



FinOHTA

TERVEYDENHUOLLON MENETELMIEN ARVIOINTIYKSIKÖ
FINNISH OFFICE FOR HEALTH CARE TECHNOLOGY ASSESSMENT

The Future of FinOHTA

an External Review

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Mr. Jarkko Eskola, chairman of the evaluation group and Ms. Marjukka Mäkelä, head of FinOHTA
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Kristian Lampe (above and Eskola, p. 3); Anders Norderman (Rehnqvist, p. 4); Sarah Prescott (Oxman, p. 4).

PREFACE

In spite of its small size, FinOHTA is a strategic player in Finnish health care. During the first eight years of FinOHTA's existence, it has become a focal point of national health technology assessment activities. In the outcomes-oriented health care of today — with its strong emphasis on a sound evidence base — the importance of actors delivering reliable and relevant knowledge cannot be over-estimated. To achieve its ambitious goals, the small unit has built strong networks with Finnish health care actors and within the international health technology assessment community.

When STAKES was established as a new organization with a new mission in the early 1990's, it had to rapidly create new ways of operating. It was necessary to show a number of audiences that the new research and development organization could deliver unbiased, up-to-date knowledge that was relevant to developing Finland's health and social services. In relation to the clinical world, FinOHTA has been the showcase for STAKES. As the part of STAKES with the highest visibility in health care, FinOHTA has helped the whole organization to establish practical collaboration with health care actors.

At the same time as the mother organization has gained from the work of FinOHTA, it has also worked the other way round. The largest health services research and health economics community in the country, STAKES, has created an environment conducive to health technology assessment. A national research organisation has been the ideal location from which to build up the critically important networks. Moreover, substantial synergies have been created by developing and sharing material and technical infrastructure that comes with a larger organisation.

In many cases, organisational evaluations are quite normative, aiming at an objective assessment of the "goodness" of the organisation. Quite often, these evaluations include league tables of several organisations, which may also be used to direct the allocation of resources.

The present evaluation of FinOHTA does not belong to the category of normative assessments. You couldn't even rank FinOHTA against other Finnish units since the role and work of FinOHTA is nationally unique. During the first years of its existence, the work of FinOHTA has been widely appreciated. There is a general consensus that the work of FinOHTA should be significantly strengthened. This has also materialized in the form of a high-level political decision, as the government has promised to more than triple the funding of FinOHTA in the next few years.

The FinOHTA evaluation was expected to be development oriented, rather than normative. In other words, STAKES wants to ensure the maximum benefit from the new phase of development that has just started. It is a joint obligation of FinOHTA and the whole of STAKES to repay taxpayers by using the new resources as wisely as possible.

A development-oriented evaluation of a health technology unit that operates in a complex context is not an easy task. To end up with long-sighted and feasible recommendations that are also practical enough to be implemented, you need to have a broad mix of expertise. In addition to understanding health technology assessment methodology and organisation, you need to understand health policy and health services as well as the clinical environment where the work is done

and where the results are utilised. When trying to locate leading experts from each of the fields mentioned above, we realised that people who could meet the requirements of the evaluation group membership are few and far between. We started ambitiously by asking the best experts we could envisage to carry out the exercise. As the commissioner of the evaluation, the STAKES senior management group was overjoyed when the composition of the expert group was confirmed. In fact, the group is a "dream team", embodying an impressive amount of expertise in a group of just five members.

This preface is written before the final recommendations of the group are published. However, it is self-evident that the work of the evaluation group will have an impact. All suggestions will be meticulously contemplated. Any recommendation given will be implemented, unless an explicit, well-grounded decision not to do so is made. STAKES is committed to making maximum use of this valuable work. On behalf of the whole senior management group of STAKES, I express our warm gratitude to the whole evaluation group. Similarly, I reiterate the commitment of STAKES to developing FinOHTA to a new level of activity and impact.

Helsinki, 6 August 2004

Juha Teperi
Deputy Director General (acting)

THE EVALUATION GROUP



Jarkko Eskola, MD, MSc

Chairman of the evaluation group

Jarkko Eskola has specialised in psychiatry and has completed the Master of Science degree in Social Medicine in the London School of Hygiene and Tropical Medicine. While working within the National Board of Health in the 1970's, he was responsible for mental health services in Finland. He then moved to the Ministry of Social Affairs and Health in 1981. After having worked as the Director General of the Department for Promotion and Prevention in Health and Social Policy, as well as the of the Department for Family and Social Policy, he retired in 2003. He has contributed as Finnish representative to various international organisations, e.g. as the chairman of the Health Committee of the Council of Europe, as the chairman of Board of Directors in the Nordic School of Public Health, and as the chairman of the Standing Committee of the Regional Committee for WHO/EURO. At present he is the Executive President of Regional Committee for WHO/EURO.



Krister Höckerstedt, MD, PhD

Professor and head of Transplantation and Liver Surgery Clinic

University of Helsinki

Helsinki University Hospital, Helsinki, Finland

Krister Höckerstedt specialised in surgery in 1977 in Helsinki and after a senior lecture period had a consultant position in the surgical department. He has held the present position since 1998 and was appointed professor in 2002. His clinical work and research interests have been abdominal surgery, in particular liver surgery and transplantation. His scientific production exceeds 300 papers. Having visited Cambridge, UK he initiated the liver transplant program in Finland and the first patient was transplanted in 1982

— it was also the first in the Nordic countries. He has lead the program since. He has held the following positions: president of the Finnish Surgical Society and the Finnish Society of Gastroenterology, general secretary of the European Society for Surgical Research, council of the International Liver Transplant Society, president of the European Liver Transplant Association and since 2004 president of the European Surgical Association.



Hanna Mäkäräinen, MD, PhD

Administrative Chief Physician

Northern Ostrobothnia Hospital District, Oulu, Finland

Hanna Mäkäräinen completed her medical training at Oulu University 1977. She gained her specialist degree in diagnostic radiology 1984, became doctor for medical sciences (PhD) 1986, and docent for diagnostic radiology 1987. She worked as clinical radiologist (resident and specialist) and administrative deputy chief physician at the department of diagnostic radiology of Oulu University hospital 1980 -1992. She obtained a diploma in Health Administration 1991 and she has been a lecturer in Health Administration at Oulu University, Medical Faculty since 1994. She has worked as chief administrative physician since 1992 first at Oulu University Hospital and since 1995 at Northern Ostrobothnia Hospital District (secondary care). Professional activities include local and regional health care reforms. She has been an active member in several national working groups under supervision of the Ministry of Social Affairs and Health as well as under the Ministry of Education since 1996. The present memberships include Advisory board of Stakes (since 2004) and Educational committee of Finnish medical Association (since 1992).



Andrew D Oxman, MD, PhD

Director

Informed Choice Research Department, Norwegian Health Services Research Centre, Norway

Andy Oxman completed his medical training at Michigan State University in 1979, married a Norwegian and moved to Norway for the next five years. He completed an internship and then worked as a general practitioner in northern Norway. From 1984 to 1994 he was at McMaster University in Hamilton, Canada where he completed a fellowship in community medicine and later joined the faculty in the Departments of Family Medicine and Clinical Epidemiology & Biostatistics. In 1994 he moved back to Norway and began work at the Health Services Research Unit at the National Institute of Public Health in Oslo. He is the director of the Unit, which has since become the Informed Choice Research Department at the Norwegian Health Services Research Centre. He has worked extensively in the Cochrane Collaboration over the past ten years. His research interest is in developing and evaluating methods of helping patients, healthcare professionals and policy makers to make informed choices about health care.



Nina Rehnqvist, MD, PhD

Professor, Executive Director

Swedish Council on Technology Assessment in Health Care, Stockholm, Sweden

Nina Rehnqvist worked at Danderyd Hospital Karolinska Institutet as a clinician and head of department in academic cardiology until April 1995. Deputy General Director in the National Board for Health and Welfare April 1995 – April 2003. Chief Medical Officer of Sweden. Major issues in the National Board were Patient Safety and Quality of Care. The National Quality registers became established and National Guidelines were introduced. Succeeded Egon Jonsson, one of the founders of SBU as Director in April 2003. Adjunct professor of cardiology in Karolinska Institutet.

Medical Officer Kristian Lampe acted as the secretary of the evaluation group on behalf of FinOHTA.

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1 EXECUTIVE SUMMARY

The Finnish health care sector is currently going through a reform process which is based on the *Decision in Principle by the Council of State on securing the future of health care*, published in 2002. The main goal of this reform is to ensure improved accessibility, timely availability, and high quality of health care services for the population. The health care system in Finland, like in other countries, must cope with increasing expectations and costs, as well as with regional variation in practices. Continuous quality improvement and reduction of gaps between research and practice are further challenges for the modern health care system.

Internationally there has been a search for tools and methods to promote the effectiveness and efficiency of health care. Evidence-based medicine, systematic reviews, clinical practice guidelines and health technology assessment (HTA) are among the responses to these needs.

The Finnish Office for Health Care Technology Assessment, FinOHTA, was set up in 1995 as part of the *National Research and Development Centre for Welfare and Health, STAKES*. FinOHTA has focused on micro-level assessment, i.e. on assessing individual health technologies. Other research groups within STAKES have been responsible for studying health services on the macro-level, focusing on organisational structures and systems.

In the context of the national health care reform the Ministry of Social Affairs and Health has decided to increase the resources allocated to FinOHTA. The leadership of STAKES — foreseeing the possibilities in strengthening FinOHTA's role in the health sector — decided to carry out an external review of FinOHTA with the aim to optimize the use of increased resources.

This report is based on the work of the international evaluation group chaired by *Dr. Jarkko Eskola*, retired Director General of the Ministry of Social Affairs and Health. The members of the group were *Dr. Krister Höckerstedt* (University of Helsinki), *Dr. Hanna Mäkäräinen* (Northern Ostrobothnia Hospital District), *Dr. Andrew Oxman* (Norwegian Health Services Research Centre, Norway), *Dr. Nina Rehnqvist* (Swedish Council on Technology Assessment in Health Care, Sweden). *Dr. Kristian Lampe* (FinOHTA) acted as the secretary of the group.

The evaluation group approached its task in two ways. Firstly, through careful examination of detailed documentation of the FinOHTA's work during the past years. Secondly, by formulating a set of key questions that were used as a framework for extensive interviews. Some 16 experts representing various national organizations were interviewed using a structured interview scheme. Additionally, views of further 14 national and international experts were obtained through phone interviews or in writing.

The evaluation group considered the background documentation and various aspects expressed in the interviews and — as a result of extensive internal discussions and analysis — concluded its work by collecting the main observations and practical recommendations in the closing chapter of this report.

The report presents 48 recommendations that address the mandate, scope and independence of FinOHTA. In the future, FinOHTA should continue developing and focusing its mission and position as the national coordinator, facilitator and expert in health technology assessment. The financiers and administrators should ensure that FinOHTA has an independent position that allows it to tackle assessment tasks that may be challenging both scientifically and from the viewpoint of health policy. The recommendations advocate FinOHTA's role as an independent advisor that bases its claims on scientific evidence, for the Ministry of Social Affairs and Health, for STAKES and for various other health care policy makers and service providers. Some of the recommendations confirm the hitherto practises and some propose the adoption of new roles and practices. An example of an issue that requires clarification in the future is FinOHTA's role in the assessment of pharmaceuticals. The evaluation group felt strongly that the roles of different organizations relevant to pharmacotherapy and its cost-effectiveness are not well defined and established, and that the mandates are not clear enough. Finally, the report also provides practical recommendations regarding the future recruitment of staff to meet the increased workload of FinOHTA.

2 BACKGROUND

2.1 International Health Technology Assessment

The Health Program of the Office of Technology Assessment (OTA), serving the U.S. Congress, initiated health Technology Assessment (HTA) as a formal process in the mid-1970's. However, a long history of concerns and developments preceded the formal establishment of HTA and has coincided with its further development. Concerns over variation in practice, the quality of health care, the cost of health care, and the ability to cope with the biomedical literature have contributed to the development of HTA and related developments. Evidence-based medicine (EBM), systematic reviews, and clinical practice guidelines are among the developments that have occurred along side of HTA. A number of organisations have been created to support these developments, both within countries and internationally. These concerns and responses to them are not independent of each other and the boundaries between them are not always clear.

2.1.1 What is HTA?

Definitions of HTA vary along with what is included within the scope of HTA. The term HTA was first used in the United States Congress in about 1967, and the U.S. Congressional Office of Technology Assessment (OTA) was established in 1972. The general definition of technology assessment used was: *"a comprehensive form of policy research that examines the short- and long-term social consequences of the application or use of technology."*¹

HTA has subsequently been defined as *"the systematic process by which the direct and indirect consequences of a particular technology are assessed; it is concerned with evaluating the safety, effectiveness and cost-effectiveness and (when appropriate) the social ethical and legal impact of a technology."*²

More recently, the European Collaboration for Health Technology Assessment/Assessment of Health Interventions (ECHTA/ECAHI) project has described HTA as follows:³

Health technology assessment (HTA) seeks to inform health policy makers by using the best scientific evidence on the medical, social, economic, and ethical implications of investments in health care. Technology is broadly defined to include the drugs, devices, medical, and surgical procedures used in health care, as well as measures for prevention and rehabilitation of disease, and the organizational and support systems in which health care is provided.

¹ Office of Technology Assessment. Development of medical technology: opportunities for assessment. Washington DC: U.S. Government Printing Office, 1976.

² Mosteller F, Falotico-Taylor J (eds). Quality of life and Technology Assessment. Washington DC: National Academy Press, 1989.

³ Jonsson E, Banta HD, Henshall C, Sampietro-Colom L. Summary report of the ECHTA/ECAHI project. International Journal of Technology Assessment in Health Care 2002; 18:218–37.

Assessment includes:

1. *Identifying evidence, or lack of evidence, on the benefits and costs of health interventions;*
2. *Synthesizing health research findings about the effectiveness of different health interventions;*
3. *Evaluating the economic implications and analyzing cost and cost-effectiveness; and*
4. *Appraising social and ethical implications of the diffusion and use of health technologies as well as their organizational implications.*

In its project on New and Emerging Health Related Technologies (NEHRT, part of OECD's Health Project, published 2004), OECD refers to HTA as a three steps process:

1. *Identification and prioritisation of research/ policy question*
2. *Systematic review of the scientific evidence*
3. *Appraisal of the evidence, including judgements about the meaning of the evidence, and views as to the values of a technology in the health care system.*

At a minimum, HTA addresses the efficacy of technologies; including health benefits, potential side-effects and comparisons of health benefits with alternatives. Frequently an economic evaluation, in the form of cost-effectiveness analysis is included.

HTA, evidence-based health care (EBHC) and cost-effectiveness analysis (CEA) have been described as three interrelated concepts: "EBHC (the extension of evidence-based medicine to all health-care decisionmakers), CEA (a group of analytic tools bringing together costs and effectiveness) and HTA. HTA is the provision for health care decision-makers of high-quality research information on the cost, effectiveness and broader impact of health technologies; where health technologies are not just high-tech 'kit', but all interventions offered to patients. These three are not synonymous, but they are converging and they have common characteristics. These include a systematic approach to the evidence, a focus on patient-relevant outcomes, and the notion that policy decisions for one set of patients will affect others." ⁴

"HTA is a broad concept with many facets and vague borders. It differs from country to country both in its foci and method. Probably a considerable part of the differences in HTA by country has depended on the interests of particular societal groups", including policy makers, insurers, clinicians, researchers, industry and the general public. ⁵

HTA may include literature reviews alone, consensus processes with varying degrees of documentation, economic analyses, primary research, including randomised controlled trials (RCTs) and methodological research. Systematic reviews have come to be viewed as a core component of HTA, but the methods used in reviews can also vary widely and HTAs do not always include a systematic review. A systematic review is "a review of a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies." ⁶

⁴ Stevens A, Milnes R, Burls A. Health technology assessment: history and demand. *Journal of Public Health Medicine* 2003; 25:98–101.

⁵ Banta D. The development of health technology assessment. *Health Policy* 2003; 63: 121–32.

⁶ Alderson P, Green S, Higgins JPT (eds). *Cochrane Reviewers' Handbook Glossary 4.1.5* [updated December 2003]. In: *The Cochrane Library*, Issue 2, 2004. Chichester, UK: John Wiley & Sons, Ltd..

2.1.2 HTA agencies

A total of 131 HTA organisations in 27 countries were identified in a directory that was published in 1998.⁷ Today the numbers are probably higher. Some of these agencies are primarily engaged in primary research on health technologies, whereas many produce systematic reviews as a core activity with varying degrees of attention given to the applicability of the evidence in specific settings, economic analyses, and other context specific considerations such as organisational, ethical and legal implications. The international network of HTA agencies (INAHTA) consists of 42 agencies in 21 countries. To become a member of INAHTA an agency has to apply, be at least 50% funded by government and address HTA from a wide perspective.

The 42 agencies in INAHTA vary greatly in terms of the number of permanent staff, funding, and operational procedures. All of them undertake or use systematic reviews and produce HTAs for varying ranges of health technologies. Some agencies are directly attached to government, others are departments within organisations under government, and others are independent organisations. Some are involved in policymaking or the production of clinical practice guidelines, some directly influence remuneration or legislation, and some inform policy decisions but are not involved directly in policymaking.

Agency staff alone sometimes produce systematic reviews, agencies sometimes commission systematic reviews, and they sometimes produce reviews in collaboration with expert groups. Because the evidence included in systematic reviews is usually international and the same evidence is used in HTAs in different countries, there have been growing efforts to reduce unnecessary redundancy and improve the quality of systematic reviews used in HTAs through collaboration among HTA agencies and the use of systematic reviews produced by the Cochrane Collaboration.⁸ INAHTA has agreed upon a checklist to use when producing systematic reviews in order to ensure quality. It has further been proposed that work should be started to try to harmonise the presentation of the scientific documentation used in HTAs so that the different agencies can better use each other's material when producing reports that are tailored to a specific context.

Denmark, Finland, Norway and Sweden all have HTA agencies which are members of INAHTA: the Danish Centre for Evaluation and Health Technology Assessment (DACEHTA), the Danish Institute for Health Services Research (DSI), the Finnish Office for Health Care Technology Assessment (FinOHTA), the Norwegian Centre for Health Technology Assessment (SMM), the Swedish Council on Technology Assessment in Health Care (SBU), and (in Linköping, Sweden) the Centre for Medical Technology Assessment (CMT). FinOHTA has a good reputation in the international HTA community and collaborates closely with the other Nordic HTA agencies. Similarities and differences among four Nordic national HTA agencies are summarised in table 1.

⁷ Medical Technology & Practice Patterns Institute. Directory of Health Technology Assessment Organizations Worldwide 1998. <http://www.mtppi.org/reports.php?repid=044&infotype=abstract>

⁸ The Cochrane Collaboration is an international organization that aims to help people make well-informed decisions about healthcare by preparing, maintaining and promoting the accessibility of systematic reviews of the effects of healthcare interventions (<http://www.cochrane.org>).

Agency	Aims	Organization	Staff ¹	Budget ² (€ per capita)	Activities
DACEHTA ³	The key aim of DACEHTA is to implement the National Strategy for HTA - this includes carrying out health technology assessments (HTAs) and evaluations of public health services with the aim of improving quality, standards and value for money. It is also an objective to integrate HTA-principles into the running and planning of the public health service at all levels. The centre primarily targets health professionals and decision-makers at all levels as well as related research communities.	National centre for HTA and a separate entity within the framework of the National Board of Health	22	3.6 (0,67)	DACEHTA coordinates, initiates and produces broad and rapid HTA-reports based on systematic reviews. DACEHTA has an early warning activity. DACEHTA implements and gives financial support to a range of HTA activities in Denmark, including 3 local HTA units. DACEHTA produces clinical practice guidelines, and evaluates health service activities. Furthermore DACEHTA gives grants to local and regional HTA-project.
FinOHTA ⁴	To promote the use of proper evidence-based methods in the Finnish health care system in order to enhance the effectiveness and impact of health care.	Department in the National Research and Development Centre for Welfare and Health (STAKES)	13	1.5 (0,29)	FinOHTA co-ordinates HTA research, disseminates information and gives methodological and financial support to research projects. It provides both methodological and financial support to projects aiming at evaluating the clinical effectiveness or cost-effectiveness of a given health technology. Inasmuch as it is feasible, the projects should also investigate the social, ethical and legal aspects related to the technology. The Finnish branch of the Nordic Cochrane Centre is based within FinOHTA. ⁵
SMM ⁶	The main task of SMM is to critically review the scientific basis for methods used in health care and to evaluate their costs, risks and benefits. SMM is concerned with weeding out ineffective technologies, and ensuring that approved technologies are applied as efficiently as possible. Both new and established technologies are assessed. These include diagnostic and therapeutic procedures, medical devices and issues concerning the organisation of the health care system.	Department in the Norwegian Health Services Research Centre	24	1.7 (0,38)	SMM prepares full HTAs undertaken by expert groups together with SMM staff, limited HTAs, evaluation of international reports in the Norwegian context, evaluation of new technologies or new applications of old technologies, "early warnings", and response to queries based on available systematic reviews and HTA reports. SMM does not conduct or support primary research
SBU ⁷	SBU has the mandate of the Swedish government to comprehensively assess healthcare technology from medical, economic, ethical, and social standpoints. SBU aims to compile impartial, scientifically based assessment reports to support decision-making in health care. Target groups include professional caregivers, healthcare administrators, planners and health policy makers. The findings also concern many patients and their families.	Independent state-financed centre	28	4.5 (0,51)	Teams consisting of experts from Sweden and abroad carry out full HTAs. In addition SBU prepares Alerts (early assessments concerning new technologies), has a network of 33 ambassadors throughout Sweden, and provides the secretariat for INAHTA. The ambassadors' role is to initiate and participate in local and regional seminars and conferences, and to become locally known as opinion leaders for evidence-based medicine. SBU does not conduct or support primary research.

Table 1. Comparison of some features of national HTA agencies in Nordic countries

1. Permanent staff - approximate full-time equivalents.

2. Budget for 2004 in millions of Euros. Population data from 2003, Statistics Finland World in Figures, http://www.stat.fi/tk/tp/maailmanumeroina/03_pinta-ala_vakiluku_ja_paakaupunki_maittain.xls

3. Danish Centre for Evaluation and Health Technology Assessment (DACEHTA), http://www.sst.dk/Planlaegning_og_behandling/Medicinsk_teknologivurdering.aspx?lang=en

4. Finnish Office of Health Technology Assessment (FinOHTA) <http://www.stakes.fi/finohta/e/>

5. More than a dozen Cochrane Centres around the world share responsibility for helping to co-ordinate and support members of the Cochrane Collaboration in areas such as training and support to reviewers and review groups to prepare, keep up-to-date and make accessible Cochrane reviews. Centres promote the objectives of the Collaboration at national level. A Cochrane Review is a systematic review of the benefits and risks of healthcare. Cochrane reviews are expected to adhere to guidelines published in the Cochrane Reviewers' Handbook. The specific methods used in a Cochrane Review are described in the text of the Review. Cochrane Reviews adhere to a structured format that is described in the Cochrane Reviewers' Handbook.

6. The HTA, Reviews and Dissemination Department includes the former Norwegian Centre for Health Technology Assessment (SMM) <http://www.kunnskapssenteret.no/smm/News/FramesetNews.htm> and the former Knowledge Support Department of the Norwegian Directorate of Health and Social Affairs. The staff and budget is for the entire Department, of which the former SMM is about two thirds.

7. The Swedish Council on Technology Assessment in Health Care (SBU) <http://www.sbu.se/www/index.asp>

2.2 FinOHTA until today

2.2.1 History and task

Several guidelines relevant to HTA were published already in 1979 by SITRA (Finnish National Fund for Research and Development). Some years later, the Academy of Finland published two reports on health care technology assessment in the second half of the 1980's. Also some other organisations made efforts to promote health care technology assessment in the 80's and early 90's.

The Finnish Office for Health Care Technology Assessment, FinOHTA, was set up on the 1st of January 1995 within Stakes, the National Research and Development Centre for Welfare and Health. Stakes is subordinate to and financed by the Ministry of Health and Social affairs. FinOHTA was thus set up to be a publicly funded, national assessment agency.

The tasks of Stakes are defined in the legislation ^{9,10}. Although FinOHTA is not explicitly mentioned in the legislation, the task to evaluate and develop technology in the field of health (and social) care is assigned to Stakes, as well as the production and dissemination of information material.

Some other groups and units within Stakes are also involved in research that is relevant to health technology assessment. Through internal division of labour, FinOHTA has had the main responsibility to assess individual health technologies or health conditions (micro-level assessment), whereas the other groups are mostly involved in studying health services on a more general level (health system research or macro-level assessment). Part of FinOHTA's projects have addressed organizational issues, too.

2.2.2 Organization and staff

Originally, and like some other units of Stakes, FinOHTA had a status of a "*special unit*" (*erillisyksikkö* in Finnish), which ensured a level of autonomy and the ability to define its own procedures for project approval and publication policies. In the general reorganization of Stakes in year 2000, FinOHTA was defined (as all other research units) as one of the "*groups*" within one of the larger *divisions* (i.e. the Health and Social Services Division).

⁹ Laki sosiaali- ja terveysalan tutkimus- ja kehittämiskeskuksesta 27.11.1992/1073.

¹⁰ Asetus sosiaali- ja terveysalan tutkimus- ja kehittämiskeskuksesta 27.11.1992/1120.

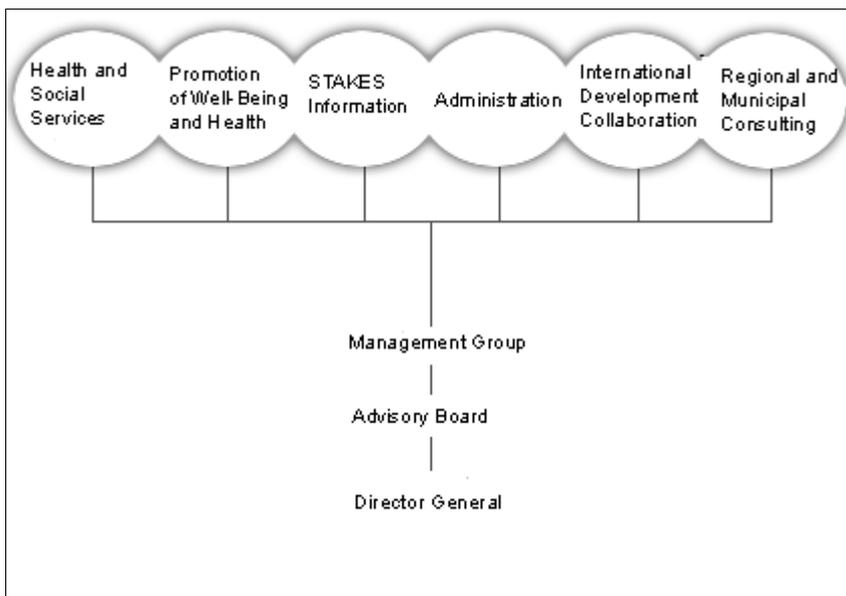


Table 2. Organization chart of STAKES (since 2000)

FinOHTA started as a small unit with only 3–5 employees over years 1995–1998. A considerable growth took place only after year 2002, as the number of full-time staff raised from 7 to the current 12. The growth of the recent years results mainly from hiring researchers and project managers to internal projects.

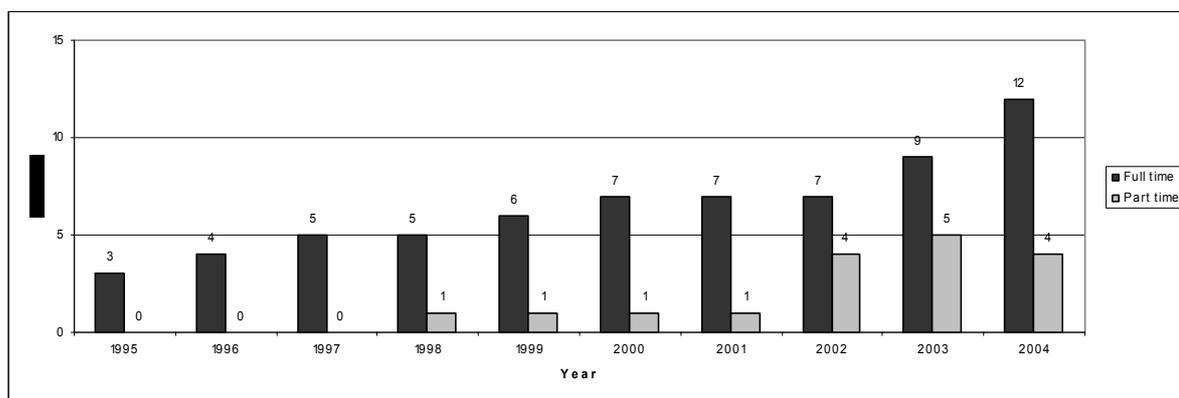


Table 3. Number of FinOHTA staff

From early on, the activities were planned on strong networking with various relevant experts and organizations. The following structures were developed during the early years of FinOHTA to support the work of the Office.

- Consultants**
Four senior consultants in medicine and biometrics provide regular and frequent support to the Office staff.
- Scientific Committee**
The Scientific Committee promotes broad multidisciplinary expertise. It participates in the selection of assessment topics and ensures the commitment of different scientific fields to collaborative assessment work. The 9-member Committee is chaired by the head of FinOHTA. The Committee meets every 2–3 months.

- Advisory Board**
 The Advisory Board represents various key interest groups and organizations of the society. It monitors and guides the operations of FinOHTA and promotes the dissemination and adoption of assessment results. The Board has 30 high-level members and is currently chaired by Dr. Jussi Huttunen, former head of the National Public Health Institute and current chief editor of the Duodecim Medical Journal. The Board convenes 1–2 times per year.
- Expert Network**
 A network of some 60 national experts of various medical specialties and other health-related fields provide expert support for FinOHTA's staff and projects whenever needed. Recently the utilisation of the Network has been relatively low, with the exception of their involvement in the information dissemination activities.

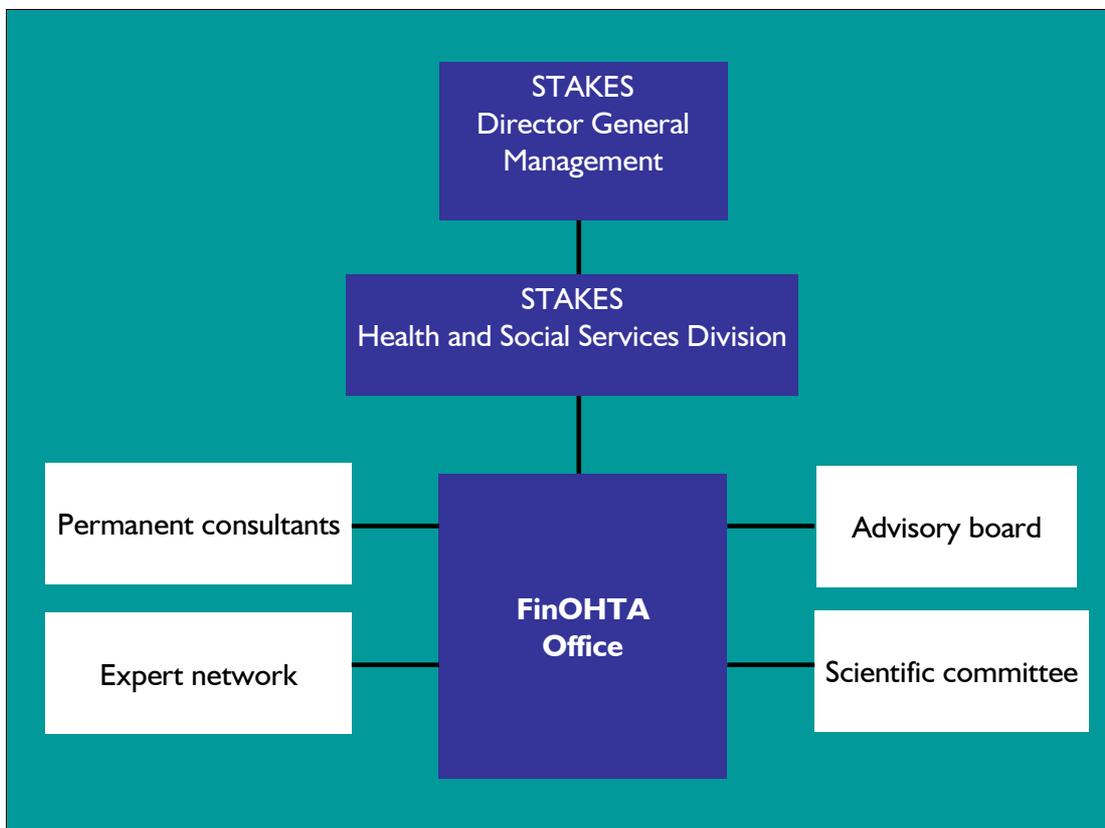


Table 4. Organization chart of FinOHTA

It can be argued that until the year 2000, the leadership of FinOHTA was not on a solid basis. The official head of unit had applied for leave of absence and the position was filled during years 1996–1999 through a temporary arrangement. Two persons had the position of the acting head of unit (periods 1996–1998 and 1998–1999). The leadership position was declared open as of the beginning of year 2000 and since then the leadership has been stabilized. The process caused some turmoil in the Office and as a result a considerable turnover in personnel took place in 2000 and 2001. As of year 2002, the staff structure has reached a new equilibrium and most employees have worked in the Office since 2002 or longer. (See Appendix 2)

2.2.3 Budget

The budget of FinOHTA is defined within the Stakes budget. No clear "earmarking" of the resources available for FinOHTA exist. Until recently, the annual total budget of FinOHTA has been approximately 0.7 – 0.9 million euro, including both Stakes budget and external project funding (the amount of the latter has varied over the years between 5 and 15% of total budget). The budget has fluctuated primarily due to changes in Stakes total budget.

As a result of the decisions that were made based on the National Health Project, the budget of FinOHTA for year 2004 is 1,08 million euro (excluding possible external project funding) and it will be increased up to the level of 2,5 million euro by the year 2007. The following figure displays the development of FinOHTA total budget over the years 2000–2004 (including external project funding). In these sums, the overhead cost is invisible. It amounts to an additional sum which is about 70% of the budget shown here and governed directly by FinOHTA. The overhead cost (that Stakes charges) covers the premises, administrative services, library and IT support, copying costs, etc.

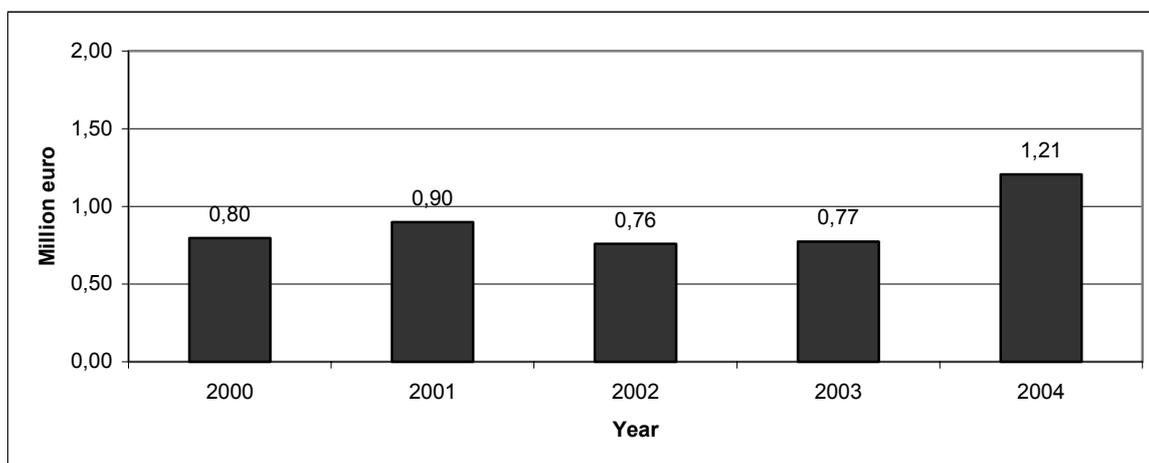


Table 5. Total budget of FinOHTA 2000–2004.

2.2.4 Brand

Using its somewhat autonomous position within Stakes and drawing from the experience of international HTA agencies, FinOHTA has consciously developed its own brand and publications. The aim has been to make health technology assessment known among health care workers and decision-makers and to bring the results of assessments into everyday use. As lack of time is a common problem within health care, the use of easily identifiable materials has been regarded essential.

The development of FinOHTA's own brand has been somewhat controversial within Stakes. In most cases, FinOHTA has been able to develop and use its own materials based on its needs and judgement. Sometimes, however, the need and appropriateness of such a policy has been criticized and questioned.

2.2.5 Activities of FinOHTA

FinOHTA's activities can be divided into the following three categories:

1. HTA research
2. Dissemination of information
3. National and international collaboration

HTA research

FinOHTA promotes HTA-related research in Finland by co-ordinating assessment activities, by launching its own assessment projects and by offering financial and methodological support to assessment projects conducted by external researchers.

FinOHTA has construed HTA as a wide range of research activities. Although some international HTA agencies produce only (or mostly) systematic reviews of available evidence, FinOHTA has also been active in other types of research that might assist decision making in health care. Hence, there is no "typical" FinOHTA project. Instead, FinOHTA chooses a methodology that fits the research question at hand and consequently the projects can be divided into the following main categories:

- Systematic reviews of available evidence
- Primary studies (etc. randomized controlled trials) that study the effectiveness of cost-effectiveness of various health technologies (when there is no or not enough prior evidence available)
- Surveys etc. (to clarify the use of technology or variation in practices)
- Modelling the costs of various approaches to technology utilization
- Development (e.g. when the technology assists further HTA information retrieval)

Since 1995, a total of 60 research projects have been completed. Currently FinOHTA participates in 27 projects. More information on the topics and statistics of FinOHTA projects is available as Appendix 4.

Dissemination of information

In addition to supporting and conducting HTA research in Finland, FinOHTA acts as a clearinghouse for information on health technology assessment. Guidance through information provision is FinOHTA's fundamental method for influencing the health care system. FinOHTA actively acquires information from national and international sources. The information is tailored according to local needs and disseminated to the health care actors, decision makers, and the general public.

The potential clientele of FinOHTA is very broad. In principle it encompasses everyone who operates within health care or whose work is in some way related to health care, as well as the general public (i.e. patients or consumers). During the early years of FinOHTA, the emphasis of communications was consciously and intentionally placed on interaction with clinical decision makers (primarily physicians). Due to public availability of information through the Internet, however, also the general public has had access to the information from early on.

Also the national media (TV, radio, newspapers, etc.) has adopted FinOHTA as an information source, both in the context of FinOHTA's own projects, and as a provider of background information in various topics. Since FinOHTA operates under the auspices of the Ministry of Social Affairs and Health, the Ministry is an obvious and central client. Likewise, other government organizations (e.g. the National Public Health Institute or The Institute of Occupational Health) are important partners.

FinOHTA has used (and mostly still uses) the following methods and media to disseminate information:

- Own publications
 - Newsletter *Impakti* (6 issues per year)
 - FinOHTA Reports (results of own research projects)
 - Technology Updates (translations of the results of foreign projects, 15 issues during 1995–2000)
 - Brochures of FinOHTA
- Targeted communication (notifications of foreign HTA results to national experts)
- World Wide Web (Site online since 1995, over 600 000 page requests in 2003)
- Project communications (to address specific needs of each project)
- Replies to information requests (from various organizations and individuals)
- Library collection of approximately 1000 items (mostly international HTA reports) available for public use
- Education (courses, seminars)
- Utilization of other media
 - Physician's CD (CD ROM with practice guidelines and a large variety of other material)
 - Terveysportti (web site)
 - Finnish Medical Journal (professional and scientific journal)
 - Kuluttajauutiset (monthly newspaper on consumer issues)
 - Duodecim

National and international collaboration

An extensive and intensive national and international collaboration network has been and is the fundamental base for FinOHTA's operations. Various forms of collaboration include e.g. research cooperation and coordination, information exchange and dissemination, and educational activities.

Until now, FinOHTA has collaborated primarily with the following organizations and bodies:

National level

- Hospital districts
- Ministry of Social Affairs and Health¹¹
- Universities
- Finnish Medical Society Duodecim¹²
- Current Care project¹³
- Primary health care centers
- Other research groups of Stakes
- National Public Health Institute¹⁴
- Occupational Health Institute¹⁵
- National Agency for Medicines¹⁶
- ROHTO¹⁷

International level

- INAHTA, the International Network of Agencies for Health Technology Assessment¹⁸
- HTAi, Health Technology Assessment International¹⁹
(formerly ISTAHC, the International Society for Technology Assessment in Health Care)
- NOHTA, Nordic collaboration of national HTA agencies
- Cochrane Collaboration²⁰
- AGREE, Appraisal of Guidelines Research and Evaluation²¹
- GIN, Guidelines International Network²²

¹¹ <http://www.stm.fi>

¹² <http://www.duodecim.fi>

¹³ <http://www.kaypahoito.fi>

¹⁴ <http://www.ktl.fi>

¹⁵ <http://www.ttl.fi>

¹⁶ <http://www.nam.fi>

¹⁷ <http://www.rohto.fi>

¹⁸ <http://www.inahta.org>

¹⁹ <http://www.htai.org>

²⁰ <http://www.cochrane.org>

²¹ <http://www.agreecollaboration.org>

²² <http://www.g-i-n.net>

2.3 Future expectations

According to many independent observations and observers, Finnish health care is effective, efficient and remarkably equitable, especially from the point of view of equity in provision. The financing of care still contains a number of unusual features that undermine an otherwise equitable system.²³ The basic design ensures that health care services are principally under the control of local populations. Nonetheless, the Finnish health care system, like other health care systems, must cope with increasing expectations and costs, variation in practice, the need for continuous quality improvement, and reducing gaps between research evidence and practice.

In response to these needs, there is growing demand for evidence-based health care and political solutions. The State Council announced the package of health sector reform proposals in April 2002 as a part of the country's "national project" with the aim to ensure the availability and quality of the health care services. Some of these proposals have already been implemented including increased funding for the evaluation of health care technology.

Health technology assessment including pharmacoeconomic assessment will and should play an increasing role in Finland. It is also important to recognise that HTA can inform decision-making but it is not a substitute for it. Values, culture, ethics, psychology and politics complicate the equation.

Assessments can be used to support decision making at the micro (clinical), meso (hospital or health authority) and macro (government, insurance) levels. Government and health care organizations will increasingly require pharmacoeconomic assessments of the costs and benefits of new drugs. Assessments will and should be used in the development of evidence-based clinical practice guidelines, e.g. Current Care -guidelines.

The role of HTA will be valuable because many widely used technologies are of uncertain effect in terms of improving patient/population health. Further, there is a need to improve the interaction between producers and users of HTA. For instance in Canada, to improve the use of HTA in decision-making Ontario Health Technology Advisory Committee was established to bring together senior hospital decision-makers and clinical experts to identify new and emerging technologies and set priorities for assessment. The committee promotes the use of HTA in decision making by bridging the worlds of evidence and decision-making.²⁴

Since the introduction of HTA in the seventies, many challenges remain, including future technologies. Over the next 20 years biotechnology will take health beyond the traditional treatment concepts of palliation, cure and prevention. Such new technologies will have important economic and bioethical consequences.

²³ Health Care Systems in Transition; Finland, written by Jutta Järvelin and edited by Ana Rico and Teresa Cetani. European Observatory on Health Care Systems (2002), Vol. 4, No 1.

²⁴ Towards High-Performing Health Systems. The OECD Health Project. ISBN 92-64-01555-8, OECD 2004.

3 REVIEW PROCESS

3.1 Mandate and aim

The Ministry of Social Affairs and Health has decided to increase the resources allocated for FinOHTA during the next years. In order to ensure optimal use of the increased resources, the leadership of Stakes decided to invite an international expert group to support the development of FinOHTA.

As the aim of the process is to support optimal future development of FinOHTA, the evaluation group decided to focus on

- 1) charting various expectations that relevant parties have of the functions and services of a national technology assessment organization,
- 2) considering these expectations in the light of experience gained in an international (mainly European) context, and
- 3) formulating recommendations for the future development.

Thus, the main angle of view of this review is towards the future.

3.2 Process

The evaluation commenced in the beginning of the year 2004. The international evaluation group convened in Helsinki three times (in February, May and June).

The group heard a broad spectrum of experts (representing relevant organizations) during the meetings.

Table 6. Organizations and persons who were interviewed

Organization	Representative(s)
Association of Finnish Local and Regional Authorities	Liisa-Maria Voipio-Pulkki <i>Administrative Chief Physician</i>
Cancer Society of Finland	Harri Vertio <i>Secretary General</i> <i>(former executive director of the Finnish Centre for Health Promotion)</i>
Finnish Medical Society Duodecim	Juha-Pekka Turunen <i>Head of Education</i>
FinOHTA	Head, professor Marjukka Mäkelä Various staff members
FinOHTA	Martti Kekomäki <i>Professor, University of Helsinki</i> <i>Permanent Consultant</i> Risto Roine <i>Chief Physician, Helsinki and Uusimaa Hospital District</i> <i>Permanent Consultant</i> Olli-Pekka Ryyänen <i>Secretary General, Finnish Lung Health Association</i> <i>Permanent Consultant</i>
Ministry of Social Affairs and Health	Risto Pomoell <i>Ministerial Counsellor, Health Affairs</i> Päivi Hämäläinen <i>former Project Manager of the National Health Project</i>
National Agency for Medicines	Erkki Palva <i>Professor, Head of Department</i>
National Authority of Medico-Legal Affairs	Antero Mäkelä <i>Chief Physician</i>
National Occupational Health Institute	Hilkka Riihimäki <i>Head of Department</i>
National Public Health Institute	Pekka Puska <i>Director General</i>
National Social Insurance Institution	Jorma Järvisalo <i>Deputy Head of Research Department</i>
ROHTO (National Development Centre for Pharmaceutical Treatment)	Arja Helin-Salmivaara <i>Development Manager</i>
STAKES Management	Vappu Taipale <i>Professor, Director General</i> Juha Teperi <i>Deputy Director General (acting)</i>
STAKES Health and Social Services Division	Ilmo Keskimäki <i>Director of Division (acting)</i>
STAKES FinSOC (Finnish Evaluation of Social Services)	Riitta Haverinen <i>Group Manager</i>
STAKES CHESS	Markku Pekurinen <i>Head of Chess</i>
Hospital Districts	Timo Keistinen <i>Vaasa Hospital District, VSHP</i> Antero Kesäniemi <i>Northern Ostrobothnia Hospital District, PPSHP</i> Anja Tuulonen

	<p>Northern Ostrobothnia Hospital District, PPSHP</p> <p>Taina Turpeenniemi-Hujanen Northern Ostrobothnia Hospital District, PPSHP</p> <p>Jorma Penttinen Hospital District of Northern Savo, PSSHP</p> <p>Jukka Puolakka Central Finland Health Care District, KSSH</p> <p>Hannu Puolijoki Southern Ostrobothnia Hospital District, EPSHP</p> <p>Eva Salomaa Lapland Hospital District, LSHP</p> <p>Olli Wanne Satakunta Hospital District, SATSHP</p>
International Network of Agencies for Health Technology Assessment INAHTA (Finn-Boerlum Kristensen, Berit Moerland)	<p>Finn Boerlum Kristensen Chairman</p> <p>Berit Moerland Ex-Officio</p>
WHO HEN (Egon Jonsson)	<p>Egon Jonsson HEN Team Leader</p>
Private individuals	<p>Marjatta Blanco retired deputy director general, Department of Health, Ministry of Social Affairs and Health</p> <p>Jussi Huttunen Reporting Adviser of the Science and Technology Policy Council of Finland Chairman of FinOHTA's Advisory Board former Director General of the National Public Health Institute</p>

Most parties were heard during group interviews that were arranged in May at Stakes. The National Public Health Institute and the hospital district directors provided their feedback through email communication. Representatives of INAHTA and WHO HEN were interviewed by telephone or personal contact.

The evaluation group agreed on ten key questions during its first meeting and used these in the interviews. The discussions, however, were not limited to the topics presented in the questions.

Table 7. Evaluation Questions

Purpose
1. What are the ideal aim/mission and practical goals for FinOHTA?
2. What should be FinOHTA's main target audience(s)? Is there currently too strong an emphasis on reaching physicians?
3. How should FinOHTA choose topics for assessment? What kinds of questions should be answered?
4. How should FinOHTA relate to pharmaceuticals within the Finnish health care system?
Position
5. Should FinOHTA be more independent? Who should define priorities in research topics and methods?
6. What is the role of FinOHTA in national and international collaboration?
7. Should FinOHTA have local "satellites" in Finland, to what extent decentralise activities?
Action
8. Should FinOHTA fund external research? If so, to what extent and what kind of research?
9. What should FinOHTA's role be in the implementation of HTA results?
Quality
10. How to ensure FinOHTA's internal competence in various fields and access to external competence whenever needed?

4 REFLECTIONS AND RECOMMENDATIONS

After listening to the relevant parties and reviewing available background documentation, the Evaluation Group considered the various views that were expressed and formulated its conclusions and recommendations in response to the 10 questions that were posed as well as additional issues that were raised in relationship to these questions. The main observations and recommendations are presented in this chapter. Some of them support and confirm FinOHTA's hitherto practices and some suggest a change and the adoption of new practices. The key recommendations are numbered sequentially and marked with a vertical bar.

4.1 Aim and mission

- (1) FinOHTA needs a clear and compelling aim for its activities. The focus of the activities should be on the provision and dissemination of evidence on the effectiveness and cost-effectiveness of health technologies, as well as on the support for HTA and evidence-based health care in Finland.

HTA does not have a precise definition and its scope varies from country to country. Its core components include systematic reviews, particularly of evidence of the effects of health technologies – which is international – and "health technology assessments" which are context specific and may include economic analyses and assessments of needs, resources, ethical considerations.

- (2) Although primary research, including randomised trials and methodological research, is sometimes included within the scope of "HTA", these should not be considered core activities of FinOHTA.

- (3) FinOHTA should be more active in initiating projects studying issues that are important to health care decision making in Finland.

Evidence from effectiveness research should be considered taking into account local information on needs, resources and costs. Hence, the information should be tailored to the local context. In this process, the benefits, harms, and costs of technologies should be considered. Values or preferences also need to be taken into account when making decisions or recommendations. Although FinOHTA does not make recommendations, it can help to clarify the role and potential impact of different values that might be used in balancing benefits against harms and costs.

All products of FinOHTA should be of high quality.

- (4) Processes to ensure the quality should continue to be developed.

- (5) FinOHTA should not make recommendations or take primary responsibility for the implementation of recommendations. A clear strategy with regard to responsibilities for translating the results of HTAs into recommendations and implementing those recommendations is needed, both within FinOHTA and more widely among the various organizations in Finland that share responsibility for this.

Currently, the role of FinOHTA in relation to other relevant health care organizations involved in knowledge production and dissemination is not clear enough. For example, the role of FinOHTA in producing assessments regarding pharmaceuticals is not clear in relation to Rohto and other organizations (e.g. the Pharmaceutical Pricing Committee, the National Agency of Medicines and the National Social Insurance Institution).

- (6) The role of FinOHTA should be clarified, particularly in relationship to pharmaceuticals and clinical practice guidelines (e.g. Current Care project and the Evidence-based Guidelines).
- (7) FinOHTA should have a role in education, particularly in training related to evidence-based health care. For example, PhD candidates can contribute to HTAs as part of their thesis. Generally FinOHTA should not have primary responsibility for education, but should support universities and others with this mandate.

4.2 Organizational Issues

- (8) The Advisory Board of FinOHTA should have a more active role, particularly in issues of strategic importance. Reducing the size of the Board, reconsidering its composition, and having it convene more often than twice a year could help to accomplish this. More active involvement of the Board will provide FinOHTA with a more stable and active contact with important actors in the field of healthcare. Alternatively, a sub-group of the Board could have a more active role. The composition of the Board should also be reconsidered to ensure that its members have enough time and interest to participate actively. The members of the Board should have an appropriate mandate from their organizations.
- (9) The Scientific Board should have a clearer decision-making role in prioritizing HTA projects. Someone outside of FinOHTA should chair the Board. This would help ensure open discussions as well as full participation of the head of FinOHTA, who should be a full member of the Board.
- (10) The Report Series of FinOHTA should have an Editorial Board with members outside Stakes. It should be considered whether the Scientific Board could also act as the Editorial Board.
- (11) Since FinOHTA is not yet very well known within Finland, interventions should be aimed at making it more known on the national level.

- (12) On national level, it would be useful to clarify roles of various organizations that are relevant to evidence-based healthcare. As mentioned earlier, such clarification would be particularly important in relationship to pharmaceuticals. Similar clarification would be important particularly in relation to the Current Care project. A comprehensive mapping of the roles and activities of all of the relevant organizations would be useful.

Some of us and also of those we interviewed raised the issue of the name of FinOHTA.

- (13) Consideration should be given to finding a Finnish name and acronym. FinOHTA could still be used in English.

4.3 Independence and priority setting

One of the key factors for the success of a HTA organization is that it is perceived to be independent and of high intellectual integrity.

Those we interviewed expressed various perceptions regarding where and how FinOHTA should be organised.

- (14) Currently it seems to be that FinOHTA should continue being situated within Stakes, provided that an independent position within the organization can be guaranteed.

In this context, an independent position includes the following: a) intellectual integrity and scientific independence, b) financial independence and c) the ability to maintain its own publications and brand.

Intellectual integrity and scientific independence includes the ability to independently select assessment methods, draw conclusions and publish results using its own editorial process. Furthermore, although FinOHTA is financially dependent on the Ministry of Social Affairs and Health, it should be independent from the Ministry in selecting methods it uses, interpretations and publishing of the results. As an organization, FinOHTA should be able to express views (based on evidence) that are not in accordance with the Ministry's current view.

FinOHTA assists the Ministry directly by providing answers to questions that have been posed by the Ministry.

- (15) Any such questions and answers should be made public.

Financial independence refers to FinOHTA's ability to control its budget.

- (16) FinOHTA should have an "earmarked" budget within Stakes budget, i.e. have its own "line" within Stakes' budget.

FinOHTA is not yet well known within the field of health care.

- (17) FinOHTA should continue efforts to make its "brand" and products known, particularly since some actors in the field of health care regard Stakes primarily as an organization active in the social care sector.

4.4 Target audience

Health care decision makers and other policy makers on all levels should be the main target audience of FinOHTA. The public health care sector should be the main audience, but the private sector should also be taken into account whenever appropriate.

- (18) The primary target of FinOHTA should be organizations responsible for making health policy and clinical practice guidelines, as well as organizations that are responsible for providing health care services - not individual clinicians.

Physicians are key decision makers on the clinical level. FinOHTA should also target other professionals and consumers. Furthermore, FinOHTA should increase awareness among the public of the results of HTA and how the results are derived.

4.5 Assessment topics

- (19) Assessment topics should be selected using explicit criteria and a transparent selection process. The criteria list should include criteria for priority setting.

The list should address the following aspects:

- how common the problem is
- how severe the problem is
- how costly it is
- the extent of variation in practice
- the extent to which practice may not be in accordance with existing evidence
- the extent of uncertainty regarding what evidence there is
- the extent of uncertainty regarding how the evidence should be applied in Finnish context

The Scientific Committee currently provides advice on priority setting, although they may not be in the best position to do that from a societal viewpoint. This is somewhat problematic.

- (20) Consideration should be given to involving the Advisory Board in decisions regarding large HTA projects.

4.6 Pharmaceuticals

Assessment of pharmaceutical therapies is important in Finland and other countries, both economically and from the viewpoint of patient safety. It is a problematic area because there are several organizations with overlapping responsibilities and some gaps in responsibility.

- (21) The Ministry of Social Affairs and Health should take initiative to have a common discussion with FinOHTA and other relevant organizations, primarily the National Agency of Medicines and Rohto, to clarify their respective roles and responsibilities.

An additional problem is that there is limited capacity to undertake systematic reviews and economic analyses in Finland and internationally. Consequently,

- (22) Formal international collaboration in the field of pharmaceuticals should be encouraged. This might initially build upon existing Nordic collaboration. Nationally, the limited resources should be coordinated to ensure optimal use of the available capacity.

If FinOHTA does not consider pharmaceuticals, it would be unable to look into issues from a broad perspective. Consequently,

- (23) FinOHTA should take responsibility for assessing different treatment options, including pharmaceuticals. This is particularly important in the context of assessments of the cost-effectiveness of alternative treatment options for a health problem. To the extent that FinOHTA assesses pharmaceuticals, it needs to ensure that it has expertise in clinical pharmacology.

Unless a decision is taken together with the Ministry and other relevant organizations to have a clear division of labour and responsibilities in which FinOHTA does not have any responsibility for assessing pharmaceuticals,

- (24) FinOHTA should not exclude technology assessments of pharmaceuticals.

FinOHTA should not accept funding from pharmaceutical industry.

One possible solution to clarifying the current situation would be to reconsider the organization of FinOHTA and Rohto (e.g. to merge the two units). It may also be appropriate to reconsider the role and position of Current Care project. This can be arranged through a formal agreement between FinOHTA and Current Care.

Until this is resolved, recent plans of FinOHTA to hire a shared economist together with the Rohto, should be reconsidered. FinOHTA should consider whether this is an appropriate arrangement.

4.7 International collaboration

International collaboration is an integral part of FinOHTA's activities.

- (25) FinOHTA should continue being active in the international HTA field, particularly by collaborating with the *International Network of Agencies for Health Technology Assessment* (INAHTA) and the *Health Technology Assessment International* (HTAi).

Currently the head of Unit has been responsible for most international tasks. More people should be involved in such tasks in the future.

FinOHTA should also continue being active in the Cochrane Collaboration.

- (26) The Finnish branch of the Nordic Cochrane Centre should continue being located in FinOHTA.

4.8 Decentralized activities

Preliminary plans of creating local satellite offices for FinOHTA in some major cities have been discussed. In the near future, however,

- (27) FinOHTA should not have such local offices, since it is important to ensure a critical mass with diverse competency in a central location, and because additional offices would require considerable resources.

For practical reasons, however, it might be feasible, to make arrangements for more permanent remote work possibilities. Such arrangements are up to FinOHTA to decide, based on current needs.

Collaboration and networking on national level is very important.

- (28) FinOHTA needs to identify people in various locations in Finland who can be engaged in HTA processes (projects, information dissemination, etc.). Local contact persons might assist in designing projects prior to sending them to FinOHTA for consideration.

4.9 Funding of external research

- (29) It is appropriate for FinOHTA to fund systematic reviews and economic analysis.

With respect to supporting primary research, the policy requires some refinement according to the following principle:

- (30) If a topic that requires clarification through a primary study is identified within a technology assessment, FinOHTA could provide methodological or limited financial support for protocol development and pilot studies for a primary research project rather than acting as a research funding agency for primary studies.

It may be important to provide methodological support to research groups so that the studies will more easily get external funding elsewhere.

- (31) One mechanism for doing this, as well as building capacity in Finland, would be to fund visiting professors or scientists to work at FinOHTA.
- (32) FinOHTA should also support implementation research.
- (33) The Ministry of Social Affairs and Health should consider acknowledging the scientific merit of FinOHTA reports, for example through awarding "EVO points" to the host organizations of contributing authors.

4.10 Implementation

Health technology assessments provide information that should be used in policy decisions and clinical practice guidelines.

- (34) FinOHTA should play a role in ensuring that information from assessments is used, but it should not be the primary body responsible for implementation.
- (35) FinOHTA should provide support for implementation organizations (such as hospital districts, health care centres, medical schools, and medical and health organizations) on the local level and relevant projects (such as Current Care). The support should include providing information about implementation strategies, advice, training and help with evaluations of implementation strategies.
- (36) There is a need to clarify the roles and co-ordination of various organizations that are involved in dissemination and implementation activities. There is a need for a national strategy on this issue, perhaps even for a new structure. Implementation strategies should be evidence-based and a national strategy should include mechanisms to help ensure that they are.
- (37) FinOHTA should also provide support to medical schools in implementing evidence-based healthcare. In this process, it would be useful to have HTA-related academic positions (e.g. professors) in medical schools.

4.11 Internal and external competence

Securing both the internal and external competence of FinOHTA requires multiple measures. Visiting professors could provide contact points to research being undertaken in various organizations.

- (38) As cost-effectiveness studies are an important component of FinOHTA's work, more economic expertise is needed.
- (39) FinOHTA should ensure that its staff has an adequate amount of internal education and that the staff have opportunities to visit other organizations to enhance their scientific skills.
- (40) Special emphasis should be placed on ensuring the stability of the personnel. (See Appendix 2)
- (41) FinOHTA should develop and use systematic self-assessment of its processes, projects and products.

It is important for FinOHTA to keep a high profile and to be recognized for scientific competence.

- (42) FinOHTA should work toward a situation where participation in its projects is also regarded as having academic merit. For example, systematic reviews should be recognised as part of PhD theses.
- (43) In addition to assessment projects, FinOHTA should also be active in research that is relevant to technology assessment. Such areas include implementation research and methodology research.

4.12 Use of additional resources

The number of FinOHTA staff will increase during the following years. A large unit, however, requires a different organizational structure than a unit that is of a reasonable size. To prevent the need for major organizational changes,

- (44) FinOHTA should limit the size of its staff. An appropriate number would be between 20 and 24. Additional resources should be used for external work.

The following rule of thumb could be used in this process:

- (45) Less than 50% of the final 2.5 million euro should be used on staff expenses, and the rest should be used for other purposes.

(46) The following competencies should be ensured:

- methodological (HTA) and statistical competence
- medical and pharmacological competence
- health economic skills
- information science skills
- communication skills
- service functions (support staff)

Considering the current division of the staff expertise and the expansion of the staff,

(47) there is a clear need to increase competence in the following areas: information science, communication, health economics, statistics and clinical pharmacology.

(48) The core activities of FinOHTA in the future should be health technology assessments, including:

- systematic reviews
- economic analyses
- application of evidence to the Finnish context (including assessments of needs, resources, organizational, ethical and legal consequences)
- horizon scanning
- monitoring, adaptation and dissemination of the findings of international HTAs
- providing rapid responses to questions raised by the Ministry of Social Affairs and Health.

5 APPENDICES

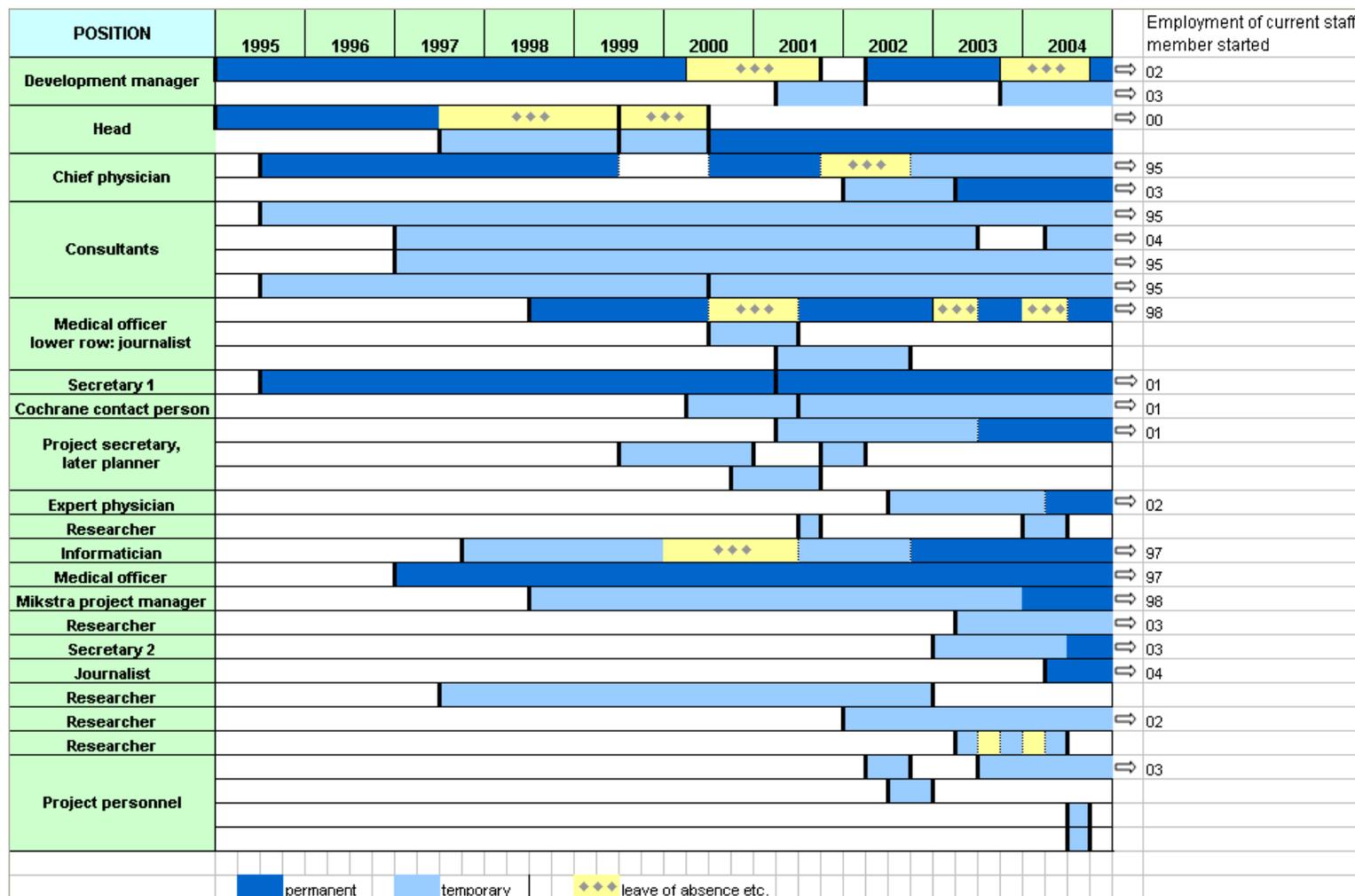
Appendix I: Abbreviations

Some common abbreviations and acronyms used in the context of health technology assessment are explained in the following table:

Abbreviation	Explanation
AGREE	Appraisal of Guidelines Research and Evaluation (Organization)
CEA	Cost-effectiveness analysis
Current Care	A Finnish project that develops clinical practice guidelines
EBM	Evidence-based medicine
EBHC	Evidence-based health care
ECHTA	European Collaboration for Health Technology Assessment (Organization)
ECAHI	European Collaboration for Assessment of Health Interventions (Organization)
GIN	Guidelines International Network (Organization)
HTA	Health Technology Assessment, sometimes also Health Care Technology Assessment
HTAi	Health Technology Assessment International (Organization)
INAHTA	International Network of Agencies for Health Technology Assessment (Organization)
NOHTA	Nordic collaboration of national HTA agencies (Organization)
RCT	Randomized Controlled Trial

Appendix 2: FinOHTA staff over time

The following figure is a graphic representation of FinOHTA's staff members over time. Black vertical bars represent change of person holding a position.



Appendix 3: FinOHTA projects

This document lists all ongoing FinOHTA projects and most of the already completed projects. All ongoing projects are marked with an asterisk (*). An analysis of the number and types of projects launched and completed during the years 1999–2004(June) follows the projects. Finally, a draft of renewed project criteria is presented.

Internal projects

The following projects have been carried out primarily by FinOHTA staff. Also external projects (i.e. projects that have been realized by external researchers) have been included, if the results have been published as FinOHTA Reports and consequently the Office has had a major role in preparing the report.

1. * Mikstra Programme (Antimicrobial Treatment Strategies), 1998–2006
2. * Effectiveness of helicopter use in emergency medical services, 1999–2001 (completed), 2003–2004 (continuation project)
3. * Blood glucose self-monitoring in diabetes, 2002–2004
4. * Elevated blood pressure, 2002–2004
5. * Rehabilitation of Cerebral Palsy, 2003–2005
6. * Effectiveness of preventive home visits in community-dwelling elderly, 2003–04
7. * Prenatal screening of foetal anomalies in Finland, 2004
8. * Glaucoma screening, 2003–2004
9. * Effectiveness of interventions for coronary heart disease, 2004
10. * Endoscopic sympatectomy, 2002–04
11. * Prioritization of clinical guideline topics, 2003–2004
12. Newborn screening in Finland, 2002–2004
13. Guidelines for health care unit costs in Finland, 2001–2002
14. Annual costs of medical technology in hospitals, 1998–99
15. Assessment of an electronic referral and teleconsultation system between secondary and primary health care, 1998–99
16. Assessment of the Satakunta Macro Pilot Project, 1999–2002
17. Breast cancer screening among women aged 60–69 years, 2000
18. Colorectal cancer screening, 2000
19. From traditional film-based radiology to digital imaging, 1999–2001
20. Coronary angioplasty in Finland - An overview of the situation in 2000 and an estimation of needs in the near future, 2000–2001
21. Treatment of pain caused by endometriosis, 2001

Currently active external projects

The following projects are carried out mainly by researchers working in various organizations (outside FinOHTA). FinOHTA provides methodological and financial support for the projects. The results are published mostly as scientific articles. Completed external projects are not included in the list.

22. * Regional variation in the treatment and treatment results of congenital malformations requiring urgent surgical treatment
23. * Effects of cardiac rehabilitation: psychosocial change, use of health care services and cost-effectiveness
24. * Effectiveness of corset in low back pain during pregnancy
25. * PSA screening for prostate cancer - An economic analysis
26. * Cost-effectiveness of lumbar support for acute low back pain. A randomized controlled trial
27. * Cost-effectiveness of rehabilitation following operative treatment of hip fracture
28. * A model for prioritizing a Finnish sample patient population
29. * Cost-effectiveness of the treatment for otitis media in children
30. * Methods to measure the cost-effectiveness of secondary care

International joint projects

FinOHTA participates or has participated in the following international assessment projects.

31. * Orthodontics, 2003–2006
(SBU, Finnish Dental Association)
32. * Sleep apnoea, 2004–2006
(Nordic HTA units, University of Tampere, Finnish Lung Health Association)
33. * IHI-QET: Internet Health Information - Aspects of quality, ethics and trust, 2001–2004
34. Hearing impairment, 2000–2003
(Sweden, Norway, Denmark, UK)
35. MedCERTAIN: Third-party evaluation of Internet health content, 2000–2004
(Finland, Germany, UK)
36. Telemedicine: a systematic review, 2001, updated 2003
(Finland, Canada, Australia)
37. ECHTA/ECAHI: Health technology assessment in Europe, 2000–2002
(15 European countries)
38. AGREE: Assessing guidelines for research and evaluation, 1999–2004
(14 European countries + Canada, New Zealand)

Cochrane projects

As the national branch of the Nordic Cochrane Centre, FinOHTA has supported the following Cochrane projects.

39. Psychodynamic psychotherapy in schizophrenia rehabilitation
40. Effectiveness of psychoeducation
41. Effectiveness of multiprofessional rehabilitation in musculo-skeletal diseases
42. Prevention of caries with sealants
43. Prevention of caries with fluoride varnish
44. EU-PSI (Database of published and unpublished controlled clinical trials in psychiatry)

Brief replies to questions

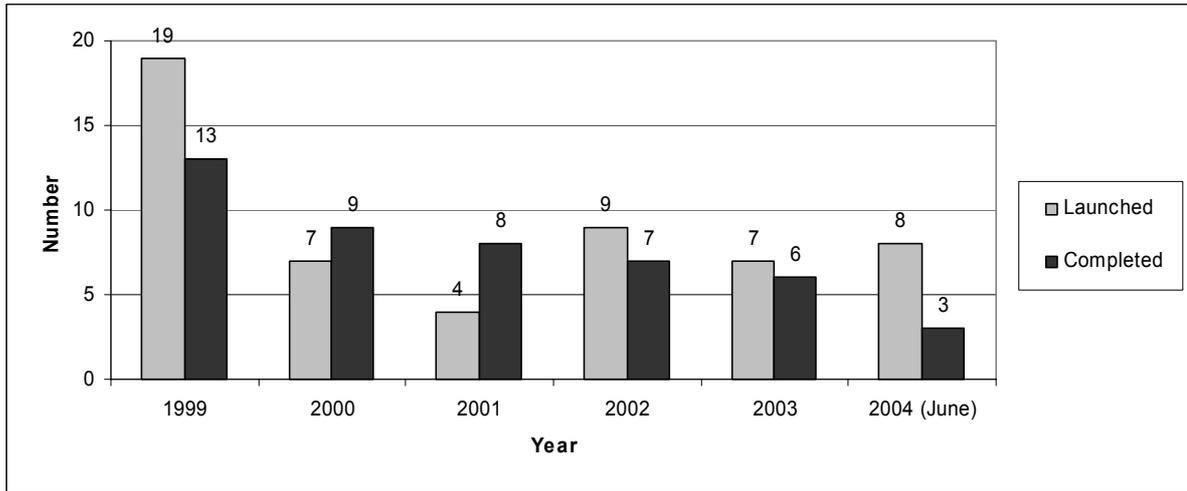
The following list is a sample of the various questions that FinOHTA receives from different sources (e.g. the Ministry of Social Affairs and Health, hospital districts, municipalities, individuals). The questions have not led into actual research projects. Instead, FinOHTA has prepared an individual response to each question.

- Cancer screening programs
- Assessment of hearing among new-borns
- Drug eluting stents
- Gamma-knife
- Effectiveness of complementary therapies
- Provider-specific effectiveness of psychiatric treatments
- Psychological debriefing

Project statistics

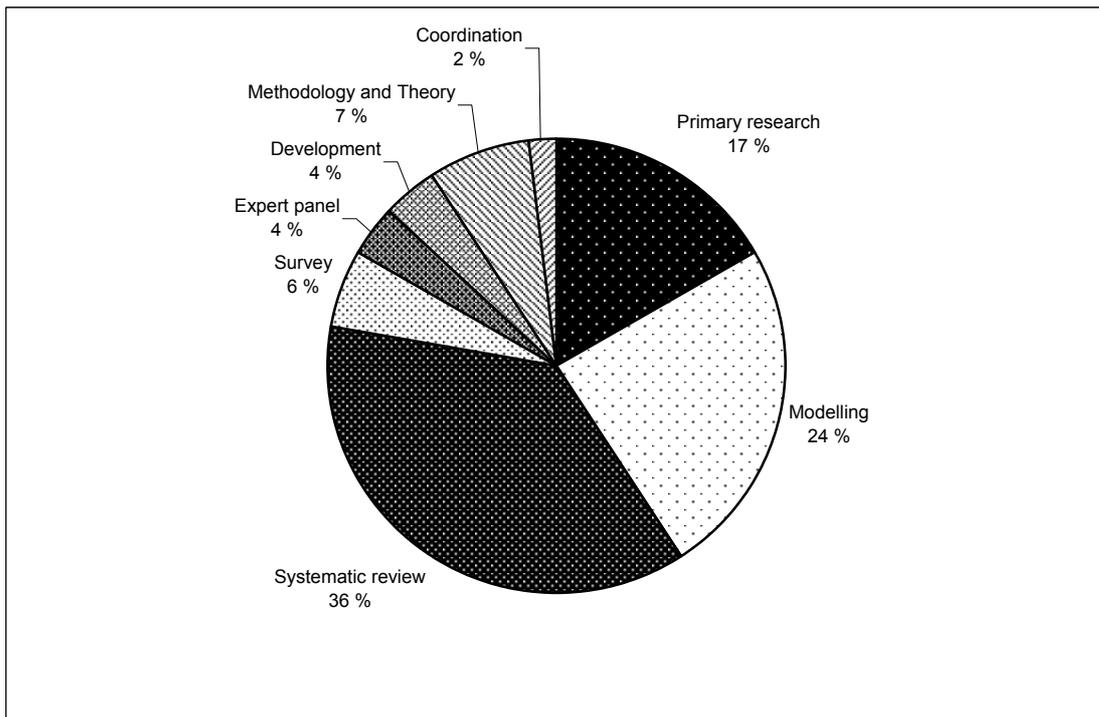
During the period of January 1999 through June 2004, FinOHTA launched a total of 54 projects. During the same period, 46 projects were completed, 15 of which had been launched prior to year 1999. The number of project launched and completed each year is displayed in the following figure.

Figure 1. Number of projects launched and completed 1999–2004(June)



Of the 54 projects that were launched during this period, the majority (36%) were systematic reviews. Every fourth project (24%) was a modelling study (e.g. modelling the costs of various treatment strategies) and 17% of the projects were primary research (e.g. randomized controlled trials). The remaining 23% or the projects used various other methods (e.g. expert panels, surveys).

Figure 2. Project types



Project criteria

The following criteria have been used while selecting project to be supported:

- The method being assessed must be important for the health of the citizens and/or for the national economy,
- The design of the study must be credible,
- The study must be ethically acceptable,
- The study must include the elements and goals of a good assessment project,
- The methods used must be of high quality,
- The results can be exploited in a concrete way,
- The scientists performing the study must have enough experience to assess the topic,
- The budget of the study must be realistic and the funding applied from FinOHTA must be reasonable compared to the whole budget,
- The protocol must include a plan for the dissemination of results and follow-up of effects

The criteria have been reviewed and refined during year 2004, and the following is a draft of the new criteria.

FinOHTA supports assessment projects that study the effectiveness and cost-effectiveness of health care technologies, as well as systematic literature reviews. The supported project may be part of a larger research project. Product development and purchase of equipment are not supported financially. The support is granted for a research group or organization. FinOHTA does not provide support in the form of tax-free scholarships and it does not directly hire research personnel. The assessment projects and literature reviews are evaluated with the help of the following questions:

A. Topic and methods

1. Is the problem significant from the viewpoint of public health or national economy?
2. Is the selected research method appropriate to answer the research question?
3. Does the proposed project contain sections and aims of a good assessment?
 - Does the project aim at assessing the effectiveness of the technology?
 - Does the project aim at assessing the cost-effectiveness of the technology?
 - Does the project address the social, ethical, juridical aspects, as well as quality of life?
4. Is the research methodology of high quality?
 - In case of primary studies, is there a systematic review on the topic available?
 - Are sound scientific methods used?
 - Is the effectiveness research prospective, controlled and randomized?
5. Can the results be utilized in practice?
 - Does the project aim at providing citizens with more health with health care resources?
 - Is the cost of the research reasonable in comparison with the new knowledge attained?

- Can the results be used in other projects as better research methods or knowledge base?
- 6. Are aspects relevant to ethics and privacy adequately addressed?
 - The applicant should also pay attention to the intellectual property rights of research results and possible products.
- 7. Have the researchers declared any possible conflicts of interests?

B. Researchers

- Are the researchers qualified to study the topic?
- Can the research group carry out the project?

C. Funding

- Is the funding in the right proportion with the aims?
- Is the share suggested to be funded by FinOHTA in the right proportion taken into account the content of the project and its total funding?

D. Timetable

- Is the timetable realistic?

E. Information dissemination, implementation and follow-up

- Will the protocol of a randomized controlled trial be made public prior to or during the project?
- How will the results be made public (final report and scientific publication) and how are the results communicated?
- How is it ensured that the results will actually lead into a change in health care practice?
- How can such a change be demonstrated? (e.g. surveys, register research, other methods)

Appendix 4: Documentation used by the evaluation group

The following documents are used in the external evaluation of FinOHTA. The abbreviation EED stands for External Evaluation Document. For referencing purposes the documents are coded in the following manner:

- A: General evaluation topics
- B: FinOHTA general topics
- C: FinOHTA communications
- D: FinOHTA research
- M: Minutes of evaluation meetings

Actual evaluation documents

- EED-A1: Work Plan
- EED-A2: Evaluation Questions
- EED-A3: Evaluation Documents (i.e. this document)
- EED-A4: Interviews
- EED-B1: FinOHTA Strategic Plan (Executive Summary)
- EED-B2: Introduction to FinOHTA
- EED-C1: FinOHTA Communication Plan (Executive Summary)
- EED-C2: FinOHTA Communication Study (Executive Summary)
- EED-D1: FinOHTA Projects
- EED-M1: Minutes of the First Meeting
- EED-M2: Minutes of the Second Meeting (including notes on interviews)
- EED-M3: Minutes of the Third Meeting (including notes on further interviews)

Auxiliary documents

- FinOHTA Brochure (FinOHTA)
- Samples of Newsletter *Impakti* (FinOHTA)
- Table of Contents of the Quality handbook (FinOHTA)
- Conflict of interest disclosure (FinOHTA)
- Members of the Scientific Committee (FinOHTA)
- Members of the Advisory Board (FinOHTA)
- Evaluation of the Satakunta Macro Pilot Project, Executive Summary (FinOHTA)
- Stakes international evaluation 1999. FinOHTA: actions from recommendations (FinOHTA)
- Presentation: FinOHTA 1995–2004 (FinOHTA, Marjukka Mäkelä)
- Journal article: 18 steps to Finnish health service reform (Euro Observer 2002; 4(3): 3–4)
- Report of the Working Group on Social Welfare and Health Care Information Reform 2005, Summary (Ministry of Social Affairs and Health, 2003)

- Social and health policy-oriented research and development activities in Finland (Report by the Ministry of Social Affairs and Health, 2002).
- STAKES Brochure: STAKES Today (STAKES)
- STAKES Web Site printouts: Organisation structure, divisions and groups (STAKES)
- Report: Jorma Rantanen et al. International evaluation of the National Research and Development Centre for Welfare and Health. Ministry of Social Affairs and Health Finland, Publications 1999:12 eng.
- External evaluation of DACEHTA 2003. Sundhedsstyrelsen 2003, Denmark.
- Decision in Principle by the Council of State on securing the future of health care. Ministry of Social Affairs and Health. Brochures of the Ministry of Social Affairs and Health 2002:6 eng.
- Lauri Nuutinen's survey on the views of hospital district directors in 2000 (FinOHTA)
- Research Programme on Health Services Research 2004–2007. Programme Memorandum. (Academy of Finland)
- Sosiaali- ja terveystieteiden tutkimuskeskuksen asetukset lääkäri- ja hammaslääkärin koulutuksen sekä yliopistotasoisesta terveystieteellisestä tutkimustoiminnasta vuodelle 2004. Asetus n:o 10, 2004. Social- och hälsovårdsministeriets förordning om grunderna för ersättning för läkar- och tandläkarutbildning samt hälsovetenskaplig forskning på universitetsnivå år 2004. Förordning Nr 10, 2004.