devices is through import, the principal problems are, first: procurement; and later, repair and maintenance of medical devices. The problems arising in these areas result from a lack of information and human resources on the buyer's side and the fact that manufacturers are eager to sell devices but reluctant to provide service. It was felt that regional collaboration through specialized training centers could be helpful to developing countries.

In developed countries, purchasing, repair, and maintenance are problems of lesser criticality. The greater concern is safety and effective utilization of a device.

USER REQUIREMENTS

The parties that affect medical device utilization include governmental bodies, which are also reponsible for the development and implementation of health policy, health administrators, physicians, other health care professionals, scientists, engineers, and physicists. It was agreed that the necessary knowledge of medical devices is different for these groups.

It was emphasized that it is the physician who leads the team. It is therefore important that the physician develop an adequate understanding of medical devices.

The number of engineers, physicists, and technicians was felt to be too low.

The need for collaboration among the various health professional groups in a hospital was emphasized.

Training in medical device technology should be included at the graduate and postgraduate level. On-site training was considered very important and in most cases is available only from the manufacturer. Training should be required by the purchaser of the equipment at the time of purchase.

Owing to the rapid evolution of medical devices it was stressed that education is a continuing process.

MANUFACTURERS

Device utilization depends to a great extent on the information provided by the manufacturer. This includes comprehensive device specifications, instructions for use, repair, maintenance, and also support in repair and maintenance with service contracts, spare parts, etc. Manufacturers should be encouraged to comply with good manufacturing paractices.

ONGOING COLLABORATIVE ACTIVITIES

A number of ongoing activities related to device management strategies, mainly for training in maintenance and repair, were identified. These include:

a meeting on maintenance and repair of health care equipment in Nicosia, Cyprus, November 24-28 1986, sponsored by WHO;

an International Centre of Physics in Trieste, Italy, in collaboration with EFOMP and IAEA, which is engaged in several training activities at the international level, mainly connected with x-ray equipment;

several other activities located in Prima, Italy, for training in quality control and maintenance, partially connected with IOMP;

WHO has several regional collaborative training centers for equipment maintenance, e.g., Cyprus, Lyon, India, and Sierra Leone;

IEC TC62 is working with guidelines for the safe application of equipment intended for health care professionals and for the technical staff;

IFMBE has established a Division on Clinical Engineering that intends to write application codes for various electromedical equipment;

other organizations identified with similar interest include IJO, IFHE, IUF, IFCC and COCIR.

A large volume of information exists. The problem is to get access to it and more importantly, to process it into a format that can be used.

NEEDS AND POSSIBLE SOLUTIONS

The problems identified are mainly related to the system of device management as a whole. A number of needs and possible actions were discussed.

There is a need to improve collaboration inside the hospital between the engineers and technicians on the one hand and the physicians and other health care professionals and administrators on the other.

There is a need to recognize the importance of maintenance and repair activities of medical devices.

There is a great need for well-educated health care professionals who are able to use devices effectively and to participate in the procurement process with adequate information and therefore provide a balance in the buyer/seller equation.

Collaboration between purchasers and users on one hand and manufacturers on the other needs to be improved.

There is a need in developing countries for assistance in device purchasing, maintenance, and repair. This is an area in which the collaborative training centers of WHO could provide help.

There is a need for information on training centers and training material. It was felt that this also could be a task for WHO.

These needs can be covered by incorporating device technology into the training of physicians and other health care professionals, both at the graduate and postgraduate level. Physicians should be involved in the formulation of policy. WHO could provide coordinating assistance in order to promote effective management of devices on the national and international level.

P. Vanasatit, Chairman
R. Magalhaes, Rapporteur
R. Saranummi, Rapporteur

IIIA4. WORKING GROUP 3: APPROACHES TO ASSURANCE OF SAFETY AND EFFECTIVENESS OF MEDICAL DEVICES

A wide range of topics was discussed, including existing mechanisms in various countries for the assurance of safety and effectiveness of medical devices, comparisons of standards of "proof" of safety and effectiveness, protection of proprietary information in submissions for review, approaches to developmental testing, clinical trials of medical devices, informed consent and human protection in clinical trials, postmarket asurveillance, and collaborative research.

During the discussion, the following problem areas were identified by the group.

LEGISLATION

Few countries have legislation for medical devices. Of the 17 countries represented in the group, only 5 had such legislation. It was agreed that there is a great need and concern within each member state. Most participants indicated that planning for medical device regulation was underway within their countries. Discussions centered around the type of regulation that should be developed and, specifically, around standards for imported and for locally manufactured devices. The working group felt that each member state should determine its own need for regulation. Regulations should not stifle innovation, development of local initiatives, and local research. Regulations should not be heavier than the real problem itself is within the given country.

Standards for safety, efficacy, etc., should recognize each country's social needs and level of socio-ecoonomic development..

IMPORTED PRODUCTS

The second and one of the most important problems that the group discussed in detail was imported devices. All 5 countries that have legislation for medical devices stated that their legislation and required standards of safety and effectiveness were applicable only to the national use of the device. Hence, they did not have general rules, regulations, or controls for exported devices. This was a growing concern of developed and developing countries.

Effectiveness was at risk in certain countries due to local conditions, including heat or humidity. It was noted that neither purchasers nor exporting manufacturers pay enough attention to these conditions. It was also noted that postmarket surveillance of exported devices was not carried out, nor were there recall processes within the importing country.

Even though it was not the task of this group to discuss GMP, eventually it came into the discussion with safety and effectiveness as it was quite closely related to import/export issues. The problems of maintenance, repairs, and availability of spare parts and necessary operating manuals were discussed in detail. Preparation of a possible guideline for GMP for medical devices was suggested.

The last problem identified was the need for collaboration and data base information and exchange of the existing knowledge among the member states.

The following tasks were put forward in light of the above identified problems.

NEEDS AND POSSIBLE SOLUTIONS

At the national level, medical device control programs should be established by member states, and they should promote national research and development for preclinical and postclinical testing. Devices should be classified with regard to safety, risk, and effectiveness.

Medical device control programs could contain the following elements:

1. notification or registration of product by the manufacturer or vendor
2. labelling of product
3. evidence of safety and effectiveness of product from vendor to meet product claims
4. procedures to register recall of product
5. guidelines and standards for safety and effectiveness
6. premarket review of a limited number of high-priority products e.g., IUDs, cardiac pacemakers.

At the regional level, focal points or clearinghouses for information exchange and collaboration on research know-how should be established. At the international level, standardization of devices and exchange of information and expertise should be promoted.

A progressive evaluation of guidelines to standards may be appropriate for developing countries. Local research and development should be encouraged and promoted by member states and WHO.

Imported devices, as a minimum, should satisfy the standards of the exporting country. Imported devices should be accompanied by intelligible, useful information, including specifications, operating manuals, as well as maintenance and repair information.

Recalls, adverse effects of devices, and accidental occurrences involving medical devices should be brought to the attention of the authorities by the manufacturer on a regular basis. Any negative result that appeared during preclinical and clinical testing must be reported promptly to the authorities or purchasers.

A need exists for a focal point for medical device safety and effectiveness. This would facilitate the exchange of information, promote the establishment of collaborating centers, and aid personnel development and training programs with particular reference to developing countries

C. Sanchez, Chairman
M. Rovere, Rapporteur
K.G. Gurzu-Hazarli, Rapporteur

IIIA5. WORKING GROUP 4: PROBLEMS RELATED TO THE REUSE OF SINGLE USE MEDICAL DEVICES

Reprocessing and reuse of medical devices intended for single use only seems to be a widespread phenomenon. "Reprocessing" is defined as the cleaning and resterilization of items that have been opened, the contents probably contaminated but not used. "Reuse" is the reprocessing and then use of a device which has previously been used in the same or another patient.

Data from United States, Canada, and the United Kingdom point to the likelihood that 50 to 80 percent of the various hospitals are reusing medical devices. There are reports also about widespread reuse of disposable medical devices in the Netherlands and Australia. Such data are not available from developing countries, but there is an impression that the practice is widespread in those countries as well.

The range of disposable devices that are reused is very wide - from "critical care items" such as hemodialysers and cardiac catheters to respiratory assist devices, insulin syringes, bedside utensils, and other "noncritical devices." Cardiac pacemakers, while not defined as disposable, are considered items for single use, yet there are reports of reuse of pacemakers in some countries.

In none of the above mentioned countries is there a national policy about reprocessing or reuse, although in Canada and the Netherlands, government regulations are now in the process of development.

Two countries - France and Spain - officially prohibit reuse of disposable items, yet it is a common practice in the hospitals of those countries. In France it is mainly limited to "high tech" items, and the responsibility for this procedure lies with the treating physician.

Israel does not have a national policy about this practice, although reprocessing and reuse are widespread for many noncritical items. In one medical center an automatic dialyzer cleaning unit is used, yet due to the drastic decrease in cost of dialyzers, there is doubt whether reuse of dialyzers will continue.

In Costa Rica there is wide reuse of disposable devices and also of cardiac pacemakers. However, there are no data about the extent of the practice and there is no national policy on reuse.

The reuse of disposables is not a major issue in Brazil (where it is limited to major hospitals) and Malaysia. In Malaysia there has been only a gradual and slow introduction of disposables.

It is probable that the examples cited above, which were presented by participants in our working group, are characteristic of most countries.

The major stimulus to reuse and reprocessing is the potential for cost savings, although evidence for such savings is often lacking. Reports in the literature about economic implications of reuse concern mainly dialysers and insulin syringes. In addition, reuse is sometimes necessary because of difficulties and delays in procurement, and the nonavailability of disposable devices.

Besides the economic implications, one has to be aware of problems related to malfunction or loss of functional integrity of the reused items and about possible infection

or reaction to residual sterilant. In only one instance - hemodialysers - does the patient gain from reuse since the "new dialyser syndrome" no longer occurs the dialyser is used.

There are also legal implications of the reuse of medical devices, but it appears that this has not been a major issue in any country.

It was the general consensus of the participants that as the financial resources for health care are limited, reprocessing and reuse of medical devices will spread, especially in developing countries, where labor costs are less. Therefore, in these countries there might be considerable economic gain in the reuse of disposable medical devices.

As for "high tech" critical care items, there must be special attention paid to quality control and functional integrity of the devices, because by definition, the adverse effects may be more serious than with the simpler noncritical devices.

A question was raised about the reuse of insulin pumps for diabetics and of chemotherapy pumps for patients with malignancies. No data are available about these specific items, however it seems that their relatively high costs may lead eventually to reuse.

There was a discussion about available resources for research in reuse of disposables. There is doubt whether industry will agree to support such research. Governments in developing countries, which are usually involved directly with paying for health services, may agree to support such research.

FUTURE NEEDS

There is an important need for heightening the awareness of issues associated with the practice of reprocessing and reuse, including the possible adverse medical effects, the technical problems of cleaning and sterilizing devices made of synthetics, the economics, the ethics, and the legal aspects

Because reprocessing and reuse appear to be widespread and there is little information about its safety and efficacy and economic benefits, there is a critical need for more studies and more data on this practice.

There needs to be an international exchange of information about the extent of reprocessing and reuse, the devices involved, adverse medical effects, and the procedures utilized in reprocessing. Such exchange of information could be accomplished using existing channels in WHO headquarters and regional offices or perhaps creating new ones, as appropriate, and establishing a focal point for such exchange.

For the purpose of allowing studies of reprocessing, manufacturers of disposable medical devices should be encouraged to provide product information, including composition or type of material used in the disposables and any information they may have as to its tolerance to heat or chemical sterilants.

S. Perry, Chairman
L. B. Saenz, Rapporteur
M. Shani, Rapporteur

IIIA6. WORKING GROUP 5: MEDICAL DEVICES AT DIFFERENT LEVELS OF HEALTH CARE

The task of this group was to discuss medical devices at different levels of health care. In doing so, emphasis was given to compatibility of level of health care and technologies. The participants exchanged information about the various selection processes for medical devices in their respective countries.

The discussions revealed that the needs in the field of medical devices are different for developing and developed countries. As a result of the discussions of Working Group 5, the following needs were identified.

National selection processes for devices and equipment at primary, secondary, and tertiary levels of health care should be established. In this selection process, countries would seek the expertise of the World Health Organization through its regional offices or through other international agencies. In this process for national selection, the following points are to be emphasized.

For primary and secondary levels of health care, all medical devices and hospital equipment should be maintained by centers established for repair and preventive maintenance, and having an adequate supply of spare parts. Training of personnel for such maintenance is an important factor of national programs.

For tertiary levels of health care and for special equipment at primary and secondary levels, (x-ray apparatus, fiber-optics, laproscopic sterilizers) maintenance contracts with manufacturing firms should be entered into for a period of 5 years. During this period a team of local technicians or engineers should be trained to carry out such maintenance after the termination of the service contract. This would, of course, be dependent on the regulations of the importing country and the training of individuals. A nucleus of medical engineers should be introduced into the ministry of health to emphasize the importance of rapidly evolving technology and to ensure efficient and effective patient care. A career structure, with appropriate incentives, would make positions more attractive to technicians and result in more lasting solutions to the problems of maintenance and repair of equipment in many developing countries. An adequate supply of spare parts must be available for maintenance of all equipment at this level of health care, stocked by the supplier.

An equipment list for different levels of health care at the national level should be outlined.

A reference catalog of medical devices for various levels of health care with descriptions of specifications and pricing should be made available (particularly to UNIPAC). Countries of a region may consider group purchasing.

A central library of manuals on repair and maintenance, with catalogs of hospital related equipment, should be available in at least one center in each country. In certain regions a regional library should be available as well, preferably with maintenance manuals in local languages.

A certain percentage of the cost of equipment should include and be allocated for repair and maintenance of equipment.

A projected life expectancy of equipment should be made and depreciation of equipment should be introduced into the budgetary process over a period of time so that, ultimately, equipment replacement should be fiscally possible within national budgetary contraints. This would, of course, depend on the type of equipment being used.

Population profiles and needs should be outlined, depending on the country's pre-eminent medical problems. This could perhaps take into account the 7th World Health Situation report of the Director-General of WHO.

Health systems research should be conducted to identify the needs of developing countries and to design and carry out research in the field for simplification and transfer of relevant technology from developed to developing countries. The ultimate aim would be self reliance, as consistent with the recommendations of the Technology Transfer Committee of the Advisory Committee on Medical Research of WHO.

Considering the limitations of funding resources of the developing countries, models like the BRS (after adequate evaluation) should be developed as technological aids and tools appropriate to the basic needs of all countries.

Integrated planning, adequate physical plants, and availability of necessary equipment is essential irrespective of level of care.

A national committee should be set up for selection of equipment, for the establishment of basic specifications and requirements for such equipment, for harmonization of needs, and for equipment audit with ultimate cost-benefit analysis. This would aid planning for equipment replacement and future purchases.

Assessments of medical devices should be made on a national scale, as a part of health technology assessment, taking into consideration the appropriateness of technology to the country concerned.

The views and needs of developing countries should be reflected in the formulation of international standard bodies on medical devices and equipment.

B. El Azmeh, Chairman
M. Torrealba, Rapporteur
B. Sankaran, Rapporteur

IIIA7. WORKING GROUP 6: INTERNATIONAL COMMUNICATION AND INFORMATION EXCHANGE

Innovation, increased sophistication, introduction of high technology, and a rapidly accelerating pace of development are characteristics of the burgeoning field of medical devices. The technology taxes the resources of developed as well as developing countries, at all levels of organization, including educational institutions that train health professionals and allied scientists; governmental authorities who develop health policy, and those who develop and implement regulatory programs to assure safety and effectiveness; those who are reponsible for program planning and priority setting at the national level, and within institutes, hospitals, and clinics; and the physicians, engineers, physicists, and technicians who must use the equipment, keep up with new developments, recommend procurement, and maintain and repair devices.

The intention of development, innovation, and application of health technology is positive: to enhance public health and save lives. In such a complex field, the realization of the positive benefits of technological health development can be maximized by the rapid and efficient dissemination of information about all aspects of this technology to all segments of the international health community. This demands intense interaction among all concerned parties including government officials, public health administrators, manufacturers, educators, scientists, physicians, engineers, technicians, health media, and the patients, whose welfare is the ultimate motivator.

The working group examined international communication and information exchange, and discussed its current status and future needs, including information exchange mechanisms and technologies. Existing and needed information regarding medical devices was discussed. Included was routine information that should be disseminated on a regular and ongoing basis, through appropriate mechanisms, in conventional media, and specialized information critical to the safe and effective utilization of the medical device technologies.

The group discussed several significant questions:

What are the benefits of establishing a system for communicating information about medical devices among the nations of the world?

How should the system be implemented?

What types of information should be disseminated?

Who should take the lead in disseminating the information?

What mechanisms should be used to disseminate the information?

PRESENT AND FUTURE NEEDS

In today's complex multidisciplinary technological society, an interactive exchange of information relating to all aspects of medical device technology is essential.

Each nation has an affirmative obligation to preserve the health of its citizens, optimize the cost-benefit characteristics of its health care system, and to protect its economic resources.

Decision makers in the regulatory and industrial levels of society need timely and accurate information to fulfill their responsibilities.

Because the information needs related to health technology in industrial and developing countries vary, it is essential that the information needs of both developing and industrialized countries be adequately considered in order to identify effective long-term solutions.

The working group identified a need for the creation of a formal permanent international mechanism to facilitate the exchange of various types of medical device information. Each nation should develop mechanisms for the internal dissemination of information to its scientific, medical, academic, and industrial community. Each nation should contribute information to the international mechanism for information transfer to other countries.

Direct communication between countries should be encouraged in addition to formal international information exchange mechanisms. Timely communication on problem areas should be direct for the protection of patients in both developed and developing countries.

Many categories of information that need to be disseminated are presently being collected and catalogued in specific data bases. These include crisis information such as hazard reports and recalls, equipment malfunctions, purchasing information, enforcement action, directories, and laws. The World Health Organization is the appropriate agency to collect and disseminate the information to its member countries in the field of devices as it does in the field of drugs.

To implement this, it was recommended that WHO obtain the names of the appropriate officials and organizations in member countries and direct and solicit information to/from them.

Additionally, it was recommended that the designation of collaborating centers should also be considered.

Working Group 6 also recognized that in order to ensure the long-term success of international exchange of information, a standard medical device nomenclature and associated coding system be adopted. If an existing and proven international standard nomenclature is adopted, this will facilitate information sharing. The system should be employed to classify and index the medical device literature, hazard reports, recalls, technology assessments, product specifications, and other related data.

Technology for the management and maintenance of large data bases exists and is rapidly decreasing in cost. Computerized systems can, at relatively little expense, allow for the efficient storage of very large data banks, permit random retrieval of the stored information, and allow for rapid transfer of information via telephone or other electronic communication media. A standardized system should be developed or adopted for the management of international medical device data bases to ensure international compatability.

W. J. Rudowski, Chairman
M. Guerrero, Rapporteur
N. Singer, Rapporteur

III.B SUMMARY OF THE GENERAL DISCUSSION OF THE WORKING GROUP REPORTS

Following the presentations of each working group, Dr. N. Susansky, chairman of the second part of Session IX, invited the participants to clarify issues and offer their observations on the Plenary Session. The following represents a summary of the discussion.

Dr. Canitrot (Argentina): Made two observations directed to Group 6 on information exchange. First he pointed out that it is necessary and desirable to add to the information system proposed by the group, which includes the classification and coding of medical devices, information on international reference prices for these devices. He pointed to the experience of Argentina in the use of a reference system for drug prices, which saw prices for imported drugs that were far higher than the international reference prices for these same drugs. Second, he pointed to the need for exporting countries to apply the same standards for medical devices intended for export that they apply to devices intended for use within their country. He claimed that the less developed countries are receiving technological scrap, citing as an example the export to these countries of used and reconstituted equipment such that is prohibited for use in the countries from which it is exported. He stated categorically that the controls for the safety and effectiveness applied to exported devices should be equally as stringent as the controls applied to products used within the producing country.

Dr. Slatopolsky (Argentina): Seconding the comments of Dr. Canitrot, he indicated the serious need for reference prices for devices in the international market. Such reference prices could serve as a guide for importing countries, producing substantial savings and diminishing the risk of unjustifiable escalation of prices.

Dr. Noble (U.S.): Indicating that he understands and sympathizes with the need for the developing countries to have information on reference prices, pointed out, nevertheless, that the creation of such a price reference system may be almost impossible from the practical point of view, based on the experience of ECRI. After 5 years of collecting and evaluating massive amounts of data on prices for medical devices, there is still no standardized system that allows for easy and unambiguous price comparisons. ECRI publishes list prices for thousands of devices but these cannot be easily interpreted. The differences in contractual terms for the purchase of similar equipment (warranties, service, parts, etc.) make the prices in the data banks useless without a human interpreter between the person asking the question and the data base. He also pointed out that the purchase price for a medical device may not be the most relevant information on cost for the buyer if it fails to take into account other cost factors such as operation, maintenance, repair, useful life, etc. He recommended that the information system to be developed for medical device management include, whenever the criteria can be standardized, the "total cost of the use cycle" of the medical device instead of simply the purchase price. The differences between procurement cost and lifetime cost may be a factor of three or four.

Dr. Azmeh (Syria): Indicated that Group 5 has included among its recommendations the implementation of a price reference system like that of UNIPAC of UNICEF.

Dr. Hanson (PAHO): Suggested that progress could be made toward preparation of a price reference system based on the experience of several countries and of PAHO/WHO in the procurement of basic radiology equipment. Although there has been a broad range in the price for this equipment - from $30,000 to $70,000 per item - a

manufacturer recently estimated a production cost of $12,000 - $15,000. Thus while the price range is broad, he thinks that a price reference system could be developed stipulating a maximum acceptable variation of 10 percent.

Dr. Banta (WHO): Made an observation directed to Group 3 which had suggested the need to avoid a degree of regulation in developing countries that might impact adversely on the development of local production. Dr. Banta noted that local production frequently was considered to be of inferior quality (relative to imports). He suggested that stiff regulation and high requirements for quality control might improve the local acceptance of local production within developing countries.

Dr. Valiathan (India): Directed his comments to Group 3, on the subject of safety and effectiveness. He pointed out that, in the process of developing local production, from the outset there is a certain mistrust on the part of consumers which can be overcome as local production matures. He expressed concern about the application of very rigid and exacting standards or regulations during this period because they can hamper the development of health technology in the country.

Dr. Gurzu Hazarli (Turkey): With regard to the observation of Dr. Banta, pointed out that Group 3 had an in-depth discussion on the subject of similar different standards for developing and developed countries. The group reached the conclusion that the developing countries should prepare their own standards in order not to perpetuate the existing situation of dependency. The group felt that this effort should include predictive and dynamic research as part of the process of developing standards and guidelines in each country.

Dr. Johnson (Canada): Supported the observations of Dr. Gurzu Hazarli but said he felt that a number of contradictions had surfaced in the conference duscussion. It has been said that the developed countries export "trash," or medical devices that could not be marketed in the producing countries. It has been pointed out that the producing countries should avoid a "paternalistic" position in the development of standards, and finally, a specific suggestion has been made that the standards applicable to medical devices for the domestic market and for export be identical. All this has been argued with a view to improving the quality of the products received or imported by the developing countries. There have also been several references to the need for developing countries to receive medical devices that are simple, suitable to the economic situation and to environmental conditions of the importing country, etc. Dr. Johnson suggested that developing countries take greater initiative, possibly through WHO or other international standards-setting bodies, to influence consensus on the principal characteristics and technical specifications that are most important and necessary.

Dr. Kouri (Cuba): Indicated, based on the experience of his country, that it is imperative for the developing countries to promote the local production of medical devices, even though, in the initial stages of production, there will be some problems related to quality. The human resources must be developed internally so as to fully assimilate the imported technology, which cannot be produced at the national level. Moreover, local production should participate increasingly as a component of overall socio-economic development. He supported the points made by Dr. Johnson: developing countries, whose environmental and climatic characteristics are different from those of producing countries, should take a more active role, probably through WHO, in determining the specific characteristics that should be incorporated into medical devices to make them suitable and appropriate to local needs and local conditions.

Dr. Noble (U.S.): Agreeing with Dr. Kouri, pointed out that in the developing countries, hospitals generally do not have air conditioning and that therefore medical equipment has to operate under climatic conditions very different from those in the developed countries. His company, ECRI, has prepared an Environmental Testing Standard for Medical Devices to determine the effectiveness of different types of equipment under various environmental and climatic conditions. He placed the testing standard at the disposal of the participants. He pointe dout that ECRI is carrying out a study on firms engaged in the reconditioning and subsequent export of used equipment. Although the results are not yet available, he expressed his conviction that it is necessary to strengthen existing controls in this area.

Dr. Higson (United Kingdom): Pointed out that the International Electrotechnical Commission (IEC) has given attention to the preparation of specific standards for countries with environmental conditions different from those in the country of origin, particularly with regard to safety (Section 60 of the IEC standards). He is not sure, however, that this adaptation covers all the problems that arise in these countries. Thus it would be desirable for the countries with these conditions to collaborate more closely with the IEC so that these standards will be enhanced with their own contributions. He placed himself at the disposal of the participants in facilitating this process.

Dr. Repacholi (Australia): Agreed with Dr. Kouri on the need to promote the local production of medical devices in the developing countries. He emphasized that the use of existing resources in these countries, with some government stimulus for research, development, and local production, could result not only in a saving of foreign exchange but also in broader collateral effects that are indispensable for the process of development.

Dr. Malloupas (Cyprus): Pointed out that all the working groups, especially Groups 2 and 6, made observations on the issue of maintenance and timely repair of medical equipment. In his opinion, WHO should expand and increase the number of its bilateral agreements with the member countries with a view to promoting policies that improve the maintenance of equipment, the training of those who operate it, the timely provision of replacements, and the implementation of programs for research and development.

Dr. Peña (PAHO): Felt that the work of the groups, as well as the general discussion underway, was very valuable in identifying the needs for information and possible forms of cooperation. However, it was weak on the discussions of the use of information by those who are responsible for making regulatory decisions. In Latin America the experience of the U.S. is being repeated in the sense that, starting with a regulatory agency for drugs, a parallel regulatory activity is being developed for medical devices. In Latin America, there are countries in which departments, ministries, or offices on science and technology have appeared which are not linked to, nor do they stem from, groups that have been working on the regulation of drugs. The question of where the medical device regulatory activity should be located, in the health sector or in intersectoral agencies, is an important one because there are aspects that transcend the theoretical scope of the health sector.

Experience in the regulation of drugs in Latin America indicates that control over the entry and price of new products on the market, as well as quality control of products already on the market, continues to be extremely weak. This deficiency is attributable not to lack of information but rather to difficulties in making the regulatory apparatus operate in the public sector. There has been little exploration, in depth, of the various regulatory strategies available. The predominant concept in the conference has been

approval prior to marketing as the regulatory strategy. There has been no in-depth discussion of other strategies such as control of importation.

Dr. Higson (United Kingdom): Presented his own observations with regard to the deliberations by the plenary of the working groups as follows, and he invited comments from the participants.

1. Regulation - Drug laws are not generally appropriate for medical devices. The severity of the regulatory approach should be related to the magnitude of the problem, which may vary with the particular class of device, and should be in keeping with local practice and needs. National regulations should clearly identify requirements relating to premarket evaluation, GMP, standards, or postmarket surveillance. Regulatory problems of importing countries (generally developing countries) could be eased if manufacturing countries applied controls to the exports. Also, more information supplied about the compliance of products with standards and compliance of manufacturers with GMP would be helpful. Cooperation with organizations such as the International Standards Organization and the International Electrotechnical Commission are extremely important, particularly for developing countries

2. Purchasing - There is a need for purchasing practice guidance for developing countries. This includes development of equipment lists to help in the identification of real needs, guidance on the acquisition of evidence of safety and effectiveness, how to apply international standards of product safety and performance, and how to encourage adherence to good manufacturing practices (GMP).

3. Maintenance - In the developing countries the maintenance of medical equipment is a serious problem. There are two reasons for this: the scarcity of properly trained personnel and the lack of replacement parts. The WHO training centers should be expanded or their number increased in order to provide more training and to serve as a firmer reference point for those countries that want to develop their own training programs. The producing firms should accept greater responsibility in the training of local personnel as well as in the provision of parts and repair manuals in the local language.

4. Research and Development - There is a need for the development of more key devices appropriate for the needs and environment of developing countries, along the lines of the Basic Radiological System. Developing countries need to introduce local manufacturing of devices suited to their needs, meeting recognized standards and in accordance with GMP. Testing facilities must be developed hand in hand with manufacturing. More research is needed on the safety and economics of the reuse of disposable devices.

5. Communication - Much useful information exists about medical devices, particularly on safety and hazards, but is not generally available outside the country of origin. The promotion of a world-wide information system should be encouraged. This might begin with developing standardized nomenclature and a priority list for the kind of information to be included. This should be considered by WHO, along with identification of global and regional focal points (collaborating centers) for assisting countries with problems related to medical devices. Countries should establish national centers to act as communication and dissemination centers in their countries.

6. Future Action - There is a need for further conferences of this type to evaluate the experience gained and to consider other issues such as development of guidelines for a device management system.

Dr. Sachot (France): Reaffirmed the vital importance of cooperation between the developed and developing countries. He identified three areas in which it is highly important to come to an understanding and resolution:

1. It is necessary to strengthen research and development of medical devices in the developing countries as a positive contribution to the process of socio-economic growth that is transforming agrarian societies into industrial ones and the latter into societies of the information age.

2. Steps should be taken to strengthen the training of personnel who operate, use, or handle medical devices, directly or indirectly, in the developing countries with the long-term view of the country's overall development process.

3. It is necessary to take concrete action, one step at a time, toward transformation of the less-developed countries.

Dr. Potter (United Kingdom): Reaffirmed Dr. Sachot's third point, indicating that most of the suggestions and recommendations expressed in the conference are appropriate but will require time and resources in order to be implemented. In his opinion, however, there are concrete measures that can be implemented easily with existing resources. The same is true of identifying all the information needed for the procurement of medical devices so that this information can be requested and obtained from the producing firms. Developing countries with different or adverse climatic conditions should ask for information relative to their particular circumstances, particularly as it relates to operation of the device under specific conditions of temperature, moisture, isolation, etc.

Dr. Susansky terminated the general discussion following the statement of Dr. Potter, and called upon the co-chairmen of the conference to ascend to the rostrum, present their summary, and adjourn the conference.

IIIC1. SUMMARY POINTS OF THE CONFERENCE

J. C. Villforth

We are public health officials concerned and involved with health technology. This conference has provided us with the opportunity to come together, and to discuss the important issue of medical devices. The experience has been personally rewarding and professionally challenging. Personally rewarding because it has given us the opportunity to meet with one another, articulate problems and develop a global prospective difficult to achieve in our own environments back home. Professionally challenging because, by raising our awareness of the global problem of both developed and developing countries, it has placed upon our shoulders the burden of funding and implementing solutions that will satisy, at the very least, our most critical needs. I hope that our participation at this meeting will make us better bureaucrats in the positive sense of that term. I thank all of you for taking time from your important duties to participate in this meeting, and particularly for putting a tremendous amount of energy into the discussions, the working groups, the deliberations, and for the sensitivity with which you presented the points of view of your respective countries and the professions that you represent.

I am very proud of the formal sponsorship of this Conference by the World Health Organization, the Pan American Health Organization, and the Food and Drug Administration. I feel particularly indebted to the Regional Office for Europe, to Canada and the United Kingdon for their support and for their assistance in the planning of the conference, and to the Regional Offices of WHO and the health ministries of the member states for their financial and logistic support. I particularly want to thank Dr. Macedo for allowing us to use these excellent facilities and for providing us with the favorable environment that contributed materially to the success of this conference.

It was said earlier that we should emphasize in the scope or the conclusion of this conference the process rather than the end result. The process being the opportunity for us to get together and discuss our problems, to learn, and to exchange information; and that we should be less concerned about reaching specific positive recommendations. I would like to think that we were able to accomplish both of these goals, that the process was certainly effective and that we did identify some needs and actions that may help us to deal more effectively with medical devices, improve the public health benefit that we can derive from this technology, and improve our ability to utilize these technologies effectively within the context of our individual health care systems.

The resources that are available for the management of medical devices are limited when we consider the priorities that face public health officials around the world. Unfortunately, those resources won't be getting any larger in the future. If anything, they will probably get smaller. The problems associated with medical devices are not getting smaller, however. They are going to continue to get larger because of the ever-accelerating developments in technology that are bringing different scientific disciplines into the clinical area to provide better medical care.

We will have to work harder to make sure that critical medical devices are safe and effective. Some of the less risky devices may need to come to market without the full degree of scrutiny that some of the more complex devices will get. We will have to examine problems carefully and will have to establish priorities that will focus our attention and apply our resources where the greatest public health need exists.

There is also a tendency to assume, though it was not too prominent at this conference, that the model that has been so effectively used in the area of drugs might be used as the model for devices. Certainly we should build where possible on the experience and the success in the drug area. However, we must constantly point out that there are significant differences between drugs and devices. It is pretty hard to get involved in spare parts with pharmaceuticals; we don't have too much in the way of maintenance for pills; and certainly the question of repair of capsules is not something we deal with very often. Purchasing and acceptance standards that are involved in devices are somewhat unique and we do not reuse too many pharmaceuticals. The technology changes in the device area are of a different kind and are occurring much more rapidly than those in the drug area.

There is a constant need for training and a constant need for re-training of the people who are involved in devices. This includes not only the clinician, but also the nurse, the technologist, and in many cases the consumer who is involved with the device. We must be constantly aware of the fact that a skill aspect frequently goes with the use of the device. The use or application of pharmaceuticals does not require the same degree of skill of interpretation or dexterity of application that is the case with some of the devices used in delicate surgical procedures. So with the constantly changing technology there is a need for constantly changing skills on the part of the professional or clinial user of the device

We must keep this concept in mind and recognize that although there are some similarities and although there is a basic public health relationship between what we might do in devices and what has been done in drugs, they certainly are not the same.

Much of the discussion has taken place in the area of problems faced both by developing countries and developed countries. It is very important for each of us to appreciate the perspectives of the other. We must, of course, point out that developed countries are not uniformly and monolithically developed. There are probably more developing areas in developed countries than there are developed areas in the same developed countries. One does not have to wander far from the large teaching university hospitals in the metropolitan area of Washington, D.C., to find certain medical practices in our Appalachian region which are not up to the standards of a developed country. Developed countries also face extreme climactic conditions, maintenance, and training problems.

We sometimes tend to oversimplify a situation by putting ourselves into pigeon holes of developed or developing countries. Within both categories there are differences of degree, and these differences also require attention. I do not say this to minimize in any way the concerns or the problems faced by developing countries so eloquently articulated at this conference. The issues of climatic conditions, purchasing specifications, language problems, training; the tremendous resources required for just transportation and getting spare parts or trained people into countries remote from the site where the equipment is manufactured - these are all very serious issues. We must constantly keep these points in mind and find ways of providing needed assistance.

We talked a bit about regulatory approaches to medical devices and about purchasing strategies or regulatory strategies involving premarket approval and postmarket surveillance and how we might look upon these various vehicles as tools for our own countries. We perhaps did not emphasize enough the role we could play as public health people using education as a tool. Much can be accomplished without the iron fist of regulation. We prefer the use of persuasion, the use of education, and communication as

tools when we deal with professionals. We perhaps have not emphasized as much as we might the use of non-regulatory tools. Given limited resources for the management of medical devices we might have placed more emphasis on that topic at this conference.

Finally, the whole essence of information exchange, the question of the role of each of us as member nations, the role of collective organizations, of regional arrangements or multinational arrangements, or ultimately WHO, becomes extremely important. I hope that we can take back and put into effect many of the good suggestions that have surfaced at this conference, whether at the national or international level. Those of us in a position to work in WHO or the regional environment may be able to exert some influence over the course of action of those member bodies.

Dr. Sankaran, I think I have covered some of the thoughts that I have gleaned from the conference this week. I have been pleased and excited to be a part of this process and to work with the participants at this conference. On behalf of all of us, I want to thank you for your leadership and for the role that you have played as the person at WHO who has made this conference possible.

IIIC2. SUMMARY POINTS OF THE CONFERENCE

B. Sankaran

Thank you very much, John. Ladies and Gentlemen, I would be failing in my duty if I did not thank you all for the zeal and enthusiasm that you have exhibited during this conference. I would particularly like to thank the government of Canada and the United Kingdom for their unstinting cooperation and fiscal support.

I would like to thank the Director General of the World Health Organization and the Regional Directors for their nominations and assistance to delegates towards attendance at this conference. We have representatives from 52 countries at this conference. This is a very significant number when we consider that there are only 163 member states in the United Nations system.

I am not going to repeat the detailed summary of the conference so well captured by my co-chairman as well as by the reports of the working groups. Rather I will try to distill some specific points in what might be considered an executive summary of the conference.

There are actions required at the national level, and actions required at the WHO level.

NATIONAL

1. A national focal point should be identified to be responsible for medical devices.

2. There is an identified need for local regulation of medical devices (locally manufactured and/or imported), to clearly identify requirements relating to regulation, premarket evaluation, standards, good manufacturing practices, post-market surveillance and import/export in keeping with national needs. There is no single master plan or panacea.

3. The role of national authorities in identification of standards for their own countries, and cooperation with organizations such as the International Standards Organization and the International Electrotechnical Commission, are extremely important, particularly for developing countries.

4. Identification of problems, experiences, trends, and sharing of knowledge among nations, themselves, and between existing groups of nations, such as ASEAM, Latin America, the Caribbean, the Commonwealth, EEC, and COMICOM, would be desirable. This facilitates WHO's role and, in this process, the experiences of major, well-established regulatory agencies in Canada, UK, Sweden, France, and USA, could be models to emulate.

POTENTIAL WHO INITIATIVES

1. Identification of global and regional focal points for assisting countries with identified problems.

2. Encouraging the exchange and flow of information between countries and regions on a rapid and regular basis, including subjects of daily interest, such as upkeep and management of sterilizers and reports on premarket evaluation, postmarket surveillance, and recalls.

3. Identification of collaborating centers having a global and regional perspective and the required capacity and expertise.

4. Finally, WHO may wish to consider a continuation of this conference activity that has been so rewarding.

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APPENDIX B. AGENDA, INTERNATIONAL STEERING COMMITTEE, LOCAL ARRANGEMENTS COMMITTEE

INTERNATIONAL CONFERENCE

OF

MEDICAL DEVICE REGULATORY AUTHORITIES (ICMDRA)

June 2 - 6, 1986

Co-sponsored by

World Health Organization (WHO)
Pan American Health Organization (PAHO)
U.S. Food and Drug Administration (FDA)

Conference Co-Chairmen

Dr. B. Sankaran
Mr. J.C. Villforth

Conference Site

Pan American Health Organization
525 Twenty-Third Street, N.W.
Washington, D.C., U.S.A.

Telephone: (202) 861-3200

SUNDAY – JUNE 1

9:00 - 12:00	**Participants arrive and register at hotels**
12:00 - 14:00	**LUNCH BREAK**
14:00 - 17:00	**Registration**
14:00 - 17:00	**Meeting of the International Steering Committee, Chairs of Sessions, Round Table Reviews A - D, and Working Groups 1 - 6**

MONDAY MORNING – JUNE 2

8:00 - 9:00 **Registration**

SESSION I. INTRODUCTION

Chair: Dr. S. L. Nightingale

9:00 - 9:15 **Opening Announcements and Introduction**

9:15 - 9:45 **Welcome**

PAHO: Dr. C. Guerra de Macedo
WHO: Message from the Director General
FDA: Dr. F. E. Young

9:45 - 10:05 **WHO Perspective on Medical Devices**

Dr. B. Sankaran

10:05 - 10:25 **FDA Perspective on Medical Devices**

Mr. J.C. Villforth

10:25 - 10:40 **BREAK**

SESSION II. A GLOBAL PERSPECTIVE ON MEDICAL DEVICES; PROBLEMS, ISSUES, AND TRENDS

Chair: Dr. R. Caram

10:40 - 10:55 **Africa**

Dr. Femi-Pearse

10:55 - 11:10 **Europe**

Dr. J. Vang

11:10 - 11:25 **Eastern Mediterranean**

Dr. M. Swicord

11:25 - 11:40 **Americas**

Dr. J. Pena Mohr

11:40 - 11:55 **South East Asia**

Dr. U.M. Rafei

11:55 - 12:10 **Western Pacific**

Dr. B. Sankaran

12:30 - 14:00 **LUNCH BREAK**

MONDAY AFTERNOON – JUNE 2

SESSION III. ROUND TABLE REVIEW OF PROBLEMS, ISSUES, AND TRENDS

14:00 - 14:10 **Introduction and Formation of Discussion Groups**

Chair: *Dr. H. Cordeiro*

14:10 - 15:30 **Round Table Review Groups A-D**

Group A. Appropriate Technologies for Health Care

Chair: *Professor M.S. Valiathan*
Co-Chair: *Dr. A. G. Liedstrom*
Rapporteurs: Dr. D. Sanchez
Dr. D. Banta

Group B. Public Health Approaches to the Management of Medical Device Health Care Technology

Chair: *L. Hernandez*
Co-Chair: *Dr. T. Onitiri*
Rapporteurs: Dr. M. Slatopolsky
Dr. D. Potter

Group C. Risk Benefit from Pre-clinical and Clinical Trials

Chair: *Dr. E. Somers*
Co-Chair: *Dr. P. Mbumba*
Rapporteurs: Dr. M. Lieberman
Dr. D. Johnson

Group D. Impact of Medical Technology on Health Care Cost

Chair: *Dr. C. Mulraine*
Co-Chair: *Dr. B. el Azmeh*
Rapporteurs: Dr. J. Noble
Dr. M. Torrealba

15:30 - 16:00 **BREAK**

16:00 - 17:00 **Summaries of Discussion in Groups A-D by the Chairpersons** (15 minutes each)

Co-Chair: *Dr. H. Cordeiro*

17:00 - 17:15 **Announcements**

TUESDAY MORNING – JUNE 3

SESSION IV. APPROACHES TO NATIONAL MANAGEMENT OF MEDICAL DEVICES

8:00 - 8:10	**Introduction by the Chair** Chair: *Dr. H. Martuscelli Quintana* Rapporteurs: Dr. I. M. Arefjev Dr. B. Wang
8:10 - 8:30	**Legislative and Regulatory Approaches** Dr. D. C. Jayasuriya
8:30 - 8:50	**Non Legislative Approaches** Dr. D. G. Higson
8:50 - 9:10	**Homologation** Dr. M. Sachot
9:10 - 9:30	**Registration** Mrs. A. Sargentini
9:30 - 9:50	**Premarket Evaluation** Dr. A. K. Das Gupta
9:50 - 10:05	**BREAK**
	Co-Chair: *Dr. J. Kouri* Rapporteurs: Dr. J. L. Ngu Dr. R. Lafetta
10:05 - 10:25	**Standards** Ms. E.A. Bridgeman Dr. G.R. Higson
10:25 - 10:45	**Good Manufacturing Practices** Mr. W. Gundaker
10:45 - 11:05	**Postmarket Surveillance** Dr. K.G. Melin
11:05 - 11:25	**Comparative Product Evaluation in the European Community** Dr. B. van Eijnsbergen
11:25 - 12:00	**Discussion**
12:00- 13:30	**LUNCH BREAK**

TUESDAY AFTERNOON – JUNE 3

SESSION V. MEDICAL DEVICES AND GOVERNMENT POLICY

13:30 - 13:40 **Introduction by the Chair**
Chair: *Dr. S. Umashankar*
Rapporteurs: Professor A. Amedome
Dr. F. Lobo

13:40 - 14:00 **Research and Development**
Dr. M. Repacholi

14:00 - 14:20 **Manufacturing**
Dr. M. Saito

14:20 - 14:40 **Import/Export**
Dr. M. Guerrero

14:40 - 15:00 **Distribution and Diffusion**
Dr. M. Slatopolsky

15:00 - 15:15 **BREAK**

15:15 - 15:25 **Introduction by the Co-Chair**
Co-Chair: *Dr. C. Canitrot*
Rapporteurs: Dr. M. Sirait
Dr. I. Lobato

15:25 - 15:45 **Evaluation of Medical Technologies in Terms of Health Outcome**
Dr. R. Panerai

15:45 - 16:05 **Forecasting and Long-Term Planning**
Dr. C. O. Pannenborg

16:05 - 16:25 **Equipment Management**
Dr. D. Potter

16:25 - 16:45 **Effective Utilization**
Dr. D. Banta

16:45 - 17:30 **Discussion**

17:30- 17:45 **Announcements**

TUESDAY EVENING – JUNE 3

18:30- 21:30 **Conference Banquet**
Speaker: *Dr. Samuel O. Thier*
President, Institute of Medicine
National Academy of Science

WEDNESDAY MORNING– JUNE 4

SESSION VI. INFORMATION EXCHANGE

8:30 - 8:45	**Announcements**
8:45 - 9:00	**Introduction by the Chair** Chair: *Dr. J. McHardy* Rapporteurs: Mr. J. Arcarese Dr. C. Gamboa
9:00 - 9:20	**National- FDA Experience** Mr. M. Barnett
9:20 - 9:40	**PAHO Approach to Regional Information Exchange** Dr. M. Bobenrieth
9:40 - 10:00	**The Tripartite Experience** Dr. A. Das Gupta
10:00 - 10:15	**BREAK**
10:15 - 10:35	**WHO Mechanisms for International Dissemination of Information** Dr. B. Sankaran
10:35 - 10:55	**WHO: The Role of Collaborating Centers - The Radiological Health Experience** Dr. J. Hanson
10:55 - 11:15	**Medical Device Data Bases - Nomenclature** Dr. G. Coe
11:15 - 12:00	**Discussion**
12:00- 13:30	**LUNCH BREAK**

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AFTERNOON PROGRAM

SITE VISITS TO FDA CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, MEDICAL DEVICE LABORATORIES, ROCKVILLE, MARYLAND

(The local organizing committee will provide schedule and details on transportation)

THURSDAY MORNING – JUNE 5

SESSION VII. WORKING GROUP MEETINGS I – 6

8:00 - 8:10 **Introduction by the Chair**

Chair: *Dr. R. Hapsara*

8:10 - 10:00 **Meeting of Working Groups 1 - 6**

Group 1 - Production and Procurement of Medical Devices

Chair: Dr. F. J. de Ranitz
Rapporteurs: Dr. P. Msaki
Dr. A. Niño

Group 2 - Effective Medical Device Utilization by Physicians and Health Care Professionals

Chair: *Dr. P. Vanasatit*
Rapporteurs: Dr. R. Magalhaes
Dr. N. Saranummi

Group 3 - Approaches to Assurance of Safety and Effectiveness of Medical Devices

Chair: Mme. C. Sanchez
Rapporteurs: Dr. M. Rovere
Dr. K. G. Gurzu-Hazarli

Group 4 - Problems Related to Reuse of Single Use Medical Devices

Chair: *Dr. S. Perry*
Rapporteurs: Dr. L.B. Saenz
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Group 5 - Medical Devices at Different Levels of Health Care

Chair: *Dr. B. el Azmeh*
Rapporteurs: Dr. M. Torrealba
Dr. B. Sankaran

Group 6 - International Communication and Information Exchange

Chair: *Dr. W. J. Rudowski*
Rapporteurs: Dr. M. Guerrero
Ms. N. Singer

10:00 - 10:15 **BREAK**

10:15 - 12:00 **Meeting of Working Groups 1 - 6**

12:00 - 13:30 **LUNCH BREAK**

THURSDAY AFTERNOON – JUNE 5

13:30 - 15:00	**Meeting of Working Groups 1 - 6**
15:00 - 15:15	**BREAK**
15:15 - 17:00	**Meeting of Working Groups 1 - 6**
17:00 - 17:15	**Announcements**

THURSDAY EVENING – JUNE 5

SESSION VIII. PUBLIC HEALTH MANAGEMENT OF MEDICAL DEVICES: THE FDA EXPERIENCE

20:00 - 20:10	**Introduction by the Chair** Chair: *Mr. J. Benson* Rapporteurs: Ms. L. Suydam Mr. E. March
20:10 - 20:30	**Management of Medical Device Technology** Dr. K. Mohan
20:30 - 20:50	**The Role of Science in FDA Decision Making for Medical Devices** Dr. E. Jacobson
20:50 - 21:10	**Training/Education in the Management of Medical Devices** Mr. J. Arcarese
21:10 - 21:30	**Post-Market Surveillance Activities** Mr. W. Damaska
21:30 - 21:50	**Discussion**
21:50 - 22:00	**Concluding Remarks by the Chair**

FRIDAY MORNING – JUNE 6

SESSION IX. WORKING GROUP SUMMARIES AND ADJOURNMENT OF CONFERENCE

8:30 - 9:00	**Announcements**
9:00 - 9:10	**Introduction by the Chair** *Chair: Dr. C. Migues Baron* Rapporteurs: Dr. G. Troya Dr. D. Picou
9:10 - 9:25	**Report of Working Group 1**
9:25- 9:40	**Report of Working Group 2**
9:40 - 9:55	**Report of Working Group 3**
9:55 - 10:10	**Report of Working Group 4**
10:10 - 10:25	**BREAK**
	Co-Chair: *Dr. M. Susanszky* Rapporteurs: Dr. L. Moreira Lima Dr. C. Mulraine
10:25 - 10:40	**Report of Working Group 5**
10:40 - 10:55	**Report of Working Group 6**
10:55 - 11:30	**Discussion**
11:30 - 12:00	**Summary Points of the Conference** Conference Co-Chairmen: Mr. J. C. Villforth Dr. B. Sankaran
12:00 -	**Adjournment of Conference** Dr. Moris Shore

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