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ASSESSMENT AND REGULATION OF HEALTH CARE TECHNOLOGY

The Dutch Experience

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Abstract

Objectives: To evaluate the characteristics, methods, and results of the Dutch Investigative Medicine Program ("ontwikkelingsgeneeskunde") in policy and health care.
Methods: Project database analyses of the initial 9 years of the program; description of characteristics, methods, and effects of the program.
Results: By the end of 1997, 53 projects had been completed, including implementation in health care policy. In 20 of 53 cases the program worked as an instrument to prevent the introduction of ineffective, inefficient, or even harmful medical interventions. In most other cases the program assisted with proper placement or appropriate application of new technologies. Apart from new or emerging technologies, already existing technologies are evaluated.
Conclusion: The Dutch Investigative Medicine Program ("ontwikkelingsgeneeskunde") of the Sickness Funds Council is an effective collaboration of health care providers, medical science, health economics, and a regulatory body in empirical technology assessment. It is also an example not only of a substantial contribution of technology assessment to decision making in practice and policy but also of a means of regulation of health care by the very activity of technology assessment itself. It appears that the program has evolved into an instrument to rationalize health care and health care policy, although some further possible improvements are identified.

Keywords: Technology assessment, Health policy, Results, Evaluation, Investigative medicine

The Dutch Investigative Medicine Program ("ontwikkelingsgeneeskunde") of the Sickness Funds Council has now been in place for 10 years. It is, both in the Netherlands and internationally, a leading program in the field of policy-driven evaluation research. The program provides for thorough evaluations of medical developments (mainly new technologies) with the aim of decision making about the location and the introduction of services or types of medical care. Those decisions may be on the macro-, meso- or microlevel. In other words, the Investigative Medicine Program covers both government policy decisions and decisions relating to the use of particular medical procedures as set out in protocols and guidelines.

The research presented in this article is part of a study of factors that determine the success or failure of the implementation of technology assessment studies in policy and practice, conducted by the Institute for Policy and Management in Health Care in Rotterdam, led by Professor A. F. Casparie.

The stage has now been reached in which the results are emerging. This article describes those results and studies the links between the results on the one hand and characteristics of the program on the other. First of all, the structure of health care and regulation instruments in Holland are discussed. Then the program itself is discussed, together with its most characteristic features. This section is followed by a systematic review of the results through 1998. We then review the major factors influencing the results. The article concludes with a discussion of the important factors contributing to the results.

REGULATION OF HEALTH CARE IN THE NETHERLANDS

Health care in the Netherlands is organized in a mixed system of public and private responsibilities. Most of the significant health care provisions are carried out by private organizations such as hospitals, general practices, and nursing homes. The health system is regulated by specific laws on health insurance, planning, quality of care, and charges.

The insurance system is divided into three components:

1. The General Act on Extraordinary Health Cost (AWBZ), which is a basic level in which all people automatically (obligatory) are included and covers care for the elderly, mental health care, nursing home care, and population screening programs;
2. The sickness funds act (ZFW), in which all people in a category below a certain level of income are automatically included; this act covers almost all types of treatment, including general practitioners, hospital and specialty care, paramedical care, and pharmaceutical products and medical devices. Approximately 60% of all Dutch people have their coverage from the ZFW. For people above the indicated level of income (40% of the Dutch population), there is a private market of health insurance for largely the same treatment provisions; and
3. A free market for all people in which coverage of all types of "extras" and "luxury" are offered.

The legal insurance system is carried out by private organizations, the sickness funds ("ziekenfondsen"). The regulation and supervision of the insurance system as such is by act of delegation from the Minister of Public Health carried out by a public executive organization: the Sickness Funds Council (Ziekenfondsraad [ZFR]). This Sickness Funds Council is a representation af all relevant parties in the field (association of insurers/sickness funds, providers' and professional associations, consumer associations, and associations of employers and of employees). The council gives advice to the Minister of Public Health concerning all questions in the execution of the Sickness Funds Act (i.e., composition of the benefits package, cost of premiums, and budgets of Sickness Funds), and supervises and directs the Sickness Funds. Apart from those advisory and supervisory functions, the Sickness Funds Council has an instrument to subsidize certain projects: experimental health care and evaluations of those experiments, and all types of research projects concerning its legal tasks. The Sickness Funds Council also publishes guidelines for efficient health care (the annual *Pharmacotherapeutical Compass* and the biennial *Diagnostic Compass*).

Planning by the government is carried out restrictively: general hospital provisions are regulated only quantitatively. Specific services (radiotherapy, transplantation, IVF) are bound by more detailed regulations in which specific hospitals are allowed to carry out these services, conditioned by specified quality and monitoring

standards. The Minister of Health is very restrictive in applying this planning instrument.

In the field of planning there is another regulatory organization in charge, the Health Council (Gezondheidsraad [GR]) which advises the government on all topics concerning the scientific state of the art of medical services. The Health Council advises the Minister of Public Health concerning such questions as what services are to be regulated by planning and what specific conditions are to be met by suppliers.

The development of new technology generally takes place within one of the eight university hospitals in the Netherlands. The phase of development where an integral evaluation of a new technology is necessary for decision making is handled by the Investigative Medicine Program ("ontwikkelingsgeneeskunde") of the Sickness Funds Council. This program is an instrument for technology assessment of these innovations. In this program these innovations are evaluated to help decision making in insurance, planning, and guideline development. The results of these evaluations are used by the Sickness Funds Council for policy making and recommendations to the Minister of Health. Some of these evaluations (in most cases immediately following this evaluation study) are followed by an advisory report from the Health Council, which summarizes the available knowledge in a recommendation to the Minister concerning the desirability and conditions for planning.

These instruments together offer a well-functioning regulatory mechanism for an important part of health services, especially the high technology/big-ticket items. Results of technology assessment studies such as those performed in the Investigative Medicine Program are directly implemented in specific insurance and/or planning decisions. Regulation of day-to-day outpatient and clinical medical care is largely dependent on the effectiveness of developing and implementing guidelines on the basis of the same technology assessment studies. In many cases a technology assessment study might lead to a policy decision on the macro-level and, at the same time, to a clinical guideline.

INVESTIGATIVE MEDICINE AS A PROGRAM

Characteristics

Investigative medicine is a program for empirical outcome research with two characteristics: it focuses on policy decisions, and it makes a joint evaluation of more than one aspect (usually effects on health parameters, quality of life, and costs). These characteristics mean that the program meets most definitions of health technology assessment.

The program works largely on a bottom-up basis. In other words, the selection of topics for evaluation projects rests with the hospital that developed the technology. In most cases, by far, the projects are developed in the university hospitals. This procedure works as an effective signal for emerging technologies. The projects usually consist of prospective comparative studies (often randomized trials) in which not only clinical effects "in real life" but also effects on the quality of life, functioning, and cost are evaluated in the same setting. The projects have traditionally been related to the evaluation of the use of new medical services. A basic requirement for investigative medicine is that efficacy in controlled conditions of the new type of care being examined must be established before a comprehensive evaluation in the context of investigative medicine is allowed.

When, after a few years, the evaluation of already existing facilities was included in the program alongside the evaluation of innovations, the Sickness Funds Council

used the so-called "126 list" for the selection of topics (1). This report of the Sickness Funds Council (1993) offered a list of 126 existing forms and modes of care, the efficacy of which is subject to doubt. The list was composed and prioritized by a group of experts in health economics and medical advisers of sickness funds, by means of a repeated Delphi process. The list has led priorities in evaluation studies not only for the Sickness Funds Council but also for the Health Council, which has an ongoing program in reporting on a selection of topics on the 126 list.

It is important to mention two other important characteristics of investigative medicine. First, it is important with a decision about the introduction of new services to compare the innovation with the best available alternative at that time. This requirement usually means that a prospective, comparative study is desirable. Second, an evaluation of a service (whether for existing or new forms of care) always relates to use for certain indications or, more generally, use in particular circumstances. In medical terms, the fact that the efficacy of types of care depends on the range of indications is a trivial fact, but it is one that has major consequences for policy decisions about forms of care.

History

The Investigative Medicine Program started in 1989 with a statutory basis in the Hospitals Act (subsection 18c); this act was the law by which planning was carried out at that time. It was the result of two developments, the first being the development of funding for applied scientific research in university hospitals, and the second, far more important, being the trend toward increasing rationality in choices in the care sector. The second of these developments requires further discussion if the historical background is to be understood.

In the Netherlands, the discussion about the limits of the care system came to the fore in the 1980s as a result of new developments in heart transplantation, liver transplantation, and in vitro fertilization (IVF). In that period the Sickness Funds Council published its first two reports about the limitation of the growth of the package of benefits of the social health insurance system (6;7). The first of these reports (1983) started the discussion in the Netherlands about limitations to the entry of new technologies in the insurance system: this should no longer be an autonomous mechanism. The second report (1986) introduced the system of integrative evaluation of new technologies prior to decision making concerning the entry in the package of benefits. At that time some preliminary experience resulted from empirical cost-effectiveness studies of IVF and heart transplantation. These studies had direct consequences for policy making concerning these technologies.

The philosophy behind these "limits reports" was the moving force behind the Investigative Medicine Program. It was possible to meet the need for rational decisions about the admission of new services by conducting a critical assessment at the time of admission. This assessment was to receive concrete form in the Investigative Medicine Program.

The program was assigned to the Sickness Funds Council and monitored by the Investigative Medicine Committee of the same organization. The fund was fixed at NLG 36 million (US $1,800,000) per year, NLG 27 million of which was to come from the premium funds of the social health insurance system, with NLG 9 million coming from the budget of the Ministry of Education and Science. These monies were made available on an annual basis in the form of a "revolving fund" for 3 years during projects.

Evolution of the Program

The Investigative Medicine Program has now developed from a mainly clinical research program into a program for policy-driven, multi-faceted outcome research, which covers, in addition to clinical aspects, economic aspects and sometimes even matters of general social interest. In the initial period in particular, many projects consisted of clinical research with an "attached" economic evaluation. This "piggy-back" method has advantages, but the drawback is that it can result in two more or less independent assessments (and therefore reports). The point is actually to obtain a single integrated picture in which the clinical, economic, and quality-of-life aspects are assessed as an interrelated whole.

During the course of the program, there have been more and more integral assessments of this kind, with the main advantage being the interaction that is established between clinical research and economic research, resulting in integrated evaluation reports. A second important process of evolution in the program is the shift in focus to existing services. The basis of this process is the awareness that there are quite a lot of types of care where efficacy is subject to doubt, at least with some indications. The aim of the assessment of existing care is to base the selective use of care on evidence. The Investigative Medicine Committee has been using a list of priorities for evaluation studies (the "126 list") since 1995 as a guideline for priority setting for research into existing facilities (1).

The third important development is top-down research. Whereas in the bottom-up approach the committee depends on initiatives made by researchers, in the top-down approach it is the committee that decides to assess certain types of care. A certain degree of conceptual clarity is required here: what is involved in top-down investigative medicine is not the development of scientific fields but the selection of those subjects that require priority in the assessment process from the point of view of health care policy. The first projects using this approach have now started. The committee has developed a systematic top-down approach in which the "126 list" will also be used and updated.

Top-down management and assessment of existing care are often linked but not always. There are new subjects that are tackled on a top-down basis because of their relevance when there is no "spontaneous" (bottom-up) proposal for assessment research. There are also bottom-up proposals for the evaluation of existing forms of care.

Procedures

The committee now works in an annual cycle. New projects are submitted to the Investigative Medicine Committee following a bottom-up procedure. The committee evaluates the proposals using the criteria for investigative medicine, of which the most important are relevance to policy and the expectation that the results of the project will be useful in policy decision making. Proposals that meet the criteria are sent to an independent Council for Medical Research for an appraisal of scientific quality. Projects that are approved are included in the annual advisory report from the Investigative Medicine Committee to the Ministers of Health and of Education. The projects are subsidized by the Sickness Funds Council. Not only are research costs covered in the project subsidy, but the experimental care itself is also included in the costs of the project. The projects are monitored by the committee on the basis of annual reports. Most projects are planned for a period of 3 years. At the end of the 3-year period, a complete report is submitted to the committee. The Investigative Medicine Committee reports, stating its final opinion, to the Sickness

Table 1. Projects Started in the First 8 Years, 1989–97

Starting year	Number of projects
1989	11
1990	12
1991	15
1992	18
1993	11
1994	12
1995	15
1996	11
1997	17
Total number	122

Funds Council and the political leadership. The Sickness Funds Council then submits a report consisting of policy recommendations on the basis of the results of the project to the Minister of Health. The Minister of Health decides about insurance, planning, or financing mechanisms.

Policy Cycle

Investigative medicine is part of the process of preparation, designing, implementing, and evaluation of policy: the research prepares for rational decisions in the context of health care policy. These decisions can relate to statutory measures in the area of admission, insurance, planning, and funding. The decisions may also relate to the conditions under which certain types of care may be supplied.

It is precisely decisions about insurance, planning, and practical use that involve matters that are virtually always studied together in investigative medicine: effects, results in terms of health measures and quality of life, costs, and organizational and qualitative pre-conditions. Decisions concerning technologies or the diagnostic or therapeutic strategy in specific conditions are based on outcomes and costs. These matters almost always emerge in comparison with available alternatives, such as the current treatment of choice. In addition, investigative medicine studies usually result in areas of application. Another important result is that the report of projects are transformed into guidelines for the areas of application of the service in question (indications) in day-to-day clinical practice: this is the way in which health care policy on the microlevel is based on evidence.

The first completed projects provide a picture of the potential significance of investigative medicine for policy. The subsequent section describes in further detail the link between investigative medicine as a program and public health policy.

RESULTS THROUGH 1997

Ongoing and Finished Projects

The Investigative Medicine Program had completed nine annual cycles on January 1, 1998. A total of 122 projects had been started in 8 years. Table 1 shows how the projects were distributed over the years.

On January 1, 1998, 53 projects had come to an end. The reports were finished and accepted, policy recommendations were formulated by the Sickness Funds Council, and decisions following this advice were made by the Minister of Health; the results of 53 technology assessment projects were implemented by that time.

Table 2. Decisions Made by the Minister of Health Based on First 8 Years' Completed Projects

Type of decision	
Coverage	38
Planning	9
Funding	12
Indications	15
Other	4
Total number of decisions	78
Total number of projects	53

Decisions Pursuant to Completed Projects

Of the 53 completed projects that resulted in one or more decisions by January 1, 1998, decisions related to one of the following policy instruments: provision of benefit (yes, no, or subject to conditions); planning (limitation to one institution or a number of institutions); funding (supplements to the institution budget or increase in rates); and guidelines for areas of application (to be recorded in an indication protocol).

Decisions relating to the granting of benefits result in amendments to legislation or in ministerial declarations that a particular type of care should be considered for inclusion in the package of insurance benefits. The second option is more commonly adopted: most forms of care are not explicitly listed in legislation about benefits pursuant to the Sickness Fund Act. Some exceptions to this rule are transplants, medical aids, and pharmaceutical products. In the case of the large area of clinical care and advanced clinical care, there is a statutory entitlement to forms of care for which there is an indication. There can only be an indication of this kind if an evaluation such as investigative medicine has shown that the care in question has a demonstrable added value in the given situation.

Decisions relating to planning are generally taken pursuant to advice from the Health Council. With this type of decision, after having received the results of the Investigative Medicine study, the minister in some cases asks the Health Council for an additional advisory report. Planning decisions generally involve financial consequences for the institution in question.

In recent years, the ministry has followed a policy that has, in part, replaced the planning arrangements. As part of the (periodically made) framework agreement between the Minister of Health and the university hospitals, agreements are made about the provision of certain types of care in certain centers without formal statutory approval being given. These agreements are therefore accompanied by financial concessions. In a number of cases, the minister does not opt for the statutory planning instrument nor for the framework agreement, but attempts to concentrate the service by means of consultation. It is almost always the case that a request for consultation is addressed to the Sickness Funds Council and associated institutions or professions. Those consultations therefore involve not only the choice for limited allocation but also indication guidelines. This type of decision is therefore included in the "indications" category in Table 2.

Putting aside these planning decisions, a decision can also relate to funding, for example, by providing additional resources in institution budgets for the fees for certain types of care.

In addition, in a number of cases, there is no question of allocating or financing a treatment or service but rather of producing a protocol, for example, for those projects that related to a problem rather than a facility (usually diagnostic protocols). One of the possibilities for introducing a protocol of this kind is the *Diagnostisch Kompas* (diagnostic compass) of the Sickness Funds Council. This type of decision is also included in the "indications" category in Table 2.

Table 2 shows, for each type of decision, how many decisions were made on the basis of the 53 projects about which the minister was able to make a decision (the total is larger than 53 because several decisions are possible per completed project). It is of interest that, of the 53 subjects selected, a negative decision was made in 20 cases on the basis of the negative results of the project in question. These decisions relate to such subjects as:

- Prophylactic sclerotherapy (injection of varicose veins in the esophagus with a sclerosant in order to prevent later bleeding from these varicose veins);
- Surgical treatment of gastric cancer (a more intensive form of surgery for gastric cancer);
- GM-CSF in neutropenia (the administration of growth factors, substances that stimulate the production of blood cells so that higher doses of substances that destroy cells can be given safely during the treatment of cancer); and
- PTCA or ELCA (laser treatment for constricted coronary arteries using laser).

It has been established that these treatments are not effective or that they are less effective than the standard treatment. In the case of these subjects, an Investigative Medicine Project prevented the mistake of introducing the treatments into the health care system. The minister's decision in these cases was that they should not be included in the package of services or that they were not considered to be a part of that package. In two cases the negative findings belonged to existing technologies, serving as a way of "cleaning up" the existing package.

Subsequent Events

Some of the decisions arrived at by the minister have been implemented. Most of the decisions relating to services have already been implemented in the form of the statement that "a particular treatment should be included in the package of services." Some decisions had to be made explicit in laws or formal regulations. This was true of bone marrow transplants and the inclusion of a part of the bone-anchored hearing aid in the arrangements for medical aids pursuant to the Health Insurance Funds Act. These decisions have been implemented.

If we look at the decisions relating to the development of planning arrangements, it emerges that three subjects resulted in an agreement under the terms of the framework agreement between the Minister of Health and university hospitals. No new formal decisions were made using the Hospitals Act.

Financial arrangements were made subject to the conditions of the framework agreement or as a separate decision on mechanism and cap of payments. Requests for the development of guidelines have been implemented in part. The Netherlands Society of General Medical Practitioners has resolved to adopt the recommendation on diagnosis for suspected thrombosis in its standard. A similar sequence of events can be seen for the diagnosis of infertility and dementia, particularly in the inclusion of the recommendations in the *Diagnostisch Kompas.*

DISCUSSION

Main Results of the Program

The results of the first few years make clear that the Investigative Medicine Program achieves what it set out to do. It results in decisions about the composition of the range of treatments and services and to other policy decisions in, for example, the areas of planning and funding. In addition, the program contributes to the justification of guidelines, notably in the area of appropriate indication for diagnostic or therapeutic procedures. In a number of cases, projects have resulted in complete diagnostic strategies.

The content of the decisions that are based on project results is also a cause for satisfaction. In 20 of the 53 projects examined, the result was negative. The demonstration in a formal evaluation study that a new technique is not an improvement provides the best safeguard against the introduction of that technique. The same findings will probably apply to subsequent completed projects that are still in the decision-making pipeline. Here, also, there are some negative assessment results. Another important phenomenon is that the program itself works as an effective regulator. Expensive innovations are not only evaluated but also financed during the project. Together with the involvement of leading clinicians in the project ("ownership") and the need to include patients in the study, it appears to be very attractive to channel the innovative technology into the project.

Lessons

The difficulties which the program has encountered can be broken down into two categories: problems with the development of assessment criteria and problems with the progress of the studies themselves.

The assessment of the initial rounds of investigative medicine was mainly conducted on the basis of criteria that virtually overlapped with the methodology of clinical research. As pointed out above, the program has evolved from one in which the focus was primarily on clinical into a program for policy-supporting outcome research (4). This approach requires a specific assessment framework in which the methodological requirements of clinical effect studies had to be combined with those of health economics and requirements relating to policy relevance.

As far as the latter is concerned, it has emerged quite often in the program that methodological purity ideally implies a very narrowly defined (and therefore usually limited) category of patients and that this detracts from policy relevance since generalization to broader categories then becomes impossible.

The formal requirements of the program also interfered on occasion with the implementation of relevant studies. The maximum of 3 years for projects is a problem, for example, when studying longer term effects, as with oncology and, even more clearly, preventive strategies.

A methodological problem concerns the evaluation of diagnostics: evaluation studies of diagnostic facilities or methods do not necessarily require the same approach as those for therapeutic techniques.

There have also been problems with project completion, albeit infrequently. In many cases, this is attributable to a shortfall in the number of patients, either as a result of a mistaken estimate both by applicants and assessors of the effects of exclusion criteria or as a result of an overestimate of the readiness of hospitals, doctors, or patients to participate in studies. In a small number of cases, these problems were so serious that studies had to be terminated before completion.

Spin-off

Alongside the direct results and the impression of projects in the program, the Investigative Medicine Program has also had a noticeable general effect. Investigative medicine is one of the most important technology assessment programs in the Netherlands. Together with the advisory reports of the Health Council, many of which can be classified as technology assessment, the program constitutes the lion's share of Dutch activities in the field. The difference with the Health Council's program is, of course, that investigative medicine is concerned with empirical research and that the Health Council is primarily involved in the synthesis stage of technology assessment. In effect, then, the programs are complementary.

The major part of Dutch experience in the field of technology assessment has been acquired in investigative medicine studies. Reviews of technology assessment in the Netherlands or studies of the methods used in health care economics are often based on experience acquired in investigative medicine. The program has therefore contributed to the development and spread of health care economics expertise and the introduction of technology assessment expertise at university hospitals.

Furthermore, the program has contributed to the awareness of clinicians of the necessity to evaluate critically new technologies.There is a growing readiness in the medical prefession to consider not only biomedical and clinical effects, but also all other relevant outcomes and costs of new technologies, comparing them with the best available alternatives.

In the area of policy support and evaluation, the Investigative Medicine Program has established a corpus of experience, albeit a limited one. The idea that policy decisions should ideally be based on rational considerations has been given a powerful impulse by the introduction of the concept of technology assessment as such.

CONCLUSIONS

The most prominent conclusion of this evaluation is that the Investigative Medicine Program does what it was created for: it serves as an effective gatekeeper for health care. Twenty of 53 technologies were evaluated and proven of no added value for different reasons.

The second conclusion is that this empirical form of technology assessment has very specific advantages and disadvantages. The most important advantage is that it provides comprehensive assessments of high scientific quality, useful for decision making, selected by those providers who develop them (so it works as an effective instrument for signaling new developments, too). Moreover, the effectivity of implementation is strongly enhanced while the professional deliverers of care are closely involved in the evaluation study itself, together with such other important parties as economists and the policy-making/preparing organization (the Sickness Funds Council). These parties work closely together during the study, which results in a restrictive introduction and application of the technology; thus the program itself works as a regulating instrument.

The major disadvantage of this type of technology assessment is the long time needed for an evaluation and the relatively high costs (although the high costs of projects consist not only of research, because the experimental care itself is also financed; this explains the regulatory effect of the program). These characteristics make the program not very useful for quick studies, which may be needed when decision making is urgent.

Another early disadvantage was that the program in its initial years had to overcome a too prominent presence of medical science. But even this involvement factor has developed into one of the program's successes. Because scientists are in favor of the results of studies in which they are involved, this involvement contributes to quick implementation if study results in policy and of policy into practice.

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