Health services research at work for national health policy

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Chapter 1

Introduction
Introduction

This thesis addresses the issue of how health services research can produce useful knowledge for policymakers. It is based on research carried out at the department of Social Medicine of the Academic Medical Center (University of Amsterdam) from 1998 to 2005 and at the Institute of Medical Technology Assessment of the Erasmus Medical Center (Erasmus University Rotterdam) from 2001 to 2004.

This introduction consists of five sections. Firstly, we describe the domain of health services research. Secondly, we address the relationship between health policymaking and health services research and focus on factors that influence the use of research by policymakers. Thirdly, we present the analytical model we use in this thesis and which incorporates four concepts: content, context, process and actors. This third section also presents the central research question. Fourthly, we introduce three cases of health services research for national health policy. These cases provide the empirical material for this thesis. Lastly, we describe the outline of the thesis.

Health services research

Health services research is an area of applied research that is multidisciplinary in nature and covers a wide range of topics in the field of health care [1;2]. There are many definitions of health services research that point to the same defining elements. Although the ultimate outcomes of health service utilization and provision are in the area of health, health services research often only analyses health care utilization or health service provision [3]. Health services research is usually policy-oriented and multidisciplinary. Some definitions point to the role of health services research in increasing the effectiveness of health care interventions or health care organization. Black et al. [4] emphasized the evaluation of advantages and disadvantages of health care interventions. Academy Health emphasized the identification of effective ways to organize, manage, finance and deliver high-quality care, reduce medical errors and improve patient safety. In sum, health services research is the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies and personal behaviours affect access to health care, the quality and cost of health care and ultimately health and well-being [5]. In this thesis the focus is on health services research for national health policy.

Health policymaking and health services research

Like all policymakers, those who make national health policies need information for their policymaking process. Sometimes this information is scientific knowledge produced by health services research [6]. Health services research for national health policy aims to produce knowledge that policymakers can use in this process. We consider health services research to be a social process of scientific knowledge production. This process takes place in an environment that often measures research output by the number of publications in scientific journals, a number that is often a factor in the financial incentive structure for researchers. To
be considered for publication, the research results need to have a high level of generalizability. Although this emphasizes the generalizable content of a research topic, it does not automatically result in better national health policy. The strength of evidence can be a weakness when it comes to usefulness [6]. The road from research to policy is not one of consecutive steps whereby the final, generalizable product of health services research is a ready-to-use building block for national health policy [7]. Our view is that health services research and policymaking are often simultaneous processes taking place in interaction [8;9]. Consequently, to be effective, the interaction of the two processes needs to be anticipated and facilitated, especially since policymakers and researchers seem to have conflicting interests [10;11].

Both international [12-14] and national authors [15;16] have addressed policymakers’ use of information and knowledge as well as the interface between health services research and policymaking [9;17-20]. Innvaer et al. summarized the facilitators and barriers for using research evidence in policymaking in 24 studies and surveys with health-policy decision-makers [14].

### Table 1. Facilitators of and barriers to the use of research evidence in policymaking [14].

<table>
<thead>
<tr>
<th>Facilitators</th>
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<td>· Personal contact between researchers and</td>
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<td>policymakers</td>
<td>policymakers</td>
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<td>· Timeliness of research</td>
<td>· Lack of timeliness of research</td>
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<td>· Relevance of research</td>
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<td>· Good-quality research</td>
<td>· Mutual mistrust, including perceived political naivety</td>
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<td>of scientists and scientific naivety of policymakers</td>
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<td>· Research that confirms current policy or endorsed</td>
<td>· Power and budget struggles</td>
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<td>self-interest</td>
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<td>· Community pressure or client demand for research</td>
<td>· Poor-quality research</td>
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<td>· Research that includes effectiveness data</td>
<td>· Political instability or high turnover of policymaking</td>
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In this thesis, although we do not test the work already done by many others, we do aim to contribute to the field of research that addresses the relationship between research and policy, including usefulness for and utilization of health services research by policymakers. We do this by presenting and reflecting on practical examples of knowledge production by health services research for national health policy. In presenting these examples, we focus on two of the above factors that influence the use of research by policymakers: the quality of research and the interaction between researchers and policymakers.

**A model for policy analysis ... and health services research**

This thesis is inspired by a model for policy analysis in health care – and more specifically, health sector reforms – provided by Walt and Gilson (1994) [21]. According to the authors, ‘The model is a highly simplified model of an extremely complex set of interrelationships, and gives the impression that each can be considered separately. In reality actors are influenced
(as individuals and as members of interest groups or professional associations) by the context within which they live and work, at both the macro-government level and the micro-institutional level. Context is affected by many factors such as instability or uncertainty created by changes in political regime or war; by neo-liberal or socialist ideology; by historical experience and culture. The process of policymaking (how issues get on the political agenda, how they fare once there) in turn is affected by actors, their position in power structures, their own values and expectations. And the content of policy will reflect some or all of the above dimensions.’ They argue ‘... that the traditional focus on the content of policy neglects the other dimensions of process, actors and context which can make the difference between effective and ineffective policy choice and implementation.’ [21] The model appreciates a specific content, but also identifies the context and processes that are related to this content. Furthermore, it positions actors in the centre of the model, indicating their central role.

Figure 1. A model for policy analysis. G.Walt and L. Gilson (1994)

This model for health policy analysis can also include health services research itself as information used by the actors. If health services researchers understand policy and the policymaking process, they can produce more useful information for policymakers [10;22]. Likewise, policymakers will be better informed if they understand a specific health services content – e.g. the cost effectiveness of an intervention or the design of a new instrument – within its context and processes and with its actors.

The emphasis on generalizable content by researchers described above is often paralleled by the interest of the contractors of health services research (like national health policymakers) to invest in the study of a specific content. The research proposals that are awarded funding by policymakers are likely to reflect this emphasis on specific content. While we as researchers were interested in answering such content-focused questions, we also hypothesized that to increase the quality of the research – and consequently its usefulness – we should address other questions as well. It is not just answering the generalizable question of ‘What works?’ but answering the additional questions of ‘What works: how, why, where, when and for
whom?’ that can improve the quality of the research and provide a better understanding of specific results so that policymakers can be better informed.

Of course, these types of questions are not unique and can also be found in studies on effective implementation of interventions in health care. However, these commonly address changes in practices of care professionals [23-26]. Here we chose to use the perspective of policy analysis. Doing so, we attempted to align the perspective of health services research with that of health policy. Consequently, the question of ‘What works: how, why, when and for whom?’ can be operationalized in a combination of researchable questions (in addition to the initial research question) regarding content as well as context and process, with actors playing the central role in all of them. The challenge of the model lies in its application: How can we address these additional questions in health services research for national health policy?

In conclusion, we explore two research questions in this thesis in order to increase the usefulness of health services research for national health policy. Firstly, how can health services research include content-, context- and process-focused research questions (in addition to the initial research question), and secondly, how can health services researchers participate in an interaction process with policymakers?

**Health services research at work for national health policy**

This thesis presents three cases of health services research at work. All are research projects in which a content-focused research question was posed by national and international health policymakers: one by a health minister, a second by the World Health Organization (WHO), who was advising a director-general for health services, and a third question by a director-general of health care [27]. All cases concerned national health policies: two in the Netherlands and one in Nepal. In two cases the initial research question was formulated as a cost-effectiveness question regarding a new health services intervention [28;29]. The decision to continue the interventions on a nationwide scale depended in part on the outcomes of our studies. In the third case a new instrument for performance measurement of a country’s entire health system was requested. In all cases we initiated research activities to address a combination of additional content-, context- and process-focused questions, i.e. in addition to the initial content-focused questions that national health policymakers were interested in.

The chapters presented in this thesis address most of the additionally formulated research questions. The choice of chapters was based on the personal involvement of the author of this thesis in addressing these questions.

The three cases are briefly presented in this introduction by describing the interventions and their general backgrounds. Also, the initial research question and its history are described, as well as the combination of content-, context- and process-focused research questions (in addition to the initial research question) and the researchers’ reflections that led to them. ‘Actors’ play an important role in all chapters. Table 2 provides an overview of the chapters in this thesis.
Case I. A national screening programme for familial hypercholesterolaemia?

The first case in this thesis concerns the genetic screening programme for familial hypercholesterolaemia in the Netherlands (see Box 1). The programme started in 1994 as an experiment and was funded by the Ministry of Health, Welfare and Sport (MoH) for a period of four years. The decision on structural nationwide implementation and long-term funding by the MoH depended in part on an evaluation of the effects of the programme in its experimental phase.

Box 1. Screening for Familial Hypercholesterolaemia

Screening for familial hypercholesterolaemia
Familial hypercholesterolaemia (FH) predisposes for coronary artery disease (CAD) and premature cardiac death [30]. The discovery of Low Density Lipoprotein (LDL) receptor gene mutations in clinically diagnosed FH patients and the subsequent development of DNA tests to detect these mutations enables the detection of FH patients before a first CAD event [31]. This is particularly relevant for relatives of confirmed FH patients, who are at much higher risk of having an LDL receptor gene mutation than the general population. Therefore, a family-based genetic screening programme for FH was implemented in the Netherlands by the Foundation for the Identification of Persons with Inherited Hypercholesterolaemia (StOEH) [32;33].

The Foundation for the Identification of Persons with Inherited Hypercholesterolaemia (StOEH) initiated an evaluation of the programme. Researchers from the Department of Social Medicine of the Academic Medical Center to the University of Amsterdam, together with the StOEH, wrote a research proposal for an evaluation study which was funded by the Netherlands Organisation for Health Research and Development (ZonMw)1 [28]. The proposal included three research questions: 1) What are the expected costs and health effects of the screening programme? 2) What is the predictive value of DNA tests used to diagnose FH? and 3) To what extent is participation in the screening and treatment of FH disturbing?

The evaluation study was carried out from 1997 to 2000 [34]. The case in this thesis focuses on research related to the question about costs and effects (Question 1). Questions 2 and 3 are both addressed in the final evaluation report [34]. In addition, Question 3 is addressed in detail by Van Maarle [35].

Reflections of the involved health services researchers that led to identifying additional content-, context- and process-focused research questions.

Some of the implicit assumptions about the disease, the programme’s context and the processes involved were challenging. Firstly, the documents of the Foundation for the Identification of Persons with Inherited Hypercholesterolaemia (StOEH) presented FH as a monogenetic, probably 100% penetrant disorder [36]. A mutation in the LDL receptor gene

1 For reasons of consistency, throughout this thesis ZonMw also refers to the organizations that preceded it, ‘Praeventie Fonds’ and ‘Zorgonderzoek Nederland’.
leads to very high blood cholesterol levels. To better understand the potential impact of the screening programme, we were curious to learn more about the correlation between the prevalence of a mutation and the prevalence of hypercholesterolemia in screened persons. We addressed this question in an additional study presented in Chapter 2.

Secondly, it was assumed the programme would detect persons with FH who were not yet known to have FH. The potential benefit of the screening programme will also depend on whether existing hypercholesterolemia is already diagnosed. Therefore, we wanted to know how many screened persons with FH had already been identified with hypercholesterolaemia in general practice prior to screening. This was also relevant, as GPs might give suboptimal treatment to persons with hypercholesterolaemia caused by an LDL receptor gene mutation and not by lifestyle factors, for example. This question is addressed in Chapter 3.

Thirdly, the chosen methodological approach for the screening was based on a pedigree analysis – ‘cascade screening’ [32] – for which previously screened persons provided the genealogical information. We hypothesized that the identification of an ‘index case’ and the subsequent methodological rigor to attain the completeness of the pedigree was important for identifying all FH mutation carriers. If an index case was missed the family would not be considered at risk, and if there were ‘blank spaces’ in the pedigree or in the programme follow-up, the potential effect of the overall programme could be influenced. We concluded that an analysis of the programme’s potential in terms of identifying all mutation carriers was important for estimating and understanding the programme’s effects.

In relation to the third initial research question (‘To what extent is participation in the screening and treatment of FH disturbing?’), the research group discussed the potential social consequences of participating in the screening programme. The discussion focused on whether participants faced difficulties when applying for life insurance. Although the existing guidelines for insurers regarding questions about health risks were clear [37] and in theory did not seem to create a barrier for applicants screened for FH, the research group felt it was important to investigate how those people who had been screened experienced trying to get insurance.

In summary, our discussions focused on the assumptions underlying the programme and we formulated the following research questions in addition to the question of the cost-effectiveness of the screening programme:

(These questions are included in this thesis.)

1. What is the prevalence of a mutation among screened persons with hypercholesterolaemia and the prevalence of hypercholesterolaemia among persons with an LDL receptor gene mutation? (presented in Chapter 2 [38])

2. What proportion of patients with FH were identified with hypercholesterolaemia in general practice prior to genetic screening? (presented in Chapter 3 [39])

(These questions are not included in this thesis.)

3. What is the potential of the current methodology of pedigree analysis and follow-up: How many family members can be reached by the programme and how many have already been reached? [40]
4. When applying for insurance, do screened persons (and persons with positive screening results) face consequences because they participated in the screening programme? [41]

The screening programme’s cost-effectiveness evaluation (Question 1 of the research proposal) is addressed in Chapter 4 [42].

**Case II. Nationwide implementation of respiratory guidelines?**

The second case in this thesis concerns the implementation of respiratory care guidelines in Nepal. His Majesty’s Government of Nepal, Ministry of Health (HMG-MoH) receives assistance from the WHO to improve the quality of care for children (over 5 years of age), youths, and adults with respiratory symptoms. For this specific topic, WHO is developing the Practical Approach to Lung Health (PAL)–initiative together with Nepal and other member-states (see Box 2.). Elements of PAL are being field-tested and evaluated in several countries to guide the further development of the package and to support policy decisions on PAL’s uptake [43].

In 1998, the WHO invited researchers to evaluate the costs and effects of PAL in order to provide support for decision-making about implementing it in participating countries. The researchers developed proposals for studying the costs and effects of PAL in Nepal, one of the countries participating in its development and pilot implementation. This resulted in two proposals: one for assessing the training’s effectiveness and one for assessing the costs and effects of developing and implementing PAL in Nepal, using a cluster randomized trial design. Only the latter proposal was funded [29].

**Box 2. Practical Approach to Lung Health.**

**Practical Approach to Lung Health (PAL)**

Respiratory diseases are an important cause of morbidity and mortality in all ages everywhere. In middle- and low-income countries there is the suspicion that primary care facilities may provide inadequate care for respiratory diseases. With the exception of case management of tuberculosis, many health systems have no standard strategy for dealing with respiratory diseases in adults [44]. In 1997, the WHO started developing integrated clinical care guidelines for adult lung health in primary care settings in middle- and low-income countries. This initiative was called the Adult Lung Health Initiative (ALHI), later renamed the Practical Approach to Lung Health (PAL), because PAL was a more appropriate acronym in Islamic cultures [45].

The Practical Approach to Lung Health initiative aims to improve the syndromic management of lung diseases in children (over 5 years of age), youths and adults in middle- and low-income countries [45]. PAL is presented as a package consisting of a generic clinical practice guideline and accompanying training materials. It targets ‘multipurpose’ health workers at peripheral primary and secondary care facilities.

The following were the core objectives of the cost-effectiveness study:

1. To compare the costs of implementing PAL in government facilities to the costs of maintaining the standard array of medical services.
2. To compare at the primary care level the effects for patients and facilities in PAL areas to the effects in areas using the standard array of medical services.
3. To allow comparison of the cost effectiveness of the PAL strategy to other potential investments in a population’s health.

These objectives were addressed in a cluster randomized trial. Some of the results have been published, others are forthcoming [46-48]. The research questions that can be considered to be part of the initial cost-effectiveness study (such as studies on PAL’s effects on prescribing drugs [49] and on the burden of respiratory diseases in Nepal) are not presented in this case. Neither are studies presented that validated measurement instruments necessary to assess the effects of PAL at patient level. This was particularly important in measuring participants’ respiratory conditions and their quality of life. Reference values for peak expiratory flow in the Nepalese population had to be collected [50] and quality-of-life instruments had to be validated within the Nepalese context [51].

**Reflections of the involved health services researchers that led to identifying additional content-, context- and process-focused research questions.**

PAL was presented by the WHO as a package of interventions and strategies. To better understand the possible effects of PAL, it was necessary to open the package and study its elements and underlying assumptions that were related to the process and context in Nepal. As a result, the team developed three research questions in addition to the cost-effectiveness evaluation.

Firstly, we observed that the study proposal did not explicitly address the context in which PAL was going to be implemented in Nepal. Much attention was given to the international importance of PAL. Only two context-specific conditions were mentioned: the absence of diagnostic guidelines and the enormous logistic difficulties existing in Nepal. We anticipated scarce resources and consequently erratic availability of specific drugs in rural areas. The team had long discussions with the WHO counterpart as to whether WHO should provide drugs to the health services while PAL was being evaluated. Such additional measures would need the full support of several counterparts in Nepal. The uncertainty about the local situation and outcome of discussions as described created the need for assessing the broader context and processes of adapting and implementing PAL. We hypothesized that with such information, the outcome of the cost-effectiveness assessment could be better understood and could potentially guide policy changes. Results of this additional study are presented in Chapter 6 [52].

Secondly, we observed that during the adaptation process, the participants in the adaptation working group shared their views on and knowledge of the primary care health services in rural areas. In the proposal, however, no opportunity was created for assessing the functioning of the primary care health services in Nepal. Nor were patient views incorporated into the adaptation process or evaluation study. We argued that an understanding of how the health services functioned should be based on information not only from the health care providers,
financiers and policymakers, but also from the users of these health services. We developed a proposal to study the health care context from the patient’s perspectives and experiences. This study is presented in Chapter 7 [53].

Thirdly, the results of the cost-effectiveness evaluation were expected to guide the policymaking process. How the results would be used was unclear. Because methods for priority-setting have attracted increasing interest in the international literature, an opportunity arose for applying a rational approach to prioritizing health programmes, including PAL in Nepal. To explore possibilities for a rational approach to priority-setting for resource allocation in low-income countries, we assessed the relative weights of different characteristics of health care programmes. The results of this exploration in Nepal are presented in Chapter 8 [54].

In summary, in addition to the question of the policymakers on the cost-effectiveness of the implementation of respiratory care guidelines, we formulated the following research questions:

(All of these questions are included in this thesis.)

1. What is, ex ante, the implementability of PAL in Nepal based on the quality of the guidelines, the implementation strategy and the social context in which PAL is going to be implemented? (presented in Chapter 6 [52])

2. What route is used by tuberculosis patients within the health care context from the moment their complaints first begin until the start of tuberculosis treatment? and What is the role of the governmental primary care facilities in this journey? (presented in Chapter 7 [53])

3. What is the relative importance of PAL in Nepal compared to other programmes? (presented in Chapter 8 [54])

**Case III. An instrument for national health system performance measurement?**

The third case concerns health services research for developing a tool to measure the performance of the Dutch health system. In 2001, the need for international comparisons of health system performance and the development of a major health system reform in the Netherlands were the driving forces behind the Dutch MoH’s development of indicators for the performance of the entire health system [55;56]. Performance measurement should inform the monitoring and control functions of the MoH. Previously, primarily volume and cost data about health care provision were collected and reported in health sector reports [57]. Inspired by activities of the Organisation for Economic Co-operation and Development (OECD) in the field of performance and quality measurement, the MoH formulated a request for research assistance for developing a performance indicator framework for the entire Dutch health system [58] [59].
Reflections of the concerned health services researchers that led to identifying additional content-, context- and process-focused research questions.

By responding to the request of the MoH, we were given an opportunity to build a new instrument that would be used in the policy practice of the MoH to monitor and steer the health system. We realized that this tool had to meet many requirements that were linked to its intended use and function (see Chapter 10 [60]). Also, we realized this tool was going to be used in an environment with dynamic organizational and policy context and processes. We hypothesized that whether or not this new tool would actually be used would depend largely on the context and processes that coexisted. Therefore, we formulated the following additional question: ‘What organizational and policy contexts and processes influence the development of the performance indicator framework?’ This additional question is addressed in Chapter 11 [61].

In this study the researchers collaborated closely with the MoH in an interactive research and development process. During this process we realized that for certain potential indicators, an extra boost in terms of additional studies might help the MoH develop these indicators. As a result, we formulated additional research questions for three specific indicators. One regarded the efficiency of allocation of resources, the second, the performance of mental health care and the third, measuring patient experiences with health care.

In summary, we addressed the following research questions in addition to the initial question of the policymakers to develop a tool for health system performance:

1. What are the organizational and policy context and processes that influence, and potentially interact with, the development of the performance indicator framework? (presented in Chapter 11, [61])

(These questions are not included in this thesis.)

2. To what extent are decisions about reimbursement by the Dutch Sickness Fund based on cost-effectiveness information? [62]

3. What are useful and feasible performance indicators for mental health? [63]

4. How can patient experiences with health care be measured as an indicator of the health care system’s responsiveness? [64]

In Chapter 10, the proposed conceptual framework for performance indicators is presented [60].

Outline of this thesis

Following this introduction, the thesis consists of three case-specific sections, each containing multiple chapters. For each case, the chapters present the results of several of the research questions mentioned above (see Table 2). At the end of each case, a retrospective chapter ‘Health Services Research at work in Case …’ addresses the position of the researchers in relation to other actors and the inclusion of the combination of content-, context- and process-focused questions (in addition to the initial research question), the interaction of the
researchers with policymakers, and describes the follow-up of events and developments in the three cases.

The thesis concludes with a discussion in Chapter 13 in which a reflection is given on the lessons learned for health services research by answering the central question in this thesis: In order to increase the usefulness of health services research for national health policy, (a) How can health services research include content-, context- and process-focused research questions (in addition to the initial research question)? and (b) How can health services researchers participate in an interaction process with policymakers? What was the added value of including the combination of content-, context- and process-focused research questions (in addition to the initial research question)? Suggestions are also made as to how we can include Walt and Gilson’s model in a structural way in health services research.

Table 2 gives an overview of the chapters in this thesis and shows which domain (content, context or process) is addressed in each chapter. Also, the involved actors are listed for each case, according to the following categories: a) intended users, b) contractors, c) subject of study and d) academic disciplines of the actors in the health services research group.
<table>
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<tr>
<th>Chapter</th>
<th>Content</th>
<th>Context</th>
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<td>Genetic screening for familial hypercholesterolaemia in 1992-1997: primarily younger patients in the care of general practitioners</td>
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<td>4</td>
<td>Cost-effectiveness of a family- and DNA-based screening programme on familial hypercholesterolaemia in the Netherlands</td>
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<td>HSR(^2) at work in Case I</td>
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<td>Developing a national performance indicator framework for the Dutch health system</td>
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<td>The Performance Indicator Framework of the Dutch Health System: A Progress Report(^3)</td>
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<td>13</td>
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1 a=intended users, b=contractor, c=subject of study, d=involved disciplines in health services research group
2 HSR=health services research
3 This chapter addresses both the context as well as the process in which the performance indicator framework was developed.
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<td>b. ZonMw</td>
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<td>c. StOEH, general practitioners</td>
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<td>d. Epidemiologists, psychologists, health scientist, medical doctors</td>
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<td>b. NWO-WOTRO</td>
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<td>c. Health care providers, patients, policymakers</td>
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<td>d. Health economists, epidemiologists, public health specialists, health scientists, medical doctor, political scientist</td>
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<td>A rational multi-criteria approach to priority setting: Should a lung health programme be implemented in Nepal?</td>
<td>a. MoH</td>
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<td>d. Epidemiologists, public health specialists, health scientists, medical doctors, political scientist</td>
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