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Medical Technology Assessment

Research Developments for Biomedical Technology

by

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1. Introduction

What is significant research in the field of biomedical technology (BMT)? A question like that is of course easier to put than to answer. It is a question which also fits into the terms of future reconnaissance indicated under the title of Medical Technology Assessment (MTA). To every research group active in the field of BMT this question is a constant subject of study.

BMT research is encountered, among other things, at all universities, technological and general. The initiative in thinking of this area of problems in a wide multidisciplinary framework arose out of inter-university consultation on the subject of BMT. The structuring of such a reconnaissance was carried out by the authors, members of staff of the Eindhoven University of Technology.

This reconnaissance was fortunate in attracting the cooperation of a large number of different experts in various fields of science and areas of policy in the Netherlands. Together they set down almost 200 orienting ideas on this theme. In two workshops, held in December 1982 and December 1983 many fruitful interchanges of ideas took place. The contents of the present report is based on the outcome. The names of the participants have been stated in the references. The ideas submitted were the personal ones of all those concerned.

In the following sections 2, 3 and 4 the concepts BMT and MTA are described in more detail and some general aspects of research development discussed. The communication process is described in section 5.

When the final result of this MTA reconnaissance is regarded in rough outline, section 6 deals with the main general points of departure for BMT research policy; a manner of dividing up the whole field of health care into part areas is discussed in section 7; all the insights obtained, projected on to a process for further study of such a partial area, are dealt with in section 8.

In view of the known complexity of non institutional health care and the conclusion that, without a wide and determined handling, little effect is to be expected from research, the problems concerned with this partial field of health care is submitted to more detailed discussion in section 9.

In the conclusion, section 10, reactions are requested to the process of opinion forming set out in this paper. When sufficient support is obtained, this MTA reconnaissance will be followed up in two part areas: The problems involved in non institutional care and ailments of the respiratory organs.
Fig. 1: The convening of a number of experts on various fields for a reconnaissance of general aspects of research on Biomedical Technology.
2. **Biomedical Technology**

In biomedical research and in our institutions for health care a great deal of scientific and technological knowledge and skills are applied. To define this the term biomedical technology (BMT) came into use.

The WHO (World Health Organisation) gives the following description of biomedical technology:

"Biomedical Technologies are those drugs, devices or procedures used in the delivery of health services for prevention, diagnoses and treatment of illness and rehabilitation".

BMT has of course a number of common characteristics with concepts such as medical research, physiology, biophysics, biochemistry, clinical chemistry, clinical and medical physics. The collective term BMT is used there in the wide sense, for all biomedical matters in which the technological aspects are not a negligible part.

The following are developments in which it is considered that technology occupies a dominant place:

- Where new technological developments create new possibilities for medical-biological research.
- Where medical-biological research is largely determined by difficult experimental or analytical facilities from the technological standpoint.
- Where the application of new fundamental insights in health care demand technological developments in the direction of new equipment, methods, systems, processes or organisations.
- And finally, where industrial activities are directed towards health care.

The estimates for the annual turnover in money in BMT systems in the Netherlands lie between 0.4 and 2 thousand million guilders. An amount of at least 45 million guilders is spent annually on BMT research in the Netherlands alone in the institutions for teaching and research.
3. Medical Technology Assessment

Technology Assessment came to the force in the United States in the sixties as a form of future research. During that time of economic growth, policy makers and politicians felt the need for scientifically based analyses of trends and developments in order to build up control and management points to facilitate channelling the development in socially justifiable directions. The government set up the "Office for Technology Assessment" (OTA).

In the seventies a department for Medical Technology was set up within OTA. This department has carried out a great deal of pioneering work in the field of Medical Technology Assessment (MTA). Gradually the accent was shifted here from influencing a development to selective influencing of the diffusion of medical technology.

Meantime initiatives were started to discuss setting up an equivalent to an OTA organisation at European level (EEC).

The World Health Organisation (WHO) described Medical Technology Assessment (MTA) as: "Technology Assessment is a form of research, analysis and evaluation that attempts to examine the various impacts of a particular technology on the individual and society in terms of the technology's safety, efficacy, effectiveness and cost effectiveness, and its social, economic and ethical implications and to identify those areas requiring further research, demonstrations or evaluation".

Current BMT research can lead to new techniques for medical application. Before such a new application is introduced the MTA aspects can be investigated.

MTA consideration can also be directed to the type of BMT research that is in the course of development. In the area of national BMT consultation the question has been raised as to what kind of BMT research should be followed in all these institutions. What criteria can be important in such a problem area? With what method should the various matters be expressed more clearly?

This led to the decision to lay down a multidisciplinary dialogue with reference to the last-named question.
4. Research development

The existing culture in our institutions for research and education is continually giving rise to new significant research. This is to a great extent determined by local history, availability of facilities, equipment, of persons who together form a specific disciplinary framework, as a general rule one single field rather than a multidisciplinary field, often also with a specific vision on man and society and as regards what is considered significant as new research.

A scientific forum (pure-science research groups, scientific committees of Teaching and Research Institutions, congresses etc.) functions for a given field of research and contributes to the training, adjustments and changes in the cultures of local research groups from a wider framework. Such a forum plays an important part in keeping the quality of research up to the required level and directing such research to the most significant targets. However, such a forum also has a specific momentum of its own, is subject to limitations with respect to the disciplinary spectrum, has a limited view of the total reality.

Society expects from researchers that they direct their efforts to things which society stands in need of. Therefore relevant standards and values must be made explicit, alternatives developed for research, choices must be consciously made in the case of new research. This is all a difficult process, however and in itself is a field of investigation for research.

In order to start out with wider vistas than those based on BMT alone and in fact, from a level ulterior to that of the BMT activities, it was felt to be worth while giving consideration to the most important general characteristics and trends in recent developments in BMT research, to general social developments in particular as regards health care, to characteristics and changes in medical science.

Such meditation on the basis of a wide insight into our society can lead to the formulation of criteria for significant new BMT research or to methods for obtaining such criteria. A dialogue on this matter, structured as widely as possible will be significant if it enables new aspects to be added to the existing system of standards within the current activities in the field of BMT. Such a dialogue can have a function in making implicitly present standards visible in the development of BMT research.

It must be stated emphatically at this point that such reconnaissance will have to be followed also by concrete steps. Criteria, made explicit in this manner, have a determinant function with regard to active research policy. The process of such a reconnaissance must remain oriented towards this goal.

From this idea the present MTA reconnaissance was structured as regards research policy for biomedical technology in general.
5. The communication process

There are many complex problem areas which do not fit comfortably within the domain of a single skill. They are called multidisciplinary. Characteristic of this situation is thus that one single person is cognitively just too limited for an adequately wide overview and detailed knowledge at a given level compared to the aspects of the problem on the one hand and scientific knowledge and methods which can be used to solve problems in the field on the other.

In a growing number of disciplines, parts of the total reality are studied. Every discipline develops its own characteristics, methodology, linguistic practice and set of standards of its own. As a result, problems of communication between disciplines arise. Communication difficulties even occur within the various streams in a single discipline.

It is therefore also a problem in a multidisciplinary reconnaissance of a complex set of problems to give a great deal of attention to the process of communication between a great variety of experts. Something like that is usually needed because the persons whose participation is greatly desired are often very busy people.

For the communication process on aspects of BMT research policy a working procedure was followed at the Eindhoven University of Technology in developing research projects on complex biomedical subjects.

The accent was laid on personal interchanges of ideas between the various experts by one or two coordinators (katalysts, integrators). In this way suggestions were put forward, worked out, tested, submitted in a form comprehensible to all participants and, moreover, in very succinct formulations. Every participant can thus contribute his own expertise from his own background at his own rate. It is only then that results can be combined and made available in a written communication to all participants. Only after one or two such communication rounds do the participants concerned meet one another at a workshop.

Elements are used of the "Delphi method" for forecasting the future, and working principles are applied which have been derived from the theory of organisation development.

Such a communication cycle was worked through during one workshop in 1982 and once again in 1983. In 1982 this led to a very large number of orientating ideas on our area of problems. It also transpired that a great deal of communication was necessary to acquire more comprehension of each other's worlds of thinking. In 1983 this reconnaissance was directed to a convergence of the joint vision and to a determination as to how all this could be brought to as concrete an advance as possible (see figure 1).
Fig. 2: Shows what activities take place in succession and which run parallel, starting from the initiative up to and including the submission of the report. The parts of the lines indicate actions. At the nodal points actions for this point have to be adequately worked out before the next one can be started.
6. Starting points for BMT research development

One starting point, as already stated in section 4, is the expectation that such multidisciplinary reconnaissances can throw new light on the question as to what BMT research projects should be developed, from the standpoint of a wide societal perspective.

A second starting point is to be found in ethics. After the second workshop this point was formulated as the general urge to humanisation of man and the world he lives in, as discussed by philosophy and ethics (be it in a pluriform manner). The welfare of man and promotion of a humane world for living in are standards in reflection on and making operational the different aspects of biomedical and public-health technology.

As a third point the attempt has been made to find a good description of the concept health. After the necessary discussion a choice was made of the description which holds the middle course between a purely biological and a widely anthropological concept of health. The health of the human being can be described against that background as enjoyment of undisturbed bodily functionality and psycho-social opportunities in order to achieve self-realisation in solidarity with fellow human beings. For the derivation of standards from this concept the starting point can be that health manifests itself in such a course of physiological, psychical and social processes in itself, in relation to one another and to the environment in such a way that disorders in and by these processes are corrected with an acceptable time without intervention from outside.

Care of health, derived from the two preceding points can be seen as the warding off of the burdens of sickness. This can be expressed in terms of decreasing mortality and morbidity but also in the promotion of the quality of life. The last-named can be concretised by means of standards, for instance such as repelling of pain and discomfort.

From this reconnaissance we arrive at the opinion that at present, owing to lowering of mortality and morbidity, the quality of living must weigh more heavily as a criterion than has been the case so far.

Also derived from the second point mentioned is the necessity of paying more attention to ergonomic aspects in BMT developments. New techniques must be effective, the efficiency of health care must be increased, made safe and easily managed. Account must be taken of the specific situations for patients, doctors, paramedical and nursing staff.

In a greater number of situations than is often thought, it applies that organisational aspects also have an important role to play in the environment of BMT. We are then dealing with things such as procedures, division of tasks, adjustment of tasks and coordination between various persons and parts of the system of health care. In many cases the necessary attention will have to be paid to such aspects as well.
Naturally, economic aspects also form an important point which must be borne in mind. A concrete measure can in many cases be the relationship of expected costs/benefits in judging a BMT development. Aspects which can make health care cheaper are interesting. In the cases concerned the extent to which employment can be influenced should also be taken into consideration. Here it is conceivable too that the promotion of a new industrial activity, with a worldwide orientation, can also justify extra expenditure.

Finally, every research development must seek a proper interconnection with the strong elements in the research capacity. Likewise, account must be taken of the international research interest in a given theme.
7. Reduction

The total field of health care is difficult to survey. A great distinction in thinking on this subject must be drawn between the organisation of this health care on the one hand and the practice of medicine on the other.

The organisation of the health care is in itself already a complex datum. Here, too, further subdivision of aspect systems into partial systems is necessary in order to make the field accessible to research development. This can now be done in a number of ways and, pragmatically, what is done is to seek connection to the already stated most important targets (priorities) in policy documents.
- Quality control, coherence and costs of the system of health care.
- Promotion of extramural (among other things polyclinical) care as opposed to intramural clinical care.
- Promotion of basic and non institutional health care.
- Promotion of preventive compared to curative care.

Consideration has been given to a number of coherent aspects of these targets for research structuring oriented to making non institutional health care more functional. This is discusses in section 9.

The Dutch Advisory Council for Scientific Policy (RAWB) states in the report on priorities in health research an approach by means of which it is hoped to achieve contraction of the field of medicine and the establishment of priorities in the process. It is suggested to do so in the total field according to groups of ailments.

The classification put forward by the World Health Organisation (WHO) has been adopted. In this way indicators can be used that have already brought together a great deal of information.

<table>
<thead>
<tr>
<th>Groups of ailments according to WHO classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Infectious and parasitic</td>
</tr>
<tr>
<td>2 Neoplasms</td>
</tr>
<tr>
<td>3 Endocrine, nutritional and metabolic</td>
</tr>
<tr>
<td>4 Blood and immunity</td>
</tr>
<tr>
<td>5 Mental disorders</td>
</tr>
<tr>
<td>6 Nervous system and sense organs</td>
</tr>
<tr>
<td>7 Circulatory system</td>
</tr>
<tr>
<td>8 Respiratory system</td>
</tr>
<tr>
<td>9 Digestive system</td>
</tr>
<tr>
<td>10 Genitourinary system</td>
</tr>
<tr>
<td>11 Pregnancy, childbirth, the puerperium, reproduction</td>
</tr>
<tr>
<td>12 Skin</td>
</tr>
<tr>
<td>13 Musculoskeletal system, connective tissue</td>
</tr>
<tr>
<td>14 Congenital anomalies</td>
</tr>
<tr>
<td>15 Conditions originating in the perinatal period</td>
</tr>
<tr>
<td>16 Injury and poisoning</td>
</tr>
</tbody>
</table>
The RAWB (Dutch Advisory Council on Scientific Policy) then suggests after the above-mentioned visual impression, setting up a process of personal weighting to achieve priorities between these groups of ailments. In this way one would have to make political decisions with regard to priorities in public health care policy. As a second step attention can be oriented to the question of how research should be able to contribute to the realisation of these priorities. In this way priorities are reached in health-care research.

In and after that second stage we are brought face to face with the question as to how the contributions of BMT in this research can be efficiently fitted in.

The participants at the present MTA reconnaissance were able to agree with the above RAWB approach. They were able to sympathise with the first reconnoitring attempts on the part of RAWB to apply this priority-finding method. The point of departure of RAWB was from the three dimensions: possible priorities in public health policy, quality considerations and the volume of the present-day research effort in Holland.

However, it was clearly established that the results of this pilot study on the part of RAWB must not immediately result in weighty implications. Before this is the case the RAWB process must first be carried out on a greater scale and with a great deal more care.

In the way sketched in the foregoing the total health care can be divided up into part areas. Certain processes will lead to priorities in the desired research effort per partial area. If there is subsequent concentration on such a part area with a high priority then there are still many interrelated elements which make a research development into a complex process. The further schematisation of these elements is discussed in the following section.
8. **Reconnaissance of a part area**

In reconnoitring a BMT theme, the identification of the relevant elements, their examination from the various viewpoints concerned and from those of the parent disciplines have been combined to form the basis of the present reconnaissance. The thinking and discussion outcome on this subject are summarised briefly in the accompanying general work scheme for the systematic reconnaissance of a part area in health care. In such a reconnaissance of a part area of the health care system all the points for consideration discussed in section 6 must be included.

Every model and every schematisation is inherently limited compared to the complex reality. This scheme is neither more nor less than a procedure which is considered useful for a multidisciplinary framework with which to start out on such a reconnaissance.

Not all elements will have the same content value for all themes. For some research developments one or two will occupy a dominant place and others will be found to be of less interest. It is however considered to be a good thing to pay attention to all the elements stated here in every research development.

In this scheme it is also made abundantly clear that many partial activities are given simultaneous attention by different branches of science and organisations within the health-care system. In addition we see elements in which the integration process of the various partial activities are assigned an important function in this working procedure.

Orientating ideas for realisation were brought together on various elements in this scheme. We shall not go into this detailed information here. We shall restrict ourselves to a brief characterisation of the various elements in this scheme so that a clearer picture can be formed of the total process. The opinion forming on such a total process of multidisciplinary reconnaissance is considered to be more important than greater completeness in part aspects.

It is now obvious that one or two of the above-mentioned MTA reconnaissances should be structured for partial areas. There is a preference on the part of the Eindhoven University of Technology and the participants for the field of problems around non institutional health care and for the category of ailments in the respiratory organs. Both themes score high in priority in policy thinking on health care. Some orientating ideas on the first subject are discussed in the following section.
Fig. 3: Medical Technology Assessment with respect to research development for Biomedical and Health Care Technology. General working scheme for reconnoitring a part area in health care.

The scheme shown in fig. 3 must be read from left to right. The nodal points are numbered for the purposes of reference.
Action 1-5 is directed to the problem of what is to be considered as belonging to the area under consideration and what does not. The drawing of such limits is in many cases a problem in itself. The characterisation of a part area must be of such a nature that no misunderstanding is possible between the various disciplines, experts and institutions involved in such a reconnaissance.

In action 5-10 as much relevant information as possible is gathered as regards the reality of that part of health care. In addition to the nature of the medical routines it is of importance to make quantitative, qualitative and economic information accessible as well.

Between 10 and 20 the reconnaissances proceed from the basis of a number of disciplinary points of attack. The research alternatives which can arise from this are considered in process 20-25 for their mutual consistency and, where possible, placed in a 'priority order.

By means of 1-15-25 it must be possible to form some idea as to the available research capacity which can be used for this purpose. In many cases the various matters will have to be considered in an international framework.

The usual actions in the case of research development are placed between 25 and 35. Special attention is considered necessary for a good, cooperative, steering framework for research on such an area. Something of this nature is all the more important according as a number of related projects are brought into being.

From this MTA reconnaissance it follows that the reconnaissance of such a part area does not fit well into one single existing institution for teaching and/or research. Something like that requires cooperation and "top down" policy consideration if the necessary organisation, actual peripheral conditions, accessibility of information and cooperation from a diversity of angles of incidence is to be brought about. With a vigorous "push" from the ministries concerned, such a reconnaissance should be able to be carried out within the space of one or two years. The structure of our teaching and research institution is of such a nature that this kind of "all in" approach from the basic position of researchers alone cannot be brought into being.

There is obvious need for a supra-university body capable of coordinating and stimulating such a development.

Many aspects of BMT research were considered. Only a number of submitted orientative ideas on one specific subject will be discussed in the following section.
9. Non institutional health care

One of the first orientative ideas, formulated as early as the beginning of 1982, assumes the significance of developments which help to ensure that health care is given a greater content within the so-called "first-line", with less incidence of reference to the "second-line" (specialist, hospital, nursing home, etc.).

During the present MTA reconnaissance it was found that the supporters of this assumption had not only economic arguments in its favour, in all it would make health care cheaper, but the aim was mainly desirable on humane grounds. There are still people who come to the second line who have no business there on medical grounds. A reinforcement of the first line also rests on the conviction that people must look after themselves to a greater extent, and/or seek help in their immediate environment ("zero line"). the first line should, among other things help to bring about such a process of change.

The reinforcement of the first line has long been a point in policy consideration. In fact it attracts a great deal of attention. Nevertheless it is true that little change has taken place. It was found that there are two mains reasons for this. In the first place the still growing concentration of "know-how" in the echelons behind the first line. This has a suction effect on the patient and possible that of keeping out the family doctor. The second important reason was the much weaker organisational structure of the first line compared to the second.

In research into basic health care, the two points to be taken as important orientating ideas are reinforcement of the organisational structure within the first line and greater accessibility of medical know-how for the first line.

It was realised as a general opinion that the improvement in quality (possibilities) of health care in the further echelons is proceeding in ever shorter steps at the price of steadily growing investments. There is a natural inclination on the part of researchers to carry out research in that direction. Progress of this development gives little hope for reinforcement of the first line.

Another obstacle to research development is found in the volume and complexity of such an area of interest. Research interest must also cover the relations between first and second line, must orient itself to a large number of family doctors and other persons active in the first line. As an ideal we see research built up on one or two towns, preferably where first-line health centres are active and where there is also a medical faculty in the area with interest in this body of problems. For such a piece of research the necessary managerial skills are accessible at the Department of Industrial Engineering and Management Science at the Eindhoven University of Technology.
On the grounds of the foregoing aspects the participants are of the opinion that a sufficiently widely based research aiming at reinforcement of the first line can only be realised by means of a "top down" structure. Something of this nature could be prepared in an oriented communication process lasting about one year in the same way as was carried out in the present MTA reconnaissance (SAM procedure).

A good method for making this area accessible to research and processes of change which are regarded as desirable, is seen by the MTA reconnaissance in an oriented application of computer systems. There are already systems available on the market for this purpose. A certain amount of wild growth is to be expected in the years ahead. The (predominantly industrial) "push" behind all this is directed to a limited number of objectives.

The MTA reconnaissance led to the conclusion that the state of the technology as regards data-processing systems already provides for all the possible requirements in this field. Further development as regards the required technology is not considered to be necessary. Making medical activities accessible to the use of these new computer facilities therefore requires considerable attention. Naturally it must begin with an investigation into the organisation and information flows within the field of health care.

As has already been stated, this will have to be structured on the basis of a sufficiently wide framework if it is in fact to get anywhere near the expected high degree of efficiency expected from the introduction of these systems. A first requirement for this is a growth in organisational structure, which in itself is regarded as a significant development.

In a first orientating picture, such a computer system is set up at the family doctor's with the following options. Computer-interactive programs which make it possible to learn how to use such a computer oneself. Assistance in "data entry" for some time and, if required, support in the learning process. A first application to the administrative matters of a medical practice in accordance with standardised software and a certain amount of room for specific own requirements.

As a second step the processing of medical information on patients in accordance with given standard routines, if necessary, supplemented with data considered personally important; in due course also suitable for trend analyses. In close cooperation with an epidemiological study centre the relevant data here are made accessible from standardised patient files for screening population groups. Naturally this goes hand in hand with the required care for the privacy of the patients.

In cooperation with medical faculties, computer-interactive programs are offered that are oriented to diagnostics, the specialist know-how per ailment being made accessible. Likewise self-teaching programs per group of ailments are offered and continuously updated by the medical faculties. In this way something can be done about knowledge transfer from the second to the first-line health care system.
The foregoing first sketch arising from the MTA reconnaissance is then supplemented with a plea for elements of general information to be developed with a priority. Widely accessible teaching situations must be brought into being with regard to the medical appreciation of certain processes of illnesses, aspects of healthy living and the room for self-care. A plea is even made for the introduction of health as a subject in the elementary and secondary school systems. Even linguistic research is considered desirable as elements within the communication of a doctor in dialogue with a patient.

With emphasis it should be stated here that this is only a first approach to opinion forming. An oriented reconnaissance on this area will have to be carried out using the working procedure already described, in cooperation with a number of medical experts in this area. For more detailed orientation a number of experts will have to be consulted. the ideas are moving in the direction of a "topical workshop" to be held on this theme at the end of 1984.
10. Conclusion

The information here given on the MTA reconnaissance is limited to the division of the total field of health care and to orientative ideas on a further reconnaissance of a part area. This is necessary to obtain answers to the question as to what could be considered as significant research developments. During the MTA reconnaissance many ideas were generated on a large number of different themes. Some additional details were only discussed with reference to the reinforcement of non institutional health care.

Many aspects considered important and which were not discussed refer to a very desirable push to more general interest in the ergonomics within a hospital.

Another line of thought which was not discussed refers to a development of models for processes in health care with respect to mutual communication, general opinion forming and decision making as regards such things as multidisciplinary diagnostics, costs management, management and research development.

This report is in the first instance intended to contribute towards the formation of opinion on the methods used in MTA reconnaissance sketched out here.

In the event of a sufficient number of positive reactions and sufficiently wide-based support, further MTA reconnaissance will then be structured on given part areas of health care. There is an expressed preference for choosing two areas for this. The one is ailments of the respiratory organs. The other is oriented to reinforcement of the basic health care.

More of this kind of reconnaissance could at the same time be given attention on the part of various institutions for education and research.

It is thought to be particularly efficient to set up a central study centre for the coordination of such MTA reconnaissances into significant research. In this way a considerable part of the already present research capacity could be oriented to health care and thus grow into a more coherent whole and, according to expectation, also make for better exploitation from a national perspective.

In many of these developments the technology will possibly assume a subordinate place. It is, however, equally clear that medical technology will remain an important factor. It will always be a matter for cooperative, wide-based multidisciplinary consultation, particularly between doctors and technologists whose task it will always be to think over the immediate and more distant future of health care in the Netherlands.
Personal communication with participants at the MTA reconnaissances in 1982 and 1983.

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  Applied Science Research Institute (biophysicist)
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