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**Medisch
Specialisten**

Advisory report
Health care evaluation
**From project
to process**

HEALTH CARE EVALUATION STEERING COMMITTEE
(STUURGROEP ZORGEVALUATIE), 2016



Advisory report Health care evaluation

From project to process

Colophon

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The appendices to this report are available as a separate background document at www.demedischspecialist.nl.



Preamble

Health care evaluation assesses existing health care and determines which health care is most effective under the given circumstances. Health care evaluation yields health benefits for patients. In addition, it underpins guidelines and tools for shared decision-making. Therefore, health care evaluation is an essential component of quality policy pertaining to medical specialties.

Health care evaluation also results in effective allocation of resources, thereby keeping health care accessible to all. Savings may be applied to keep health care affordable but may also be used to further improve the quality of health care. This concept of shared savings brings into motion a type of ‘flywheel’ through which health care evaluation maintains itself.

In order to achieve this:

- medical specialists, in cooperation with patient associations, are taking the initiative to examine (take inventory of) and prioritise knowledge gaps in daily health care (description of requirements and criteria for examination and agenda-setting);
- medical specialists are involving other parties in the examination and prioritisation process (including GPs and health insurance companies);
- medical specialists, together with institutions, are setting up health care evaluation networks to be able to perform health care evaluations in a reliable, quick and efficient manner;
- medical specialists are applying the results of health care evaluation to their decision-making processes;
- the flywheel has to be brought into motion; seed capital will have to be invested for this.

The health care evaluation file has become thicker in recent years. A number of medical specialties have, together with patient associations, taken inventory of and prioritised knowledge gaps in an agenda. A number of consortiums have been set up in the country, and results have been implemented in the health care sector. Both the Ministry of Health, Welfare and Sport (VWS: ZonMw) as well as health insurance companies (ZN) have provided financing on a per project basis.

These are the initial successful projects. The health care evaluation process has thus been launched, and we are taking the step from project to process: health care evaluation must become a part of regular health care. We want to structurally evaluate our medical activities. This cannot be done on a per project basis; we need structure. That’s why in 2014 the Dutch Association of Medical Specialists (Federatie Medisch Specialisten) commissioned the Health Care Evaluation Steering Committee (Stuurgroep Zorgevaluatie) to investigate which structure would be most suitable for facilitating the next step, from project to process. The report provides an inventory of existing structures and looks ahead to (necessary) new opportunities and framework conditions to be able to implement this step.

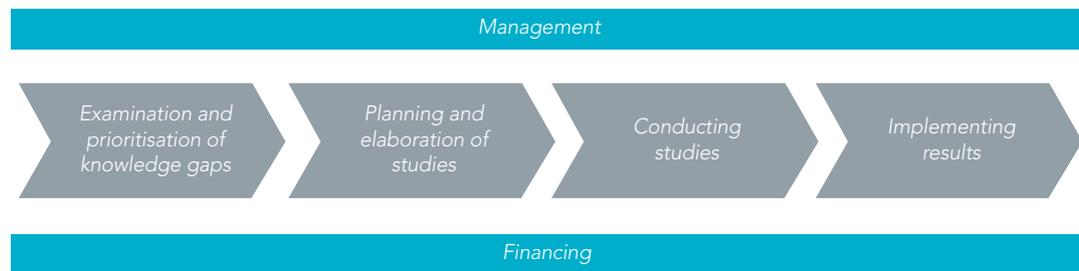


Summary of recommendations

This chapter contains a summary of the most important recommendations in the report. This summary does not contain the explanations and considerations that led to the recommendations. Please refer to the complete report for this information.

DEFINITION OF HEALTH CARE EVALUATION

Health care evaluation is clinical evaluation research into the (cost) effectiveness of existing health care. It is aimed at correct determination of interventions (indication for treatment or diagnostics). Health care evaluation is more than merely conducting a comparative analysis; it is a process entailing a number of important components:



EXAMINATION AND PRIORITISATION OF KNOWLEDGE GAPS

Compiling an agreed-upon knowledge agenda is the first step in the health care evaluation process. A knowledge agenda is a description of the most important knowledge gaps of existing health care within a discipline and an action plan as to how these knowledge gaps can be resolved with clinical research.

Given the large number of knowledge gaps in medical practice, it is important to examine these gaps, prioritise them and then place them on the agenda for research. Some recommendations in this respect are as follows:

- Establish a working group comprised of medical specialists focusing on:
 - good distribution of academia/non-academia;
 - good geographic distribution;
 - good distribution of focus areas;
 - good involvement of doctors in specialist training (AIOS) and young medical specialists.
- Identify and prioritise the knowledge gaps together with patient associations.
- Identify and prioritise these knowledge gaps, if relevant, together with other involved parties, such as GPs, physical therapists and health insurance companies.
- Prioritise the knowledge gaps based on the following criteria:
 - relevance (severity, incidence/prevalence, costs);
 - urgency;
 - researchability/feasibility;
 - impact on the discipline / societal impact.
- Conduct an exploratory search for the topics with the highest priority.
- Create a link between the topics with the highest priority and the guidelines in the Guideline Database.
- Formulate the topics with the highest priority into a concrete question with a brief explanation.
- Take stock of the lines of research of the UMCs, the Association of Top Clinical Teaching Hospitals (STZ) and teaching hospitals to see whether the prioritised knowledge gaps can align with existing

lines of research.

- Have the topic with the highest priority be confirmed by the board of the scientific association.
- Examine whether the agenda needs to be updated in three years.

PLANNING AND ELABORATION OF STUDIES

The next section of the report describes the process of how scientific associations go from a health care evaluation agenda to a full-fledged study design by forming networks within the discipline. The most important recommendations in this respect are as follows:

- Aim for network formation in order to optimise the planning and design of the studies and maximise the conduction and implementation of the studies.
- Development of a network is a growth model in which certain phases (scenarios) can be distinguished. Choose a scenario that is suitable for the association; this has to do with existing cooperation and the quantity of studies.
- Aim for comprehensive involvement of specialists working at various institutions, ideally at all hospitals where the health care that is to be evaluated is being provided.
- For elaboration of the study, it is necessary for the network to have easily accessible methodological expertise available to it (clinical epidemiology/biostatistics).

CONDUCTION OF STUDIES

It is important to organise health care evaluation studies at hospitals/institutions efficiently and in good quality. Important aspects in this regard are the required infrastructure, monitoring procedures, use of research nurses and trial offices.

- It is important for clear agreements to be established regarding data monitoring, review by MECs and use of research staff, so that good-quality studies can be efficiently conducted at hospitals.
- The development of an efficient and sustainable infrastructure is desirable, in which the possibilities for sharing facilities need to be elaborated. Within this context, it must be investigated together with the hospitals (STZ, NVZ and NFU) whether agreements can be made regarding the set-up and functions of trial offices and research staff.
- It is desirable to investigate the standardisation of the costs of health care evaluation studies and the sustainable use of the required infrastructure, such as trial offices and research staff. In addition, structural financing is important for maintaining a sustainable infrastructure.
- Sustainably maintaining the infrastructure for health care evaluation is very important for the efficiency, speed and quality of study conduction. Such an approach requires structural investment.

IMPLEMENTATION OF THE RESULTS

Health care evaluation is only useful if the research results are actually implemented in the workplace. The report provides the following recommendations for this:

- Compile an implementation plan for each research proposal. This is the responsibility of the researcher in cooperation with the medical specialist / scientific association. Execution and monitoring of this are the responsibility of the scientific association.
- As a scientific association, guarantee implementation of the results in practice.
- This includes issues such as the following:
 - visible streamlining of guidelines in the Guideline Database;
 - involvement of hospitals through a national structure of a health care evaluation network;
 - distribution of new knowledge by means of additional training and continuing education, quality visits, etc.
- Promote implementation through health care procurement and through the institution's Board of Directors.

MANAGEMENT

Both the scientific associations as well as the other stakeholders play an important role in making health care evaluation successful. Joint action is desirable in this context.

- Central management/coordination and support at the Federation's level is required in order to guarantee health care evaluation. This way health care evaluation will be jointly managed, and a service portfolio will be created for supporting the development of health care evaluation networks (facilitation of organic growth, from opportunity network to sustainable network).
- In addition, it is necessary to set up a health care evaluation advisory committee within the Federation that will set policy in cooperation with various boards, elaborate generic procedures and standpoints and maintain contact with the most important stakeholders with regard to health care evaluation.

FINANCING

In addition to benefiting patient health, health care evaluation also benefits efficiency. Some recommendations in this regard are as follows:

- Finance health care evaluation studies through the shared savings concept. A part of the shared savings will go to:
 1. the premium payer, because the insurance company will translate this profit into a lower premium for the basic insurance;
 2. the hospital, because this gives the hospital time to write off its investments more quickly;
 3. the health care evaluation researchers, because follow-up or other health care evaluation research can be instigated with this.
- It is important that, in order to be able to achieve shared savings, investments must be made for health care evaluation to be initiated. This concerns investment in making agendas and setting up networks, carrying out health care evaluation research and implementing results.



01 Background

This advisory report examines the following question: How can we continuously find out more about the positioning of existing health care, thereby ensuring that every patient benefits most from certain diagnostics and treatment? Medical specialists and citizens consider this to be an important key question in health care. It makes health care effective, safe and efficient. Health care evaluation is something we do every day, among other things by adapting guidelines according to the latest scientific developments, by maintaining registrations and analysing and sharing the results thereof, but also daily during peer consultation and when transferring patient care.

This report discusses clinical research on the efficiency (in all of its facets) of daily applied health care with whose (relative) effectiveness we are insufficiently familiar. What is required to make this a reality? Who needs to be involved and how? These questions are discussed in this report.

1.1 COMMON INTERVENTIONS IN HEALTH CARE ARE FREQUENTLY INADEQUATELY SUBSTANTIATED

The core of the medical specialist's field is to provide the best suitable health care to patients. The health care that patients receive on a daily basis is partly based on scientific evidence and partly on pathophysiological reasoning or experience. The health benefit is either not or insufficiently scientifically researched and/or not proven for half of the treatments. This does not mean that such treatment is not good, but that the outcome of the treatment has not been scientifically researched in relation to the indication. For example, we know that IVF works for treating infertility in women with blocked fallopian tubes. However, this technology is also being used for other indications for which the effectiveness has not been or has not been sufficiently researched. In a U.K. study on 3,000 commonly applied treatments, 43% were proven effective and 7% were proven ineffective. However, the effectiveness of 51% of the analysed treatments appeared to be unknown (Figure 1).

There are good reasons to assume that comparable figures apply to the Dutch situation. One indication for this can be deduced from the medical guidelines where about half of the conclusions or recommendations are based on limited reasoning or conclusion level 3/4 (Figure 2).

Lack of clear proof leads to various interpretations and different treatments for the same clinical picture, called 'practical variation'. This results in questions in the consulting room. Take the example of an elderly patient who breaks his wrist. Often this is treated with surgery, while some patients with this injury could make do with a cast or splint. It is factually (based on evidence) unclear what the best strategy is. This situation makes it so that doctors cannot always provide clear medical advice.

51% OF ~ 3,000 COMMONLY USED TREATMENTS IN THE UK WAS OF UNKNOWN EFFECTIVENESS

UK EXAMPLE

Rating by a team of advisors, peer reviewers, experts, information specialists & statisticians



Note: Study based on ~3.000 treatments

Source: Clinical Evidence website 2011, how much of orthodox medicine is evidence based? 2007, Booz & Company analysis

Figure 1: 3000 commonly used treatments in the UK

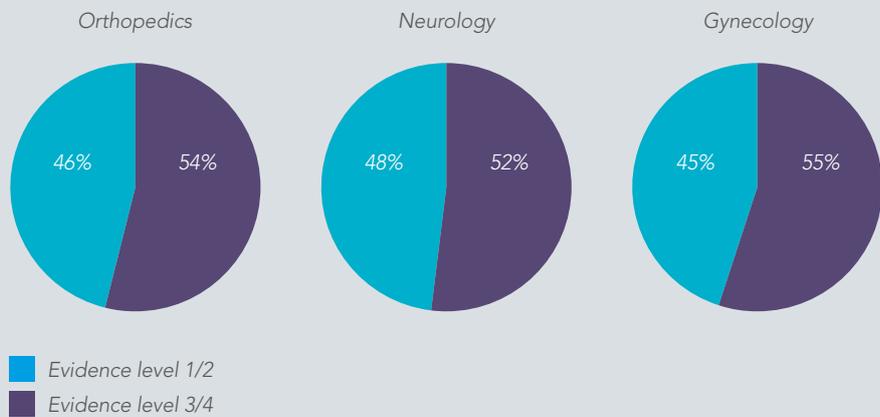


Figure 2: examination of knowledge gaps in Dutch guidelines (Knowledge Institute of Medical Specialists, 2014)

1.2 SOCIAL VALUE OF RESEARCH

In 2014 a series of five articles was published in *The Lancet* about improving the added value of research and decreasing research that is not meaningful (research: increasing value, reducing waste). The impetus for this was the fact that a lot of research does not yield valuable results. This is in part inherent to research, but there is also in part the issue of avoidable wastage (Ian Chalmers talks about an avoidable wastage figure of 85%, Chalmers et al., 2009). A number of important issues is addressed in this series:

- the research topic must be relevant for clinicians and patients as the end-users of research (Chalmers et al., 2014);
- the design, method and analysis of the research must be adequate in relationship to the research topic (Ioannidis et al., 2014);
- research regulations and management must be designed to be efficient (Salman et al., 2014);
- research data must be entirely freely accessible (Chan et al., 2014);
- unbiased and useful research reports are essential (Glasziou et al., 2014).

The general thread in the articles states that current research does not adequately align with what the users of the research (including doctors and patients) need. The research hence offers insufficient social value. Medical scientific research is geared too much towards generating publications and exciting new results. The publication and selection bias is also a point of attention: approximately half of the studies that are conducted and completed are not published. These are primarily studies with negative/no effect outcomes. In addition, sometimes only a selection of the outcome measures is published.

1.3 INITIATIVES THAT HAVE LAID THE FOUNDATION FOR STRUCTURAL HEALTH CARE EVALUATION

Gynaecological consortium

In 2003, a group of gynaecologists initiated the structural evaluation of common treatments in gynaecology. This resulted in important health benefits (e.g. decreased fatalities and disease burden) but also in more effective health care.

Some 70 hospitals are participating in the NVOG consortium in the meantime. Every year there are an average of 8 new and 20 existing health care evaluations on-going with annual subsidies of about € 3,000,000. Due to this studies are assured of sufficient inclusions. Furthermore, the participating hospitals appear to actually be implementing the results of the studies.

ENT knowledge agenda

The ENT doctors put together a knowledge agenda in 2013. In this agenda they worked together with patient associations to take stock of and prioritise issues whose effectiveness is not based on scientific research. This resulted in a list of top 10 knowledge gaps. The knowledge agenda was well-received and was the incentive for various studies: five topics out of the top 10 list were actually expanded into an on-going health care evaluation study.

The “Stimulate Effective and Eliminate Non-Effective Health Care” (“Stimuleer Effectieve En Elimineer Niet Effectieve Zorg”) (SEENEZ) project

The SEENEZ project was set up in order to give health care evaluation further impetus in the medical specialist domain. In this project (initiated in 2014), financed with funds from the Quality Funds Foundation of Dutch Medical Specialists (Stichting Kwaliteitsgelden Medisch Specialisten) (SKMS), seven scientific associations formulated - in consultation with patients and health insurance companies - a top 5 list of knowledge gaps. The highest-priority knowledge gaps have been elaborated into a research proposal. Six of the seven research proposals have been approved in the meantime and will be financed by ZonMw and the health insurance companies' sectoral association Zorgverzekeraars Nederland (ZN). Thanks to this, the field parties are working together, which is a positive development.

Based on the experiences gained from the ENT knowledge agenda and the SEENEZ project, more and more scientific associations are working on establishing an agenda with prioritised knowledge gaps. In

2015 the agendas of clinical geriatricians and orthopaedists were published. Various other scientific associations are currently or will soon start developing a knowledge agenda, such as the following: the Dutch Association of Gastroenterology and Hepatobiliary Diseases (Nederlandse Vereniging van Maag-Darm-Leverartsen - NVMDL), Dutch Association of Urology (Nederlandse Vereniging voor Urologie - NVU), Dutch Association of Obstetrics and Gynaecology (Nederlandse Vereniging voor Obstetrie & Gynaecologie - NVOG), Dutch Association of Internists (Nederlandse internisten vereniging - NIV), Dutch Association of Rehabilitation Specialists (Nederlandse Vereniging van Revalidatieartsen - VRA), Dutch Association of Radiotherapy and Oncology (Nederlandse Vereniging voor Radiotherapie en Oncologie - NVRO), Dutch Association of Neurology (Nederlandse Vereniging voor Neurologie - NVN), Dutch Association of Clinical Chemistry and Laboratory Medicine (Nederlandse Vereniging voor Klinische Chemie en Laboratoriumgeneeskunde - NVKC) and Dutch Association of Radiology (Nederlandse Vereniging voor Radiologie - NVvR). These agendas will be published in 2016 and 2017.

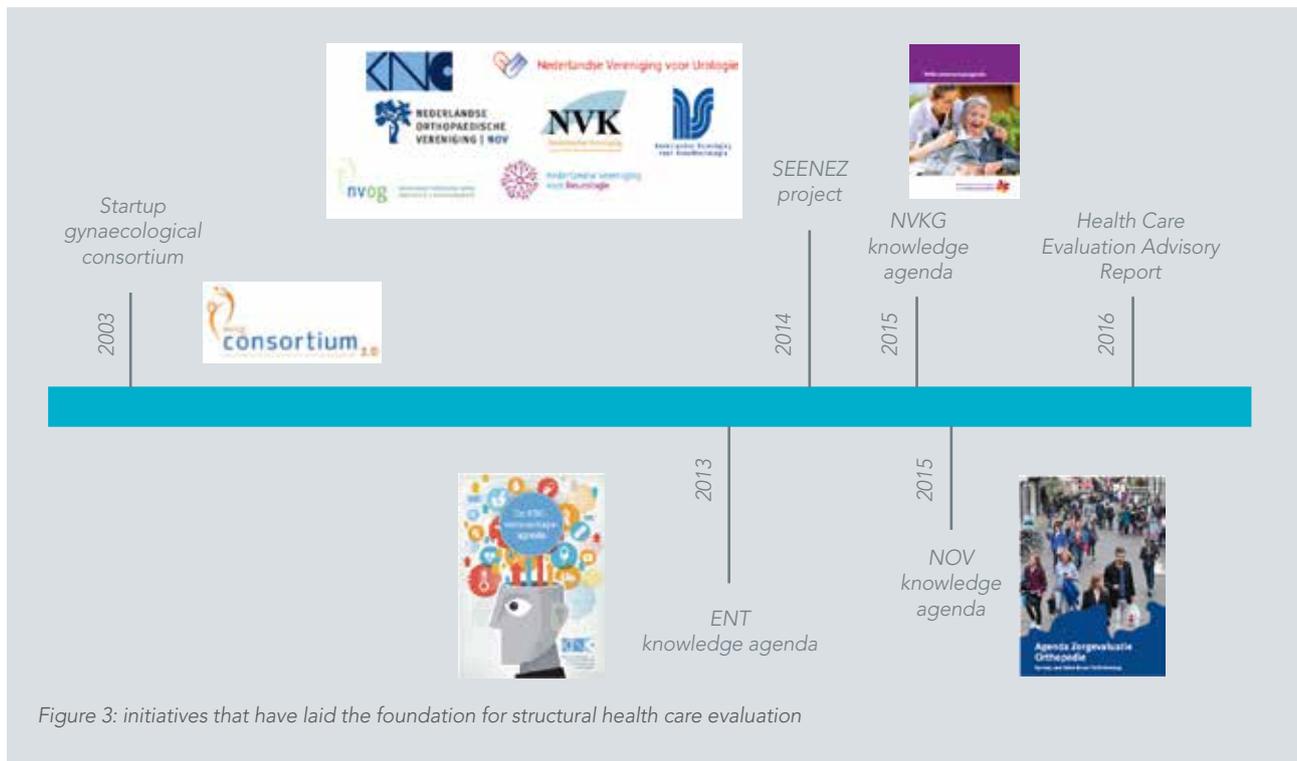


Figure 3: initiatives that have laid the foundation for structural health care evaluation

1.4 THE HEALTH CARE EVALUATION QUALITY COUNCIL PROJECT

More and more scientific associations are developing initiatives in the area of health care evaluation, and health care evaluation is considered to be an important social development (see Chapter 2). The question now is how we can best continue down this road together in order to achieve optimal results.

Given the importance of the topic, the Quality Council of the Dutch Association of Medical Specialists has set up a project (with financing from the SKMS and ZonMw) and a steering committee. The Health Care Evaluation Steering Committee is comprised of representatives of the 'front runner' scientific associations from the SEENEZ project.

The goal of the project is to further entrench health care evaluation in the medical specialist quality policy. The steering committee's task was as follows:

- bundle experiences pertaining to health care evaluation research (agenda-setting, execution at the institutions and financing);
- work out scenarios for the organisation and infrastructure of health care evaluation networks;
- elaborate models for structural financing of health care evaluation and provide tools for developing a revolving fund or shared savings. This was done in cooperation with stakeholders such as patient associations, health insurance companies, hospital groups and the National Health Care Institute (Zorginstituut Nederland).

The results of this project have been incorporated into this report.

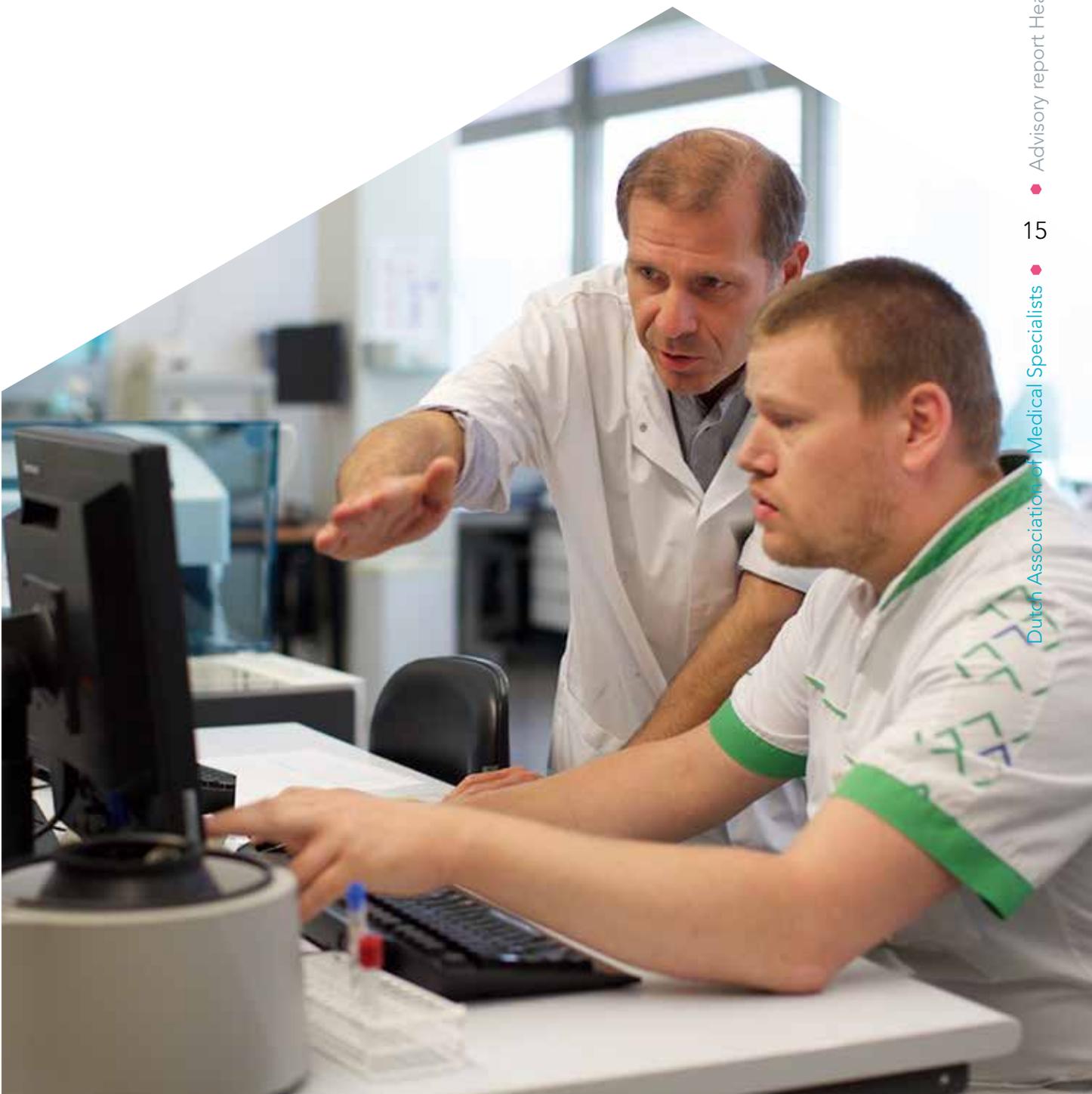
1.5 READING GUIDE

Chapter 2 delves in more detail into the ideas behind health care evaluation: What is health care evaluation and what are its components? In addition to the medical specialists' vision of health care evaluation, the vision of various stakeholders is also explained.

Chapters 3-6 further elaborate the components of the health care evaluation process. What does a good agenda entail and what are the important focus areas and criteria that must be required for each component?

Chapter 7 and 8 discuss two important preconditions for health care evaluation to succeed: managing and financing health care evaluation.

The appendices to this report are available as a separate background document at www.demedischspecialist.nl.





02 Definition of health care evaluation

2.1 INTRODUCTION

Chapter 2 delves in more detail into the vision and positioning of health care evaluation in the medical specialist quality policy. The Health Care Evaluation Steering Committee spoke with important stakeholders in order to find out their vision of health care evaluation. Important points stemming from these discussions are described.

2.2 QUALITY POLICY OF MEDICAL SPECIALISTS

When they take the Hippocratic Oath, physicians vow to uphold certain professional rules (KNMG oath of 2003). This oath describes the professional responsibility of physicians.

"I swear/promise to practice medicine to the best of my ability for the good of my fellow humans. I will care for the sick, promote health and alleviate suffering.

I will put the patient's interest first and respect his convictions. I will not harm the patient. I will listen and properly inform him. I will keep confidential that which is entrusted to me.

I will promote my medical knowledge as well as that of others. I recognise the limits of my capabilities. I will be open and verifiable, and I am aware of my responsibility to society. I will promote availability and accessibility to health care.

I will not misuse my medical knowledge, not even when pressured. I will in this manner respect the medical profession.

So help me God almighty.

or:

This I promise."

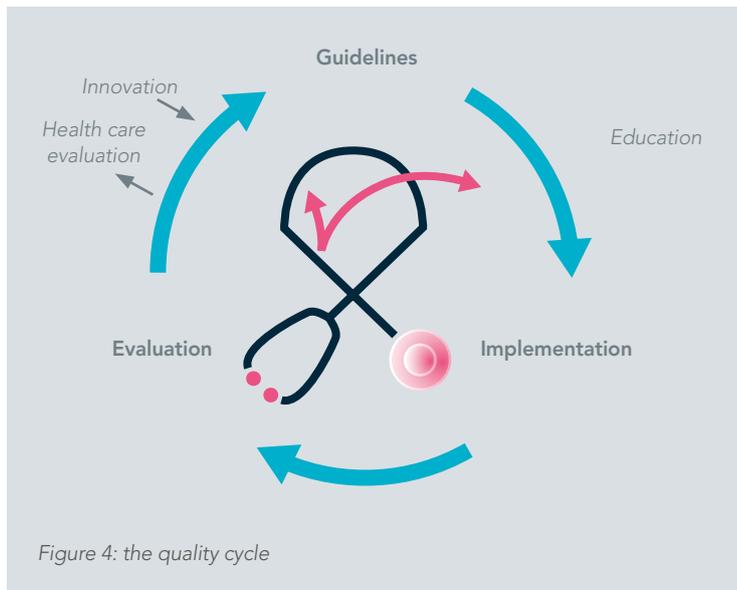
Physicians do much to demonstrate this professional responsibility. The values inherent to this oath form an important foundation for the quality policy of medical specialists. The fundamental principle of the quality policy of medical specialists is continuous improvement and guaranteeing of health care quality. Implementation of a quality cycle is an important objective.

Guidelines and norms form the professional standard for good health care. Implementation tools help apply the professional standard as best as possible in the workplace (e.g. provision of information to patients, training and further education materials and wise choices). Indicators and quality registries give specialists insight into their own actions. The quality visit validates the use of guidelines and quality information. The quality cycle is created thanks to this integrated quality policy (see Figure 4).

This cycle can only be completed after determination of the 'evidence' for (treatment) options in conjunction with their indication. This requires structural health care evaluation.

2.3 DEFINITION OF HEALTH CARE EVALUATION

Health care evaluation is clinical evaluation research into the (cost) effectiveness of existing care and is aimed at correct determination of interventions (indication for treatment or diagnosis). Various methodologies can be applied for this: experimental, observational or research through registries. By conducting research on important questions of effectiveness (questions from patients and doctors from clinical practice), clinical activities can be substantiated and guidelines can be refined. This results in health benefits for patients and effective care (see Figure 4). It therefore forms an important component of the quality cycle.



Important principles for successful health care evaluation are as follows:

- adequate examination and prioritisation of health care evaluation, resulting in alignment with knowledge questions from clinical practice;
- elaboration into a proper, feasible research topic and research design with support among the professional group(s) and patients;
- solid and extensive involvement by institutions (health care evaluation network) for fast inclusion, well-founded results and implementation. The clinical research must take place where health care is provided in the standard situation (in vivo), with a representative patient population. This is generally the case at a large number of Dutch hospitals;
- for implementation of the results in daily practice, it is necessary for the results to be clearly borne by the professional group. The results of the research must be included in the quality cycle by means of modular updating in guidelines (Guideline Database, www.richtlijndatabase.nl) and implementation in clinical practice (health care pathways, additional training and continuing education, health care procurement, patient information).

Health care evaluation is hence more than merely conducting a comparative analysis; it is a process entailing a number of important components (see Figure 5). It is important for there to be sufficient financing available in order to conduct extensive health care evaluation. Management is also necessary in order to make the health care evaluation process go as smoothly as possible. This process and the preconditions are described in chapters 3-8.

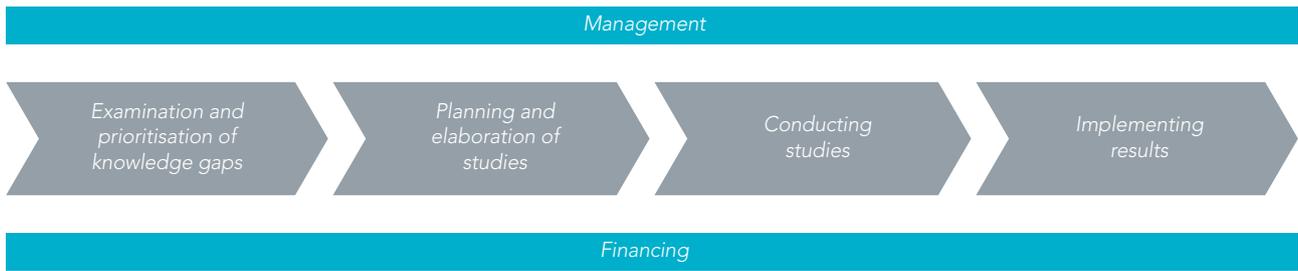
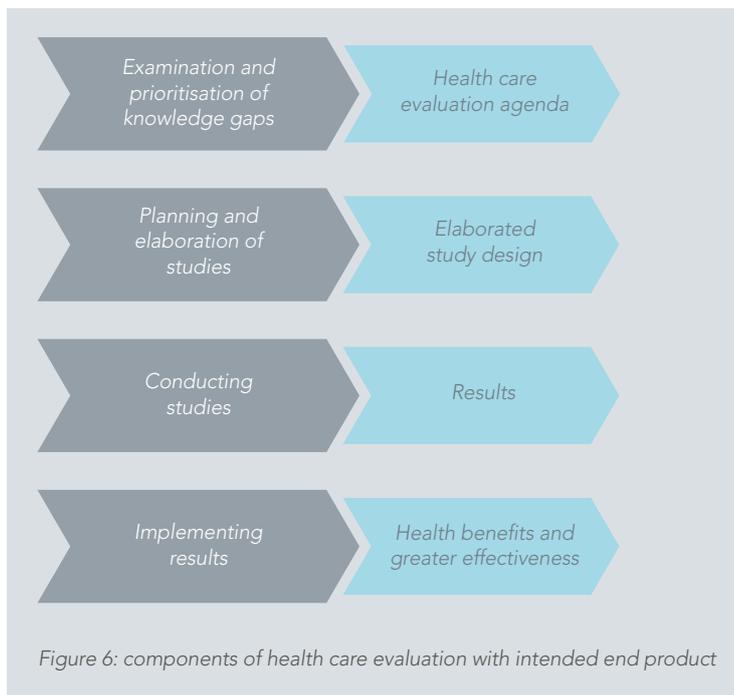


Figure 5: components of health care evaluation and preconditions

Figure 6 shows the end product per component.



2.4 STAKEHOLDER VISION

In order to find out the vision of stakeholders as regards their role in health care evaluation, interviews were held with the NPCF Federation of Patients (NPCF), ZonMw, the health insurance companies' sectoral association Zorgverzekeraars Nederland (ZN), Association of Top Clinical Teaching Hospitals (Samenwerkende Topklinische opleidingsZiekenhuizen - STZ), Netherlands Federation of University Medical Centres (Nederlandse Federatie van Universitair Medische Centra - NFU), Dutch Association of Hospitals (Nederlandse Vereniging van Ziekenhuizen - NVZ) and the National Health Care Institute (Zorginstituut Nederland - ZINL).

Appendix 1 of the background document (to be found at www.demedischspecialist.nl/onderwerp/zorgevaluatie) has a table which elaborates the stakeholders' vision regarding various components. Below is a brief summary of the most important points of each stakeholder.

1. **NPCF:** the NPCF considers health care evaluation to be an important component of the medical quality policy and wants to actively participate in it. This is already happening with the health care evaluation agenda, both with regard to examination and prioritisation of the knowledge gaps. The NPCF sees a role in making health care evaluation a point of discussion in the conversation between physicians and patients/clients in order to facilitate inclusion in the research and implementation of the results.
2. **ZonMw:** ZonMw considers health care evaluation on the (cost) effectiveness of existing health care to be an important form of effectiveness research. Continuous health care evaluation costs money, but in the end these evaluations produce a multitude of the original investments. This is, however, under the



condition that the results of the research are actually applied in practice. ZonMw therefore proposes that a part of the resources that are saved by health insurance companies and public authorities through health care evaluation be used for a research and implementation fund. With this fund, the sector itself can also benefit from the savings, making it possible in the long term to generate even more savings with the output of the conducted evaluations. ZonMw has worked out this shared savings fund in its 'Shared Knowledge, Shared Revenues' statement (February 2015). In addition, ZonMw wants to facilitate the creation of networks, whereby it views networks as formalised joint ventures between research and practice. Their 'Usefulness and Necessity of Networks' report shows that the use of networks creates more possibilities in order to (a) conduct better and more applicable research and (b) be able to apply research results more quickly.

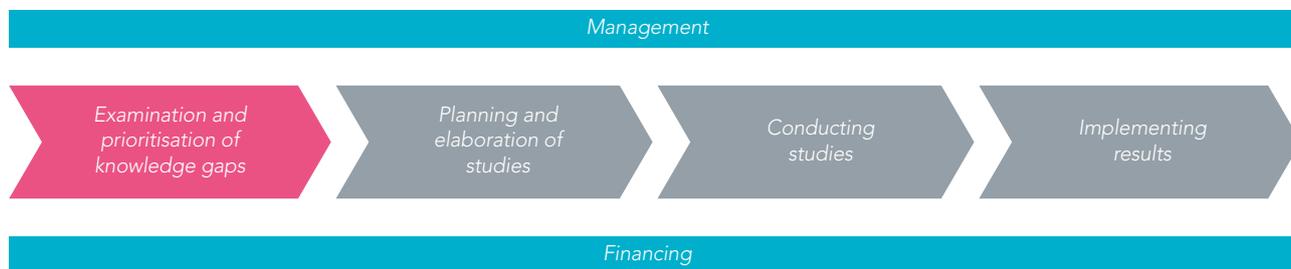
3. **ZN:** the management of ZN expressly wishes to give impetus to the movement within the medical professional group in order to bring about more effective health care. They deem this to be a particularly positive development. This is also the reason why they want to financially support the SEENEZ initiative. ZN has also developed a number of criteria to indicate what constitutes relevant health care evaluation research for them. ZN's viewpoint is that it does not finance research in the strict sense because this is not one of the health insurance company's core tasks.
4. **STZ:** improving health care quality by means of clinical scientific research is high on the STZ's agenda, and it sees itself playing a role in conducting health care evaluation research. In recent years, the infrastructure for this type of research at STZ hospitals has been made possible by the development of local research centres, united in a national network. The STZ has pledged its commitment to conduct studies within the scope of SEENEZ and also to implement the guidelines stemming therefrom (letter to the Ministry of Health, Welfare and Sport, 5 August 2014).
5. **NFU:** the NFU, the umbrella organisation of the UMCs, jointly has access to the Citrien Fund (Citrien-fonds). This fund was created by the Ministry of Health, Welfare and Sport in order to tackle a number of social challenges and has a budget of EUR 25 million. One of its focus areas is to curb unnecessary health care. The NFU believes it is crucial to co-ordinate with existing initiatives in order to curb unnecessary health care, such as the Wise Choices (Verstandig Kiezen) initiative by the Dutch Association of Medical Specialists and the Stimulate Effective and Eliminate Non-Effective Health Care (SEENEZ) project. The NFU sees itself as playing the role of an expertise centre for the conduction of health care evaluation research. They see possibilities of using the Training and Education Region (Opleidings- en Onderwijs Regio - OOR) association for conducting research in networks.
6. **NVZ:** the NVZ considers 'value based health care' to be important, and health care evaluation is consistent with this principle. The member institutions provide volume health care, which is often the topic of evaluation. They deem it their responsibility to provide this health care in an effective manner. Research is a clear priority at the STZ. This is not the case at the NVZ. They do, however, find it important for general hospitals to be involved, especially in order to effectuate implementation of the results (guidelines). There is little experience and infrastructure at the general hospitals, so cooperation with university hospitals and STZ hospitals is desirable.
7. **ZINL:** at the request of the Ministry of Health, Welfare and Sport, the National Health Care Institute launched a 'sensible health care' programme with the objective of fostering suitable use of health care. This programme employs a comprehensive, systematic analysis of ICD areas to determine which focus areas there are from the perspective of good and sensible health care. The scientific associations and the Federation are involved in this programme. This programme is being implemented with a top-down design, while health care evaluation topics are derived from the practice of medical specialists. The Health Care Institute is motivated to investigate how the involved parties can work together in an effective manner.

2.5 CONSIDERATION

Stakeholders view health care evaluation as an important development to which they wish to contribute as part of their responsibility. The stakeholders' vision is clearly an extension of the vision of the medical specialists. What is important to them is that health care evaluation be more than just a research project but rather a process for truly achieving health benefits and greater effectiveness. All parties stress that implementation is an inextricable part of health care evaluation. In order to truly achieve health benefits and greater effectiveness, it is necessary to work on implementation during the entire project instead of merely viewing this as the next step after the research phase.



03 Examination and prioritisation of knowledge gaps



3.1 INTRODUCTION

Compiling an agreed-upon knowledge agenda is the first step in the health care evaluation process. With regard to the agenda, it is important for the scientific associations to take the initiative on this. After all, health care evaluation is a part of the quality cycle of their medical care.

Given the large number of knowledge gaps in medical practice, it is important to examine these gaps, prioritise them and then place them on the agenda for research. Experience with this process has been gained within the scope of the SEENEZ project. In addition, a number of scientific associations have now compiled an agenda within their discipline. This chapter summarises the experiences and provides recommendations.

Various names are used for the agendas that describe knowledge gaps. The Health Care Evaluation Steering Committee recommends the following definition:

Health care evaluation agenda: A description of the most important knowledge gaps of existing health care within a discipline and an action plan as to how these knowledge gaps can be resolved with clinical research. The goal is to improve the quality and efficiency of the health care. The health care evaluation agenda can be a separate component of a 'more extensive' knowledge agenda which also entails other types of knowledge gaps.

Before an inventory of the knowledge gaps can be taken, it is important to put together a working group of medical specialists who have a high degree of support within their own professional group. Furthermore, there must be a good distribution between:

- 1) academia/non-academia;
- 2) geographic distribution;
- 3) focus areas;
- 4) involvement of doctors in specialist training (AIOS) and young medical specialists.

3.2 EXAMINATION/INVENTORY-TAKING

There are 3 sources for examination of knowledge gaps:

1) Analysis of knowledge gaps in the guidelines of the initiating scientific association and chapters from guidelines of which the scientific association is not an initiator but in which it is involved.

Knowledge gaps are:

- conclusions with an level of evidence of 3/4 or low/very low;
- recommendations for further research;
- sometimes a separate chapter or appendix with knowledge gaps, which is then adopted.

2) Examination of knowledge gaps by members of the scientific association(s) and members of the patient association(s).

- Online questionnaire about the top 3 or top 5 knowledge gaps that are encountered (when practicing the profession) in daily practice. The request is to write down the knowledge gaps in the form of a research topic.

3) Examination of knowledge gaps among the remaining stakeholders.

- This includes GPs, physical therapists, the health insurance companies' sectoral association Zorgverzekeraars Nederland, the National Health Care Institute and the Health Care Inspectorate;
- Data entry form for the top 3 or top 5 knowledge gaps from their perspective and expertise. The request is to write down the knowledge gaps in the form of a research topic.

3.3 PRIORITIES

The knowledge gaps will be prioritised based on the following criteria:

- relevance (severity, incidence/prevalence, costs);
- urgency;
- researchability/feasibility;
- impact on the discipline / societal impact.

These criteria are in line with the criteria or preconditions for compensation of effectiveness research that Zorgverzekeraars Nederland wants (see Appendix 3 in the background document).

The number of topics that are included in the agenda can be determined per association and will depend on the number of sub-areas. Both the working method, the formation process as well as the prioritisation criteria and the substantiation of the prioritisation must be included in the explanation of the agendas as a standard component. Questions with the highest priority will be placed at the top of the agenda.

3.4 THE AGENDA

A number of issues are important when developing the agenda:

1) Formulation of the knowledge gap in a research topic

When examining knowledge gaps for both the members of the scientific association as well as for the other stakeholders, the preference is for the knowledge gap to be formulated as a research topic. The PICO (patient group, intervention, control of intervention and outcome measures) must be clear for this. Based on this, the researchers further elaborate the research topic in consultation with the scientific association (see Chapter 4).

2) Exploratory literature search for the top 10 knowledge gaps

An exploratory literature search for both domestic and foreign studies of current research is done for the top 10 in order to prevent unnecessary repetition of research. For the same reason, a check of the trial registry is also part of the procedure. The next step is international coordination of the agenda and distribution of the conduction of studies. International coordination and cooperation is also essential for conducting evaluation studies on the diagnosis and treatment of rare disorders.

3) Linking to guidelines

How a topic is linked to the guideline in the Guideline Database is indicated for each topic, so that it is clear how the result is incorporated into (a module of) the guideline.

4) Examination of lines of research

The lines of research of the UMCs, STZ hospitals and teaching hospitals are examined. The objective here is to see whether (and how) the prioritised knowledge gaps relate to existing scientific activities and whether alignment can be established here.

5) Definition of the validity period

The validity period of an agenda must be mentioned in the agenda. The Steering Committee believes that the topicality has to be verified after a period of three years. Appendix 2 of the background document (to be found at www.demedischspecialist.nl/onderwerp/zorgevaluatie) contains a step-by-step plan that explains the methodology for developing an agenda, along with the time frame that must be adhered to for this. This methodology ensures that the knowledge agenda complies with the checklist that ZonMw has established for the usability of knowledge agendas for the ZonMw programme (see Appendix 4 of the background document).

3.5. RECOMMENDATIONS

Establish a working group comprised of medical specialists focusing on:

- good distribution of academia/non-academia;
- good geographic distribution;
- good distribution of focus areas;
- good involvement of doctors in specialist training (AIOS) and young medical specialists.

Identify and prioritise the knowledge gaps together with patient associations.

Identify and prioritise these knowledge gaps, if relevant, together with other involved parties, such as GPs, physical therapists and health insurance companies.

Prioritise the knowledge gaps based on the following criteria:

- relevance (severity, incidence/prevalence, costs);
- urgency;
- researchability/feasibility;
- impact on the discipline / societal impact.

Conduct an exploratory search for the topics with the highest priority.

Create a link between the topics with the highest priority and the guidelines in the Guideline Database.

Formulate the topics with the highest priority into a concrete question with a brief explanation.

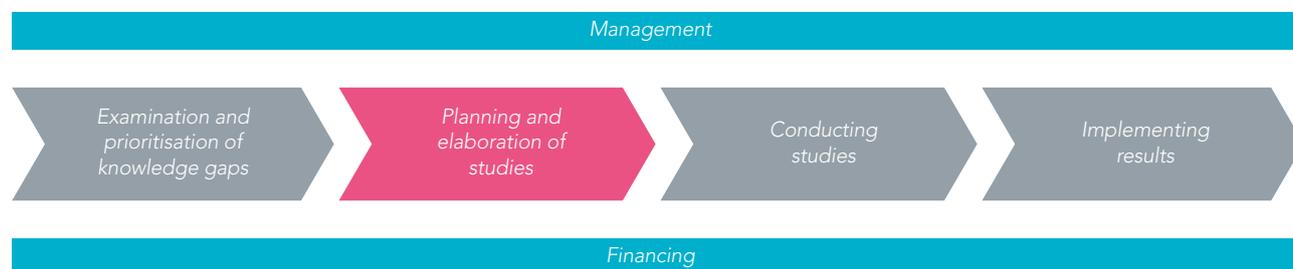
Take stock of the lines of research of the UMCs, the Association of Top Clinical Teaching Hospitals (STZ) and teaching hospitals to see whether the prioritised knowledge gaps can align with existing lines of research.

Have the topics with the highest priority be confirmed by the board of the scientific association.

Examine whether the agenda needs to be updated in three years.



04 Planning and elaboration of studies



4.1 INTRODUCTION

This chapter describes the process of how scientific associations go from a health care evaluation agenda to a full-fledged study design by forming networks within the discipline. Conducting an evaluation study in a reliable manner in a relatively short amount of time requires the direct involvement and cooperation of medical specialists within a scientific association. Thanks to the formation of a network, multicentre studies with a large number of inclusions can be conducted in a uniform manner. Extensive involvement of the professional group also ensures that the results of the evaluation study become widely accepted, thereby allowing the results to be quickly implemented in daily practice.

Chapter 5 delves in more detail into the required infrastructure for conducting the studies, such as monitoring, research staff and trial offices.

4.2 PLANNING AND ELABORATION OF STUDIES

The prioritised knowledge gaps must be translated into a good research proposal. Various forms of evaluation may be chosen, such as comparative research in existing quality registries or an RCT. The evaluation form is context-specific and depends, among other things, on the topic of the study, treatment or diagnosis, long-term consequences, required evidence level, etc. When elaborating the studies, the programme frameworks that the intended financiers, such as ZonMw, stipulate must be taken into account.

In the current situation, cooperation between researchers, medical specialists and patients is often lacking within a certain discipline when elaborating and designing clinical research. Cooperation leads to more and better knowledge in clinical practice. It often results in more solidly substantiated questions. Achieving coordination between researchers within a scientific association is desirable. This is important for obtaining support and for reliable conduction of health care evaluation studies. The scientific association has a facilitating role in this. This facilitating role must ensure:

- widespread and reliable inclusion;
- guaranteed implementation of the results.

The first coordination effort can, for example, take place by means of a meeting, organised by the scientific association and attended by researchers and medical specialists who work at various institutions in the area of the research topic. At this meeting, the participants can jointly select the principal investigator and find out who wants to be involved in the study. Such a method increases support for the study and the initiator within the association. In addition to researchers and medical specialists, it is wise to involve doctors in specialist training in these meetings. This not only ensures obvious incorporation of the concept of health care evaluation in the training, but these doctors also often play an important role in the conduction and implementation of the study.

In short, it is important for there to be a shift towards more cooperation and network formation in the elaboration and conduction of studies. Ideally, this cooperation in networks should involve as many hospitals/institutions as possible who provide health care at those locations being evaluated. The scientific association can have a facilitating role in this.

4.3. EXPERIENCES OF EXISTING NETWORKS

Based on a literature study and interviews, experiences with respect to networks were examined both internationally as well as in the Netherlands. The search justification and a comprehensive overview of this can be found in Appendices 5 to 10 of the background document (<http://www.demedischspecialist.nl/onderwerp/zorgevaluatie>).

The described networks are heterogeneous in nature, and the data reporting in the publications is faulty, making it difficult to reach clear conclusions regarding efficiency and success factors. Success factors that are repeatedly listed: good (central) coordination; clear agreements about (joint) publication policy and regular meetings. Solid agreements regarding (structural) financing are also mentioned.

The reporting is also faulty and heterogeneous in nature with respect to the results of the networks. Globally, it can be concluded that networks promote cooperation and support, thereby having a positive effect on inclusion and implementation of research results.



4.4 SCENARIOS OF NETWORKS

Different phases (scenarios) in network formation can be distinguished. The various scenarios are elaborated in Table 1, including the advantages and disadvantages per scenario.

Scenario	Characteristics	Advantages	Disadvantages
1. No network within the association	Ad hoc submission of studies (is often the current situation)	None	Risks of: - coordination problems, - inclusion problems, - support problems and hence extensive implementation.
2. No network, some in-house coordination within the association	Committee/working group/ point of contact within the association that coordinates with the researchers, with the association supporting studies from the existing health care evaluation agenda of the respective association.	The support of the association gives a greater chance of receiving financial backing Prevention of duplication between studies.	Compared to Scenario 1, fewer risks of: - coordination problems, - support problems and hence extensive implementation. Inclusion problems
3. Network of researchers within an association	Researchers consult each other, submit studies jointly and coordinate issues regarding inclusion. Conclusion of agreements about conducting studies and distributing tasks. The association coordinates/ facilitates. Knowledge is shared within the network.	In addition to the points listed in Scenario 2; broad support within the association, hence better implementation of results. Coordination between researchers. Reliable and faster patient inclusion. Increased quality of research proposals.	Investment is needed within the association. Time needed to achieve collaboration and coordination between researchers. No complete management.
4. Integrated network	The facilities, such as a trial office, are integrated within an association. There is central management of the association.	In addition to the points listed in Scenario 3; broad support within the association, hence better implementation of results. Extensive coordination between researchers. Reliable and faster patient inclusion. Increased quality of research proposals. Increased chance of reliable study conduction. Complete management.	Major investment is needed. Financial risk for the association. Can only succeed if there is a considerable number of studies conducted per year within the network.

Table 1: description of various phases (scenarios) of networks

The above scenarios comprise a growth model of the situation 'no network' to 'an integrated network'. Which scenario fits best with the scientific association depends on existing cooperation and the quantity of studies. Scenarios 3 and 4 ensure widespread support within the association. Integrating facilities within the network in scenario 4 requires major investment and is associated with financial risks. The NVOG consortium shows that this can only be sustainably achieved with a continuous stream of 20 on-going studies. However, it must be ensured that not too many studies are conducted in the same patient population, as this would put pressure on rapid and reliable patient inclusion.

Multiple scientific associations may be involved in forming a network for multidisciplinary topics. Facilities (generic functions) can be shared between associations. Chapter 5 contains an elaboration of this.

4.5 METHODOLOGICAL SUPPORT

Methodological expertise is important for a high-quality design of the studies. This includes, for example, power calculations, outcome measures, study design, cost effectiveness analysis (CEA), etc. This must be easily accessible and can be obtained, for example, through the clinical epidemiology/HTA departments of the university medical centres, or from the epidemiologists/HTA experts associated with the larger trial offices. Making agreements about the use of this is desirable.

4.6 RECOMMENDATIONS

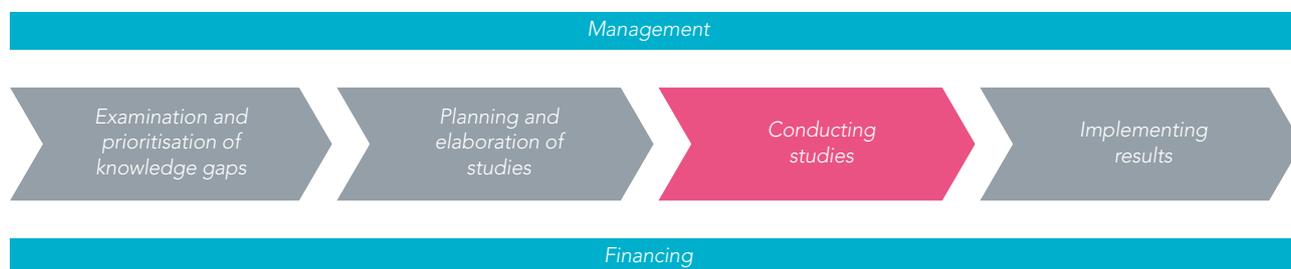
Aim for network formation in order to optimise the planning and design of studies and maximise the conduction and implementation of studies.

Development of a network is a growth model in which certain phases (scenarios) can be distinguished. Choose a scenario that is suitable for the association; this has to do with existing cooperation and the quantity of studies.

Aim for comprehensive involvement of specialists working at various institutions, ideally at all hospitals where the health care that is to be evaluated is being provided.

For elaboration of the study, it is necessary for the network to have easily accessible methodological expertise available to it (clinical epidemiology/biostatistics).

05 Conducting studies



5.1 INTRODUCTION

How can health care evaluation studies at hospitals/institutions be organised efficiently and in good quality? In the current situation there is a lot of heterogeneity in the conduction of studies, which is manifested, for example, in various monitoring procedures. Furthermore, increasingly higher requirements are being placed on research, and the budgets are not becoming bigger. This chapter discusses in more detail a number of aspects relating to conducting studies, such as the required infrastructure, monitoring procedures, use of research staff and trial offices.

5.2 UNIFORM CONDUCTION

When conducting a health care evaluation, various functions are needed for supporting the studies. This concerns the following:

1. quality monitoring/monitoring;
2. data management: entry and processing of data from the studies;
3. statistical and economic analysis;
4. communication.

These activities are frequently shaped in a trial office and offered at various locations. The NVOG network, for example, has its own trial office, but there are also trial offices in the university centres and STZ hospitals.

In the current situation, there are many differences in the manner in which studies are being conducted, and different hospitals/institutions employ their own procedures for medical ethics review and data monitoring. It is important for the research to be conducted in a uniform manner at each hospital and for data monitoring to take place using a standardised process. The data monitoring procedures must be centrally established and offered, and agreements must be concluded about this.

Interviews with researchers have exposed bottlenecks in particular with regard to medical ethics committees (MECs). Studies must be submitted to a central MEC for approval, and locally only approval for the conduction should have to be given. However, this procedure varies greatly, and it is a regular occurrence for a study to have to be entirely reviewed again at the local level. In addition, high requirements are stipulated, often the same as for new drug studies. However, in order to compare treatments that are being regularly applied in practice, adoption of a less strict review process is desirable.

Such central agreements about clear procedures will benefit efficiency and the duration of the study conduction. The costs of the research are also expected to decrease due to this.

5.3 RESEARCH STAFF

Medical specialists and research staff are involved in patient inclusion at the hospitals. Medical specialists select the patients who are eligible for on-going research, after which patients are informed and included (or not) by the research staff. In an ideal world, patient inclusion in a study takes place by research staff members who explain the study, handle the inclusion and complete the Case Record File (CRF), before, during and after completion of the study.

If health care evaluation studies are extensively conducted at an institution (multiple studies across various disciplines), then it is of increasing importance to optimise the use of research staff. In this case an important question is to which extent research staff should be used per speciality/discipline (specific) or in a more cross-discipline (generic) manner.

Pro specific:

- The research staff members know the discipline and can therefore also answer many of the patients' questions. This is to the benefit of inclusion;
- Cross-discipline use also requires comprehensive competency and knowledge on the part of the involved staff. In the current situation, this comprehensive knowledge and competency is generally lacking among the respective staff.

Contra specific:

- required use of many employees with a small scope of (part-time) employment. Difficult in terms of management, less flexible and efficient.

Further elaboration of how to efficiently use research staff at institutions is desirable. The task description and training of the research staff must be discussed.

5.4 COOPERATION WHEN CONDUCTING STUDIES

It is expected that various networks will be created in the near future, with various trial offices being involved (see Figure 7).

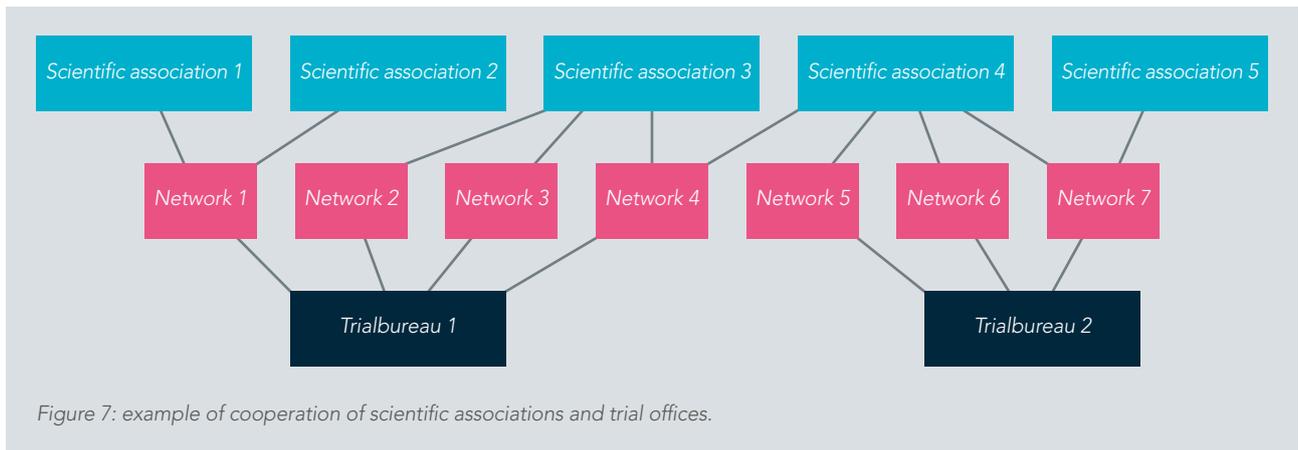


Figure 7: example of cooperation of scientific associations and trial offices.

In order to create an efficient and sustainable infrastructure across all networks, it seems to be important to share facilities. It is desirable to investigate further how this facilitation can take place and how many networks and trial offices are needed. This needs to be further elaborated in cooperation with the hospitals (STZ, NVZ and NFU).

5.5 COSTS OF CONDUCTING STUDIES

In recent years, the quality requirements and regulations with which studies (including health care evaluation studies) must comply have been further refined, which is also associated with increased costs for these studies. However, it appears that the research budgets at financial backers and sponsors has not increased at the same speed. Furthermore, it proves to be difficult to invest in the sustainable maintenance of the research infrastructure.

Globally, costs for conducting health care evaluation can be divided into the following components:

- the time spent by the project manager;
- the hiring of a physician-investigator as a study coordinator;
- the costs of methodology, monitoring, study software, a (national) network, decentralised (for a small number of studies (<5) without central management, or centrally managed by a trial office (>=5);
- inclusion compensation to participating sites for activities related to including patients;
- costs (related to) drugs for drug studies;
- other costs (MEC/local approval).

Based on the experiences of the NVOG consortium, it may be calculated that the costs associated with conducting a regular health care evaluation study are currently around € 420,000 (see Appendix 11). For health care evaluation studies with drugs, this figure is higher by € 120,000 (see Appendix 11 in the background document).

The inclusion compensation is an important item in this calculation. In practice there are significant differences in compensation for / costs of inclusions. On the one hand, this is caused by differences in the type of study and the associated time needed for patient inclusion. On the other hand, differences are also caused by the degree to which costs are or can be passed on for the principal investigator (medical specialist), for example. Differences in the classification of research staff (research nurses) also affect the inclusion costs. The NVOG consortium applies a uniform hourly rate for use of research staff for the inclusion process of € 51.

It is important to conduct more comprehensive investigation into the standardisation of the costs of studies and the sustainable use of the required infrastructure, such as trial offices and research staff.

Based on this, it will be possible to make agreements with the financial backers of research about the budgets for the health care evaluation research that is to be conducted.



5.6 RECOMMENDATIONS

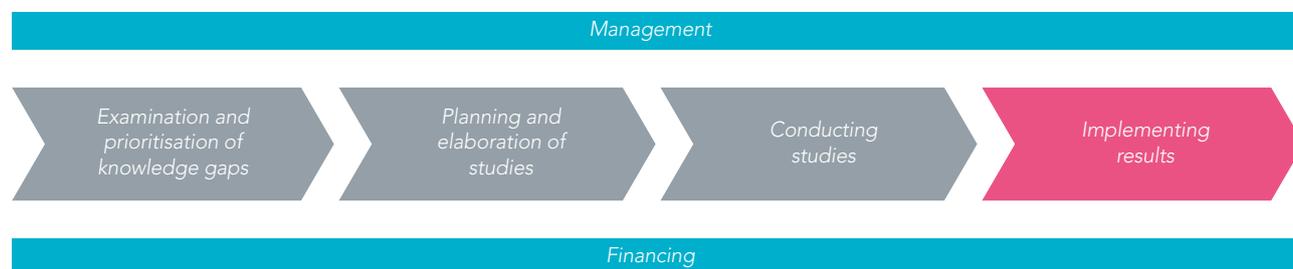
It is important for clear agreements to be established regarding data monitoring, review by MECs and use of research staff, so that good-quality studies can be efficiently conducted at the hospitals.

The development of an efficient and sustainable infrastructure is desirable, in which the possibilities for sharing facilities needs to be elaborated. Within this context, it must be investigated together with the hospitals (STZ, NVZ and NFU) whether agreements can be made regarding the set-up and functions of trial offices and research staff.

It is desirable to investigate the standardisation of the costs of health care evaluation studies and the sustainable use of the required infrastructure, such as trial offices and research staff. In addition, structural financing is important for maintaining a sustainable infrastructure.

Sustainably maintaining the infrastructure for health care evaluation is very important for the efficiency, speed and quality of study conduction. Such an approach requires structural investment.

06 Implementing results



6.1 INTRODUCTION

Health care evaluation is only useful if the research results are actually implemented in the workplace. In the past, projects were frequently carried out whose sole result was scientific publication (or no publication at all), with daily health care not or barely benefitting from the new knowledge. Implementation of the study results ensures that patients can actually benefit from the health care evaluation. Here implementation is described as the last phase of the health care evaluation process. This is somewhat artificial, given that implementation is a part of all phases of the health care evaluation process. For example, implementation already begins with compiling a well-balanced working group that stipulates the agenda.

6.2 EXPERIENCES AND INTERPRETATION

Implementation via the quality policy of scientific associations

In the past, knowledge was incorporated into guidelines with a significant delay. Thanks to the arrival of the Dutch Guideline Database (Richtlijndatabase) (www.richtlijndatabase.nl), inroads were made into faster incorporation into guidelines due to the possibility of modular maintenance. This way health care evaluation can have a direct impact on guidelines. Continuously incorporating the outcomes of the studies into guidelines makes an important contribution to implementation of the results.

A condition of this direct impact on guidelines is that the health care evaluation be a study with sufficient power that was widely conducted in the Netherlands. This is important because this is the only way that the study can achieve a higher evidence level both in the guideline as well as within the scope of the implementation of the results. Extensive conduction of the studies at the hospitals that are part of a national network ensures that the results of the evaluation study become widely accepted, thereby allowing the results to be quickly implemented in daily practice. Health care evaluations conducted within the gynaecologist network show good implementation and demonstrate the importance of good, efficient organisation.

Implementation is different from conducting research. The researcher or research group cannot be held responsible for implementation of the results in the workplace and has no power to push anything through within the professional group. Moreover, the researcher lacks the objectivity required to correctly assess the study results. However, responsibility for implementing the research results may be expected from a scientific association. Especially since the respective research is also the result of a careful assessment process of knowledge gaps within the respective scientific association. It is therefore logical that the scientific associations and not the researchers assume responsibility for the implementation process. This concerns at the very least quickly adapting the respective guidelines based on the research results (modular maintenance via the Guideline Database) and the dissemination of new knowledge using the regular tools of the scientific association such as additional training and continuing education, and quality visits.

The researchers are expected to provide the research results to the scientific association for implementation. The study first has to be published in a peer-reviewed journal before it can be included in the guideline. It is important for the scientific association to monitor the implementation. The researchers and the scientific association must agree on the required budget and who is responsible for the implementation. The research proposal must mention that the implementation will take place in consultation with the scientific association as well as how any costs incurred will be settled. The costs for the implementation project can differ per scientific association. This has already been widely entrenched in some scientific associations, for example through guidelines, visitation, etc., and the costs have already been included in the budget for the scientific association. At other scientific associations, implementation will be at the expense of the research project. A combination of these two options is also possible.

Implementation through health care procurement

Health insurance companies can also make an important contribution to fast implementation of the research results. By translating the results of the studies into the procurement policy, insurers can stimulate the field parties to provide health care in compliance with the guidelines that are based on the results of the respective new research. In addition, it is conceivable that health insurance companies will conclude multiple-year contracts with institutions that permanently participate in health care evaluation studies and directly entrench the study results into workplace activities.

Implementation through the Boards of Directors of institutions

In accordance with existing legislation, the Board of Directors (BoD) of a health care institution is directly responsible for the health care provided at the respective institution. Cooperation with research by an institution allows experience to be gathered with the respective types of health care during the research period already, which in turn permits entrenchment to take place through institution protocols and health care pathways after the research has been completed. The BoD has an encouraging and facilitating role in this. Furthermore, participation in research also appears to have an effect on the implementation culture at institutions. Experiences from institutions that are part of the NVOG consortium, for example, show that participation in the consortium also resulted in faster implementation of NVOG guidelines other than those pertaining to the research.

6.3 RECOMMENDATIONS

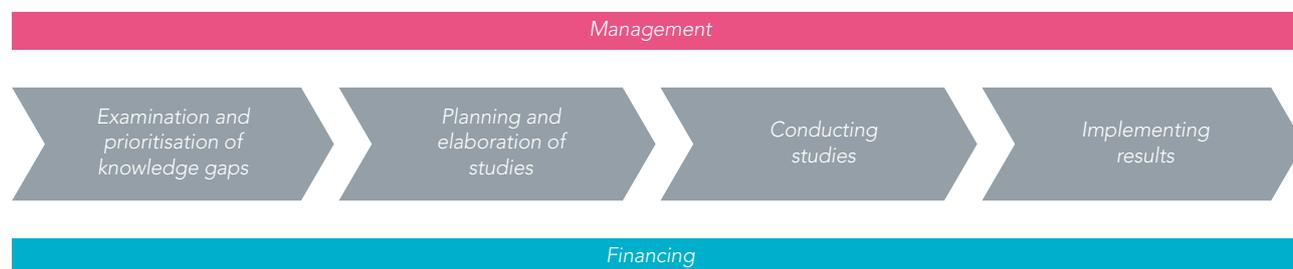
Compile an implementation plan for each implementation plan. This is the responsibility of the researcher in cooperation with the medical specialist / scientific association. Execution and monitoring of this are the responsibility of the scientific association.

As a scientific association, guarantee implementation of the results in practice. This includes issues such as the following:

- visible streamlining of guidelines in the Guideline Database;
- involvement of hospitals through the national structure of a health care evaluation network;
- distribution of new knowledge by means of additional training and continuing education, quality visits, etc.

Promote implementation through health care procurement and through the institution's Board of Directors.

07 Management



7.1 INTRODUCTION

This chapter makes a proposal for the organisation within the Federation and the anticipated role of the stakeholders in order to be able to solidly entrench health care evaluation into the medical specialist quality policy, thereby making it a success.

7.2 COOPERATION OF SCIENTIFIC ASSOCIATIONS

7.2.1. Role of scientific associations

The scientific associations united within the Federation have an important role in the success of health care evaluation. In order to make health care evaluation a part of the quality cycle, it is necessary for the scientific association to fulfil a clear central and coordination function. The role and responsibility of the scientific associations concerns:

- examination, prioritisation and agenda-setting of knowledge gaps, so that the knowledge questions align with clinical practice and structural agenda-setting takes place;
- coordination to ensure correct programming: elaboration of the research topic by a researcher nominated by the scientific association;
- ensuring that network formation takes place within the discipline for efficient elaboration of the health care evaluation; the organisational level should be aligned with the scope and level of the development of the association in this area (see also Chapter 4);
- overall monitoring of the course of the studies and signalling of bottlenecks;
- implementation of the results through integration into the quality tools (such as guidelines) and quality policy.

The conduction of the studies is primarily the responsibility of the researchers, in connection with the hospitals who can provide the required infrastructure.

It is recommended that the association guarantee the health care evaluation process from an administrative perspective. The manner in which this is done depends on the organisational form of the scientific association and the phase in which the health care evaluation file currently is within the association. Given that the health care evaluation file intersects with quality, education, science and professional interests, delegating this to a separate committee with members who represent related committees could be a consideration.

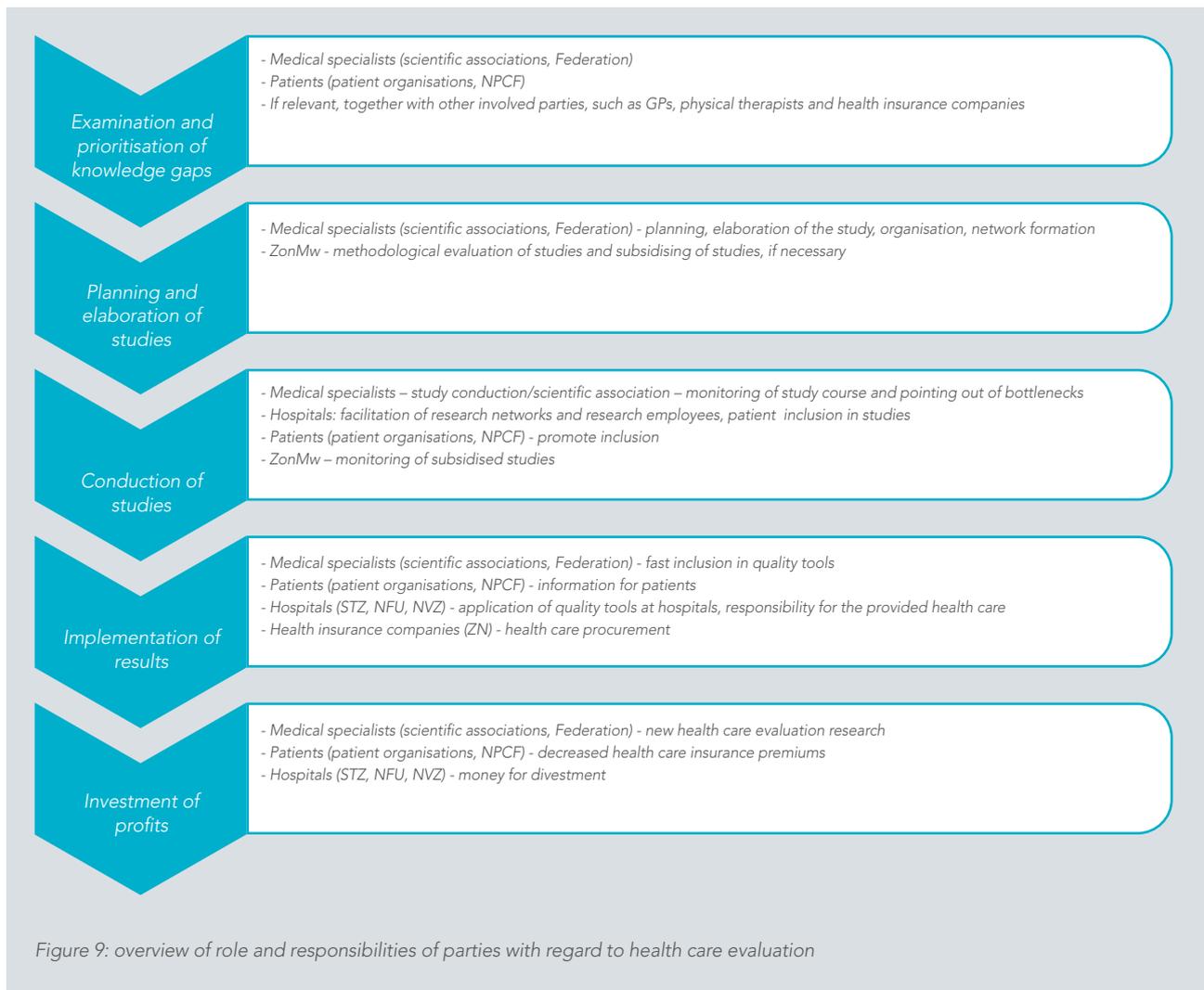
7.2.2 Cooperation of scientific associations within the Federation

It is also desirable for scientific associations to jointly coordinate and facilitate a number of matters within the Federation:

- 1) Joint policy regarding health care evaluation (interorganisational positioning in the Federation), support of scientific associations in formulating an agenda, forming networks, incorporating results into the quality policy (implementation, including revision of guidelines);
- 2) Facilitation to help networks work uniformly: generic procedures for monitoring and inclusion, among other things;
- 3) Consultation, coordination and cooperation with (umbrella) stakeholders: NPCF, ZonMw, ZN, STZ, NFU, NVZ.

7.3 PROPOSAL FOR STAKEHOLDER ROLE AND RESPONSIBILITY

Based on the vision of medical specialists and the various stakeholders (see section 2), a proposal has been elaborated regarding the role and responsibility of the involved parties in the steps of the health care evaluation process. The main idea of this proposal is illustrated in Figure 9.



7.4 RECOMMENDATIONS

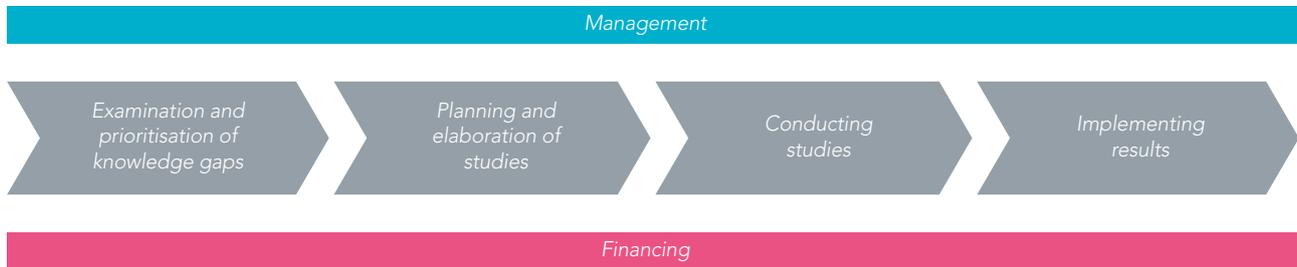
Central management/coordination and support at the Federation's level is required in order to guarantee health care evaluation. This way health care evaluation will be jointly managed, and a service portfolio will be created for supporting the development of health care evaluation networks (facilitation of organic growth, from opportunity network to sustainable network).

It is necessary to set up a health care evaluation advisory committee within the Federation that will set policy in cooperation with various boards, elaborate generic procedures and standpoints and maintain contact with the most important stakeholders with regard to health care evaluation.



08

Financing



8.1 INTRODUCTION

In addition to benefiting patient health, health care evaluation also benefits efficiency. In its reports ('Gedeelde kennis gedeelde opbrengsten, ZonMw, February 2015, and 'Notitie Kostenbesparingen door onderzoek en innovatie in de zorg', Zorgmarktadvies [Health Care Market Advice], October 2013), ZonMw calculates that a one-time investment of EUR 1 in health care evaluation research produces an annual revenue of about EUR 3. Such a return on investment is also established by the NVOG consortium (Hooft van 't et al., 2013). However, investments must first be made in order to produce these revenues. This concerns investments in agenda and network formation (Chapters 3 and 4), conduction of the health care evaluation studies (Chapter 5) and implementation of the results in clinical practice (Chapter 6). In addition to investments, agreements between the parties about (reinvesting) the revenues are also necessary. A flywheel situation can be brought about in this manner. This concept of investments, revenues, agreements and reinvestments is also called 'shared savings' and it is discussed in more detail in section 8.3. Preceding this, in section 8.2, a brief outline is provided of the market situation regarding medical specialist health care.

8.2 BRIEF OUTLINE OF THE CURRENT MARKET SITUATION

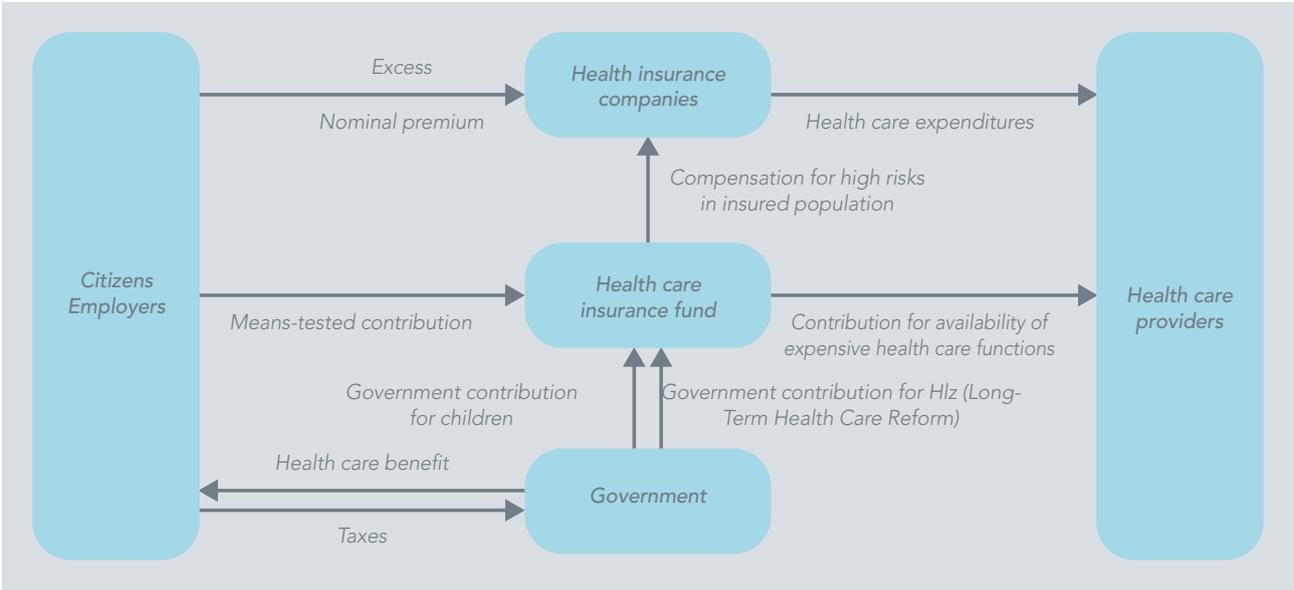
Medical specialist health care is a regulated market. The Health Care Insurance Act and the Health Care (Market Regulation) Act form the foundations for this regulated market of medical specialist health care.

Highly simplified, the market works as follows:

1. Every health insurance company concludes agreements with hospitals on volume, quality and price of the medical specialist health care;
2. The insured party chooses the health insurance company with which he/she concludes basic insurance;
3. The insured party then chooses, as a patient, which hospital he/she will go to for receiving medical specialist health care; this choice may be restricted by the policy terms;
4. The Government looks after the interests of its citizens in the area of quality, affordability and accessibility of health care;
5. The Government regulates this tripartite market, for example by a) making the health insurance company responsible for purchasing sufficient health care for its insurance holders, b) letting the National Health Care Institute determine which indication-intervention combinations are insured in the basic insurance, c) allowing the NZa to determine performance and (any) rates based on which health care is declared ('DOT' health care products) and d) imposing a national macro framework including management tool (MBI).

Money flows

The figure below from the Financial Picture of Health Care (Financieel Beeld Zorg), which is part of the National Budget, provides an outline of the money flows.

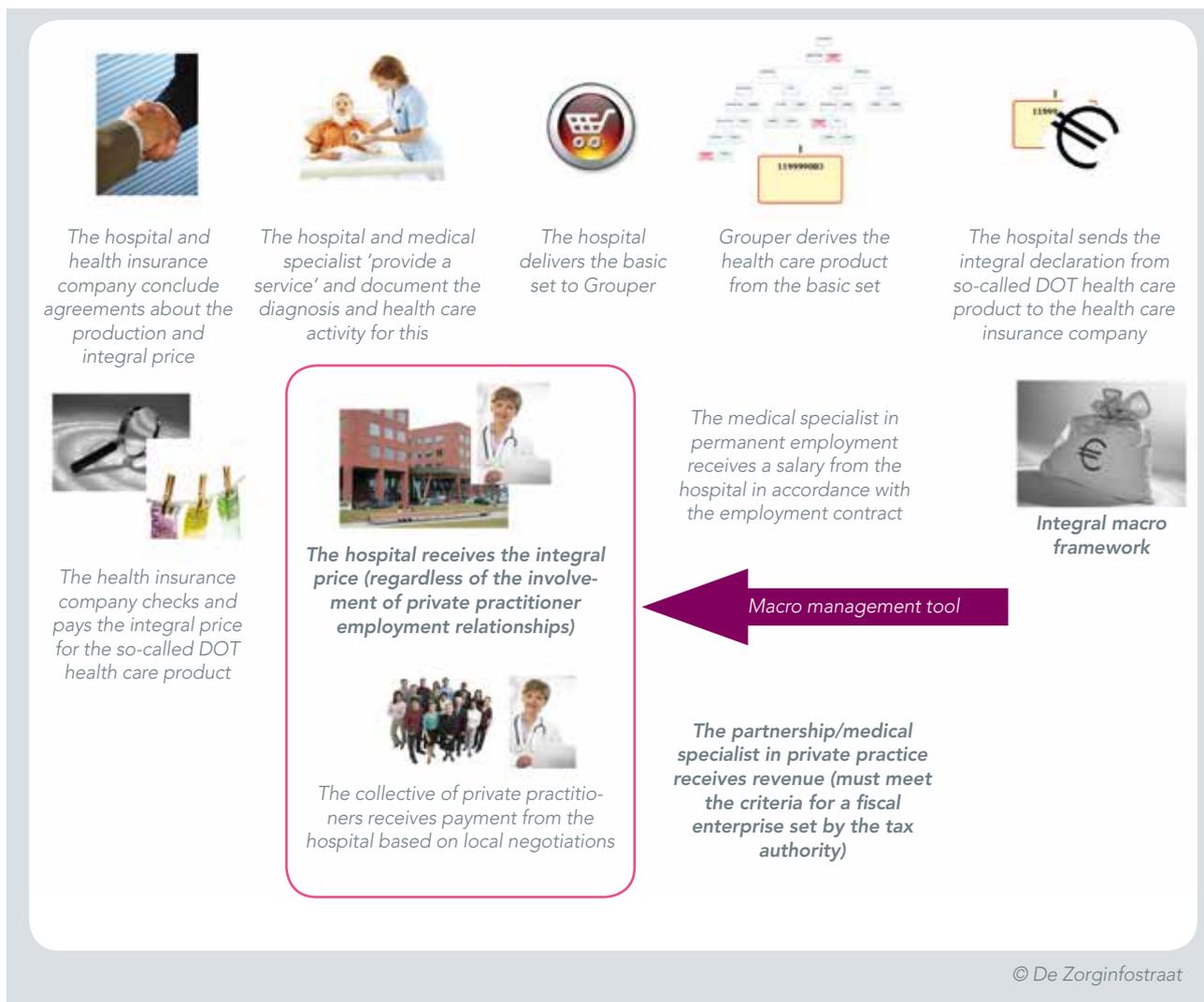


The health insurance companies' expenditures for hospitals (health care providers) are based on so-called DOT health care products. This concerns about EUR 22 billion per year.



The DOT system

The figure below (© De Zorginfostraat) shows how the money flow regarding DOT health care products comes about and is set up.



A fictional example is provided below to try and show the impact of health care evaluation in concrete terms. First the initial situation is outlined:

- The hospital and health insurance company conclude agreements about the treatment of Achilles tendon ruptures.
 - It is agreed – for example, based on historical numbers – that 80 DOT health care products will be supplied with the code/name 199299059 epidermis/soft tissue other major for a price of € 2,481. This concerns surgical treatment of an Achilles tendon rupture.
 - It is agreed that 20 DOT health care products with the code/name 199299012 injury/diagnostic/therapeutic light will be supplied for a price of € 529. This concerns conservative treatment of an Achilles tendon rupture.
- The hospital and medical specialist will then provide and record this health care per patient. In the case of a conservative course of treatment:
 - specialism: orthopaedics (0305)
 - health care type: regular health care (11)
 - diagnosis based on DBC (diagnosis treatment combination) type list 0305: 3403 Achilles tendon
 - health care activity: 190060 first outpatient visit

- e. health care activity: 039879 ultrasound
- f. health care activity: 038677 conservative treatment

3. In the case of a surgical course of treatment:
 - a. specialism: orthopaedics (0305)
 - b. health care type: regular health care (11)
 - c. diagnosis based on DBC type list 0305: 3403 Achilles tendon
 - d. health care activity: 190060 first outpatient visit
 - e. health care activity: 039879 ultrasound
 - f. health care activity: 038675 surgical treatment
 - g. health care activity: 190090 outpatient treatment
4. The associated DOT health care products are derived within the Grouper:
 - a. conservative course of treatment: 199299012 injury/diagnostic/therapeutic light.
 - b. surgical course of treatment: 199299059 epidermis/soft tissue other major.
5. In accordance with the price agreed upon with the health insurance company, the claim will be submitted and – after verification by the health insurance company – will be paid.
 - a. conservative course of treatment: 199299012 injury/diagnostic/therapeutic light – € 529
 - b. surgical course of treatment: 199299059 epidermis/soft tissue other major – € 2,481
6. If the hospital really supplies the agreed-upon 80 and 20 DOT health care products, it will receive a total revenue of € 20,9060.

The effect of the health care evaluation will be as follows:

1. Based on the health care evaluation study, it appears that, from the quality/outcome perspective, a shift from intervention to conservative treatment is desirable for an Achilles tendon rupture (from 80/20 to 20/80).
2. The scientific association revises this in its guidelines.
3. The hospital and health insurance company use this new guideline in the treatment, with the following effect:
 - a. 20 DOT health care products are supplied with the code/name 199299059 epidermis/soft tissue other major for a price of € 2,481. This concerns surgical treatment of an Achilles tendon rupture;
 - b. 80 DOT health care products with the code/name 199299012 injury/diagnostic/therapeutic light are supplied for a price of € 529. This concerns conservative treatment of an Achilles tendon rupture.
4. If the hospital really supplies the agreed-upon 20 and 80 DOT health care products, it will receive a total revenue of € 91,940.
5. This therefore not only improves the effectiveness of the health care quality, but also of the health care costs (a savings of € 117,120 in the above example).

8.3 SHARED SAVINGS

The question is which party will end up with any savings that are achieved and what will be done with these savings, based on the experience that the health care will, on average, become less expensive.

Looking at the money flows in medical specialist health care, these savings can be passed on to:

- the health insurance company, for covering risks;
- the premium payer, because the health insurance company will translate this profit into a lower premium for the basic insurance;
- the government, because it will lower the macro framework knowing that the revised guideline will result in lower revenues in the market.

It seems like a simple win-win diagram. But there is a footnote for this. Based on the fictional example above:

1. The hospital has invested in infrastructure and capacity in order to perform 80 surgical interventions for

Achilles tendon ruptures. This includes things like OR, equipment, outpatient treatment capacity, medical specialists, medical support staff;

2. This investment must then be immediately largely written off as a result of the health care evaluation study, the correspondingly revised guideline and the modified agreements with health insurance companies to suddenly scale back to 20 surgical interventions.

The solution to this footnote resides in the shared savings concept. Here the savings achieved as a result of the health care evaluation study, revised guideline and new contract agreements are distributed across several parties:

- the health insurance company, for covering risks;
- the premium payer, because the health insurance company will translate this profit into a lower premium for the basic insurance;
- the government, because it will lower the macro framework knowing that the revised guideline will result in lower revenues in the market.
- the hospital, because this gives the hospital time to write off its investment more quickly;
- the health care evaluation researchers, because follow-up or other health care evaluation research can be set up with this.

This concept of shared savings requires the possibility of multiple-year agreements being concluded between health insurance companies and hospitals, in order to truly facilitate the so-called 'landing strip' for hospitals and structurally set up the health care evaluation research. This also offers advantages for health insurance companies, because it is associated with fewer risks.

The government can facilitate this concept by postponing the lowering of the macro framework or spreading it out across several years.

The question remains how a part of the shared savings will be passed on to the health care evaluation researchers. This can be done through the health insurance companies who make a part of the DCB price available for this (compare with SKMS). Or through the budget of the Ministry of Health, Welfare and Sport.

8.4 RECOMMENDATIONS

Finance health care evaluation studies through the shared savings concept. A part of the shared savings will go to:

1. the premium payer, because the insurance company will translate this profit into a lower premium for the basic insurance;
2. the hospital, because this gives the hospital time to write off its investments more quickly;
3. the health care evaluation researchers, because follow-up or other health care evaluation research can be set up with this.

It is important to be able to achieve shared savings, and investment must be made for health care evaluation to be initiated. This concerns investment in making agendas and setting up networks, carrying out health care evaluation research and implementing results.

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