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The assessment path is seldom level or straight. HTA project schedules and budgets may need revision, as the task turns out to be more complex than anticipated. We can go around some of the unexpected stones on the path, or narrow down the scope of assessment so that timelines can be kept to. More time or support from another expert can help the team through.

Occasionally new issues emerge that cannot be circumvented or postponed. An entirely new type of technology can make a whole family of treatments redundant almost overnight, or new data may challenge prevailing views on safety. Discussions with patient groups can bring important ethical questions to the stage. When such developments highlight generic methodological problems – rather than technology-specific details – they must be taken seriously. Not just stones on the road, these are mountains that change the landscape of HTA. “Too high, you can’t get over it”, sings a negro spiritual, “gotta go through”.

The European network for health technology assessment, EUnetHTA, is working to get through one mountain. We aim at producing assessments that are transferable across different populations and health systems, using common methods in a permanent collaboration (see pages 4–6). A promising new way of structuring assessments breaks the work down into a set of clearly defined core items. When this succeeds, we can provide information to support health policy decisions in each country more often and more rapidly than before.

One aspect of HTA that has been difficult to transfer across countries is ethical evaluation. An international group has struggled to find ways of presenting ethical issues in a systematic and balanced fashion. At Finohta, assessment projects on screening have been a fruitful ground for methodological work. An eclectic approach to examining ethical issues identified the benefits and harms that each screening programme brings to relevant stakeholder groups. This method has successfully been used for other types of topics, too. Read more on pages 9–11.

Health care leaders increasingly call for assessment results. Finohta is building links with hospital directors to provide them with timely answers. Read the unfolding story of Managed Uptake of Medical Methods, as adapted from Denmark and Great Britain, on pages 12–13. The first assessments will soon be ready for joint decisions. These will test our ability to strike the balance between voluntary collaboration and bureaucracy.

Time will tell if our methodological tunnels are passable. A key feature in all three developments has been international collaboration. Even small national HTA units are together so strong they can break through the mountain.

Editorial

Through the mountain

The assessment path is seldom level or straight. HTA project schedules and budgets may need revision, as the task turns out to be more complex than anticipated. We can go around some of the unexpected stones on the path, or narrow down the scope of assessment so that timelines can be kept to. More time or support from another expert can help the team through.

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Europe needs sustainable HTA collaboration

The new EUnetHTA network supports national decision-making

EUnetHTA, the European network for Health Technology Assessment, has gained momentum and is now aiming at efficient and sustainable HTA collaboration in Europe. The Finnish contribution to the project is being handled by Finohta.

There is an overt need in Europe for more enhanced co-ordination of HTA, and collaboration between HTA and health care decision-making should be further reinforced, says Kristian Lampe, Senior Medical Officer.

The importance of HTA (Health Technology Assessment) was clearly understood in Europe in November 2004, when the European Commission and the Council of Ministers identified HTA as a “political priority”. Indeed, Europe requires sustainable HTA collaboration. Demonstrating this need, the related call from the Commission was answered within one year by 35 organisations across Europe, and the Danish HTA organisation, DACEHTA, expressed its interest in leading the broad-based collaboration project.

The European network for HTA, EUnetHTA, was officially launched in January 2006, while the three-year EUnetHTA project is being funded by the European Union and various organisations. The network consists of over 60 organisations from 24 EU countries, Norway, Switzerland, WHO, the OECD and the international Cochrane network. Countries outside Europe are also represented by Israel, Australia, Canada and the United States.

TARGETING SUSTAINABLE COLLABORATION

EUnetHTA is pursuing two courses of action. On the one hand, the participating organisations will form working groups in order to develop both an operational structure and effective tools for the network, the latter for producing assessment data and enabling its transmission from one national HTA organisation to another.

– Our larger strategic goal is to lead national HTA units into collaboration with respect to the exchange of information and support for health
Finnish efforts will oversee the completion of the EU project's key Working Package.

FINOHTA IDENTIFYING CORE HTA
EUnetHTA is a collaborative project involving 27 European countries which will create a functioning and permanent European HTA network through the development of practical tools for conducting assessments and for the exchange of information.

– The content of HTA reports needs to be developed. Using reports prepared in other countries requires finding certain information in the report content. We divided the content of an assessment report into standard question–answer pairs. Basically, we are formulating general level questions essential to, say, effectiveness or ethics, explains Kristian Lampe.

The core model, co-ordinated by the Finns, includes descriptions of technology, safety, current use, effectiveness, cost-effectiveness and ethical, organisational, social and legal aspects. Each of these will contain a more detailed definition of the topic and issues presented in the form of questions. Data obtained will be transferred to element cards, thus enabling hierarchical inspection, while elements forming the core will be further defined in terms of transferability and significance. ☺️ KK

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EUNETHTA WORK PACKAGES
The EUnetHTA project consists of eight separately managed work packages (WPs), each led by one Associated Partner (Lead Partner).

**WP1 Coordination**
Lead Partner: DACEHTA, Danish Centre for Evaluation and HTA, Copenhagen Denmark

**WP2 Communications**
Lead Partner: SBU, Swedish Council on Technology Assessment in Health Care, Stockholm, Sweden
Co-Lead Partner (Clearinghouse strand): DAHTA@DIMDI, German Agency for HTA at the German Institute for Medical Documentation and Information, Cologne, Germany

**WP3 Evaluation**
Lead Partner: NOKC, Norwegian Knowledge Centre for the Health Services, Oslo, Norway

**WP4 Common Core of HTA**
Lead Partner: Finnish Office for HTA/STAKES, Helsinki, Finland

**WP5 Applying common core information and adapting existing HTAs into local/national settings**
Lead Partner: NCCHTA, National Coordinating Centre for HTA, Southampton, United Kingdom

**WP6 Transferability of HTA into health policy**
Lead Partner: DACEHTA, Danish Centre for Evaluation and HTA, Copenhagen, Denmark

**WP7 Monitoring emerging/new technology development and prioritization of HTA**
Lead Partner: HAS, Haute Autorité de santé / French National Authority for Health, Paris, France
Co-Lead Partner: LBI-HTA, Ludwig Boltzman Institute of Health Technology Assessment (former ITA), Vienna, Austria

**WP8 System for support of countries without institutionalized HTA**
Lead Partner: Catalan Agency for HTA and Research, Barcelona, Spain
The EUnetHTA, the European network of HTA

Assessment core model to be published in Barcelona

“This has proven a genuine challenge, with members of the working group coming from all over Europe, but we have slowly found the harmony required for collaboration,” reveals Kristian Lampe, Senior Medical Officer in charge of co-ordinating the core project of EUnetHTA.

The Working Package led by Finohta includes the efforts of ten international teams. After hundreds of e-mails, several conference calls and two workshops, the WP4’s next milestone is the HTAi meeting to be held in Barcelona in June, where the assessment model will be published.

Health technology assessment lacks common practices in Europe, and it is just this diversity in reporting and publishing styles which is being addressed by the EUnetHTA project. The objective of the international working group is to create a common, detailed structure for HTA reports.

– Our aim is to identify the transferable core of HTA, meaning a set of key issues for which the assessment needs to provide answers. The first draft concerning intervention assessment has now been sent for feedback. Under its co-ordination by Finohta, the EUnetHTA project will produce an assessment model, tested by using medical stents as an example,” explains Kristian Lampe, Senior Medical Officer.

The authors of assessment studies must first decide how the general level questions of the model should be further refined into research questions and then expressed in the report. The reform is not intended only for report authors and researchers, but a clear and uniform reporting model would also benefit the readers of the assessment reports, decision-makers and health care professionals.

 MODELS FOR COMMON CORE HTA

Finohta’s WP4 focuses on exploring Common Core HTA. Different types of technologies (such as medicines and equipment) and multi-faceted application areas (such as therapy or diagnosis) require slightly different assessment models. These models should contain, in a sufficiently comprehensive manner, all domains involved in assessments, i.e. safety, effectiveness and costs as well as organisational, social, ethical and legal aspects. If assessments are conducted in compliance with harmonised models, they are easier to apply in countries in addition to the country performing the assessment.

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For more information on the EU project, visit www.eunethta.net.
Evidence-based medicine includes the conscientious, explicit and judicious use of the best evidence currently available in the care of patients. The related method comprises five steps: Ask clinical questions you can answer; Search for the best evidence; Critically appraise the evidence; Apply the evidence in the care of your patient; Conduct a self-evaluation of the above steps. Searching for the best literature and critically appraising the evidence are essential in conducting systematic literature reviews. Randomised controlled trials (RCTs) constitute the backbone of evidence-based medicine.

Clinicians need to know how to evaluate the relevance and applicability of RCTs and reviews to their own patients, but it is impossible for them to be aware of all the essential literature within their speciality. Systematic reviews offer clinicians a solution to this problem. Much attention has been paid to improving the validity and reproducibility of reviews.

A factor improving the quality of reporting of RCTs is the CONSORT statement, adopted by major medical journals as a benchmark for the assessment of the quality of reporting on trials. Since the adoption of this benchmark, the validity of research data in particular has been in focus.

FIVE FUNDAMENTAL QUESTIONS
The Cochrane Back Review Group recommends using five questions in the assessment of the clinical relevance of study results. The first three questions ensure the assessment of applicability, while the last two concern the study results’ relevance to patients.
1. Are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?
2. Are the interventions and treatment settings described well enough so that you can provide the same for your patients?
3. Were all clinically relevant outcomes measured and reported?
4. Is the size of the effect clinically important?
5. Are the likely treatment benefits worth the potential adverse effects?

FORMULA FOR IDENTIFYING GOOD ARTICLES
We used these five questions in preparing a review of exercise therapy for low back pain. Included were 49 RCTs, most of which did not provide sufficiently detailed descriptions of patients, treatment and circumstances. Sufficiently detailed descriptions of patients were provided in 88 per cent of the studies, those of intervention in 51 per cent, those of outcomes in 67 per cent and those of the extent of the effect in 35 per cent of the studies. None of the studies described the treatment’s benefits in relation to its adverse effects.

Due to frequent shortcomings in reporting, it was difficult to assess clinical relevance. We therefore developed a more comprehensive list of criteria for assessing applicability and clinical relevance of results, and tested it with the 49 studies in the review. After testing, the new criteria...
were sent to the Cochrane Back Review Group editorial board members and, in response to the comments, a final list of items was constructed. (Table 1)

CLEAR REPORTING BRIDGES THE GAP TO PRACTICE

In our study, we describe a method for assessing the applicability and clinical relevance of study results in back research. We also provide examples on how studies of the effectiveness of exercise therapy for back pain still lack important information.

The clinical relevance of an RCT can be assessed if the researchers have provided descriptions on issues based on which a clinician can interpret the RCT’s applicability to his or her own clinical situation. The quality of reporting should be significantly improved. Shortcomings in reporting on patients, treatment methods and outcomes have also been detected in cardiovascular RCTs4.

RELIABLE DATA AS A BASIS FOR THE GENERALISABILITY OF A STUDY

The CONSORT statement offers readers the keys to understanding the risk of bias related to trials. While this is important, the importance of the applicability of information is often underestimated. A high quality RCT may provide clinically insignificant information. Authors of primary research studies and systematic reviews, their readers, peer reviewers and journal editors should pay more attention to the assessment of the applicability and clinical relevance of study results.

The reliability of research data is a prerequisite for the production of abstract and generalisable information. Furthermore, the applicability of a study requires adequate descriptions of the study’s design, patient data, intervention and outcomes.

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This article is based on the following article:

REFERENCES

Table 1. Items Related to Applicability and Clinical Relevance of Results of RCTs (Malmivaara et al 2006).

1. DOES THE REPORT ENABLE THE ASSESSMENT OF APPLICABILITY?

Study population
- Age
- Gender
- Setting
- Type of disease/disorder
- Duration of disease/disorder
- Severity of disease/disorder
- Recruitment procedure
- Description of inclusion and exclusion criteria

Index intervention / Comparator (control intervention)/
Cointerventions per study group
- Type/content
- Intensity/dosage
- Frequency
- Duration
- Experience of provider
- Proper intervention and proper control group to answer the research question

Outcome measures
- Main symptom, disease-specific disability, health-related quality of life
- Validity and reproducibility of instruments
- Follow-up moment
- All potential adverse effects

Analysis
- Intention-to-treat analysis
- Confounding considered
- Effect modification considered
- Economic evaluation

2. ARE THE STUDY RESULTS CLINICALLY RELEVANT?

- Baseline values of main symptoms and disability
- Adherence in all study groups
- Dropout rate
- Follow-up of main symptoms and disability
- Magnitude of difference between groups
- Confidence intervals of between-group differences
- Incidence of all adverse effects
In general, the core task of HTA is to provide neutral assessments of the cost-effectiveness of interventions used in health care. However, in addition to effectiveness, health care decisions that relate to adopting or refusing technologies also need to take account of ethical and legal issues as well as social and economic impacts.

For years, the International Network of Agencies for Health Technology Assessment (INAHTA) has supported a working group on ethical issues in HTA. According to its report, approximately half of all HTA units consider ethical issues that are closely related to the intervention in addition to effectiveness data. A balanced presentation of ethical aspects and effectiveness data increases the possibility of taking equitable health care decisions.

HOW SHOULD AN ETHICAL EVALUATION BE MADE?

HTA units increasingly view analysing ethical issues as an integral part of health technology assessment. Ethics have also been taken into account in the new EUnetHTA project (see pages 4–6).

Clear and internationally uniform methods exist for the analysis and updating of effectiveness data. Ethical evaluations, however, cannot be conducted using a rigorous structure, since the depth and scope of the evaluation depends on the technology to be assessed and the ethics expertise available. Although a consensus on the best method for ethical evaluation has not yet been reached, the EUnetHTA project has succeeded in identifying the core elements of ethical evaluation (Table 1).

### Table 1. Core items of ethical evaluation.

- Identification of the major health outcomes of the assessed technology and agreeing on how these outcomes are measured
- Identification and classification of stakeholders whom the use or non-use of the technology affects
- Examination of ethical issues related to the adoption or rejection of a technology for each group
- Presentation of the ethical evaluation in the assessment report
EVALUATION OF SCREENING WAS A TURNING POINT

The importance of ethical evaluation was understood in Finland when screening was being assessed. Public health care decisions on screening imply many value-laden choices. The ethical evaluation of screening involves not only common problems – those of false positives and false negatives – but also specific problems. For example, the stigmatisation caused by screening, the magnitude of its harm and significance to an individual and the extent of the benefits obtained from an early diagnosis all depend on the disease for which participants are being screened.

Finnohta has decided that, in the future, all technology assessments will include an ethical evaluation. While ethical problems vary according to the topic, generalisation problems due to eligibility criteria of studies are common. How can research data be applied to patients with multiple problems? From where can resources be taken and allocated to new activities? How does the introduction of a technology affect other patient groups? For example, if new procedures are performed as emergency duties, this entails reduced resources for other emergency service patients.

What should be done if the effectiveness data is based on a technology which will no longer be used? In imaging, for example, new technologies rapidly cause modifications in practices, whereas the related research data lags behind. When mammography goes digital, a long time will elapse before the characteristics of the new screening method are learned to the same extent as those of the old method.

PATIENTS AND PROFESSIONALS INVOLVED

In Finnohta, an ethical evaluation is performed in co-operation with content experts. Identifying ethical questions, finding possible answers and reflecting on them in relation to the effectiveness data and its problems form a process which continues throughout an assessment. A literature search for ethical evaluation is challenging, since searches often need to be performed again after the ethical issues related to a specific method have been identified.

Ethical values can vary between societies.

The introduction of new technologies, enhancement of processes and striving for cost-effectiveness can create possibilities but also risks. The use of an effective intervention may cause suffering to some patient groups, this must be detected prior to the introduction of the technology in question. This problem concerns screenings in particular.

For some patient groups, investing in evidence-based health care may reduce the opportunities for care, if actors interested in financing research that is related to the group cannot be found or if the research is exceptionally challenging. In particular, the disabled, mental health patients and patients with multiple problems may be subject to exclusion.

While evidence-based operations are gaining ground in health care, it is necessary, for the joint benefit of both individuals and society, to identify which problems are caused by lack of evidence. In the vast international medical industry, the development of pharmaceuticals and equipment is subject to a different set of rules that do not always coincide with e.g. the attempt to ensure equitable treatment commonly abided by in Nordic health care.

It is not feasible to develop products with commercial value for all health problems. For example, prevention and rehabilitation add quality to people’s lives and reduce health care costs, but creating suitable products can prove difficult. Society’s support for the development of such health technologies can therefore be justified.

The individuality of care is an important ethical principle as well as quality objective in health care. One doctor’s ethical view on the selection of treatment may, according to another doctor, limit the opportunities for care of other patients or cause a significant risk of harm. Society’s values do not prevent individuals from deciding for themselves, but it is necessary to understand how broad an impact each decision taken in health care may have.

Each patient is an individual with his or her own special characteristics, and the best know-how must be applied specifically in each person’s care. It is the duty of health care decision-makers to ensure that treatments proven effective are equitably available and that society can provide sufficient resources for them.

The common good and individual rights can diverge. This source of controversy and the attempt to be equitable both within and between patient groups creates tensions in the discussion of values in health care, calling for an up-to-date dialogue which reflects society’s values.

Ethics as a guideline on the path to equality

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Values can vary greatly between societies, as can be seen in attitudes towards the legal time limit for abortion or euthanasia. Consequently, literature sources are used as a basis for discussion rather than as indicators of Finnish values.

In the ideal situation, patients take part in the ethical discussion. When deemed necessary, Finohta has consulted patient organisations in various project phases in order to identify people’s expectations and fears. Broad consultation of stakeholders offers a social perspective in the assessment report, which is likely to facilitate the adoption of the report and improve its value to users.

MORE THAN ONE RIGHT ANSWER

In Finohta’s assessment projects, many ethical issues have caused divergent opinions among the project’s expert group members. While it is important that these opinions be published, it should be noted that the divergence in opinions within society and among stakeholders is most probably even greater.

A discussion on Down’s syndrome and the definition of a severe malformation in the context of screening for foetal abnormalities was subject to strong disagreement both among experts and citizens. For ethical issues, no single right answer exists, and this must be borne in mind in decision-making.

In Finohta, the in-depth ethical appraisal did change the course of an entire HTA project. The original goal of the assessment project for screening for foetal abnormalities was to describe the characteristics of screening methods (sensitivity, specificity, costs) and to clarify clinical practices on the basis of this data. However, during the course of the project and in its conclusions, ethical issues related to screening foetal abnormalities played a significant role. Since then, the Ministry of Social Affairs and Health has taken a stand and drafted a screening programme, taking account of the ethical issues presented in Finohta’s report.

A WISE DECISION TAKES TIME

When discussing evidence-based medicine, the slowness of decision-making on the adoption of effective methods is frequently criticised. Speed is not, however, the only aspect to be considered in the application of effectiveness data. A wise decision requires broad-based understanding. Evidential data informs us about the past, but decisions must also consider the future. Health care decision-making therefore necessitates not only evidence on effectiveness but also an in-depth ability to understand society’s values and anticipate the future.

National assessment reports cannot be based only on a mechanical summary of research data. Evidence must be related to the data’s clinical relevance, everyday reality and the values prevailing in society. The adoption of an effective intervention does not, in each and every case, entail unambiguous benefits to society. The cornerstone of wise and equitable health care operations comprises both reliable evidence and the identification of citizens’ values.

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REFERENCE


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Managed Uptake of Medical Methods
– the MUMM-programme in Finland

MUMM is a joint venture of the 21 hospital districts providing specialized care and Finnish Office for Health Technology Assessment at STAKES. The aim is to develop a structure for critical appraisal and joint decisions in uptake of new methods.

It has been estimated that as much as 50% of new expenditures in specialized care may be incurred by new medical technologies. Discussion on managing uptake of new technologies in Finnish specialized care has continued for some years. In December 2005 the MUMM-programme was launched (see IMPAKTI Newsletter 2/2006 in English).

The general aim of MUMM is to develop a structure for critical appraisal and joint decisions in uptake of new methods. The challenge is that health care decision making is extremely decentralized in Finland. Little structure for national recommendations exists. Finohta only gathers and evaluates published data, but has no remit to give recommendations.

MUMM ROAD SHOW
The programme leader visited 19 hospitals during the spring of 2006, meeting mainly with chief physicians and hospital managers. In all, about 450 professionals discussed MUMM. This is 2% of the 18 000 physicians in Finland.

The hospital round discussions were lively, with several topics recurring. The Programme as such was considered a welcome and even long awaited step. It was made clear that uptake processes vary between hospitals. A number of hospital clinics may already be using a certain method routinely, while others are still contemplating whether to implement it or not. Yet others may not even consider the method, and some are already moving ahead to the next.

During these meetings, altogether 56 topics were suggested for critical appraisal. Some were formulated as relatively clear questions such as the use of laser therapy in the treatment of varicose veins. Others were wide clinical topics such as use of PET-CT in the diagnosis of diseases. The idea was to gather a list of topics to start working with, and teach the formulation of answerable questions later. The MUMM-network was convened in May 2006 to discuss topic selection.

PROVIDING EFFECTIVENESS DATA
In December 2006 preliminary evidence on the five first methods was presented. Also an outline of the process in each MUMM-project was depicted. First challenges were easy to identify: recruiting clinicians into the small working groups (especially vacations before summer) and the
known bottleneck of librarian resources to do the searching.

A heated discussion ensued on whether a separate committee should be elected to help in preparing joint statements or decisions. On the one hand, it was clear that the allocated four hours was not enough for presenting and discussing the evidence, let alone making joint decisions. On the other hand, there is a genuine reluctance to build new bureaucratic bodies or systems. This first meeting did receive suggestions of next methods to be evaluated and a set was selected.

THE WAY AHEAD

The year 2007 will see reports published short, and possibly the first joint decisions. It will not be a great disappointment if decisions are not reached. The process needs practice and different possibilities should be tested. The very organized and structured way of formulating recommendations at the British Interventional Procedures Programme’s (IPP) Advisory Committee meeting did make an impression on the small group from Finland who was invited to attend. However, the aims of IPP are to ensure first and foremost the safety of new interventional methods that are in development. It is a different kind of challenge to set up a system for deciding on whether or not to start using new methodology – especially when these may not be new to all organizations.

THE FIRST FIVE TOPICS selected in May 2006 were: Intravenous laser therapy for varicose veins; MARS – liver dialysis; Vacuum treatment of wounds; Long antithrombotic treatment in conjunction with joint replacement surgery; and 64-multislicing-CT in the diagnosis of coronary disease.

THE SECOND SET OF MUMM-TOPICS selected in December 2006 included: Spinal Cord Stimulation for chronic back pain; Radiofrequency ablation for snoring; Vagus nerve stimulator treatment for treatment resistant depression and epilepsy; and Treatment of macular degeneration with intravitreal anti-VEGF injections.

The first five topics are close to being published, and the second set is being evaluated. The next seminar was arranged at the end of March. Again, four hours were allocated for the finalized reports to be presented and new topics to be selected. No doubt the discussion about getting organized and how best to do it will continue. In short, 2007 will strengthen or dispute viability of MUMM, but then again, it is a change in culture that is in the making. Since changing a culture always takes several years, patience and clear vision are of essence. A certain kind of Finnish stubbornness, *sisu*, will not harm.

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The most reliable evidence on the impact of a specific health technology can be obtained through randomised controlled trials (RTCs). In such trials, the participants are randomly allocated to groups receiving different interventions. The subjects’ health and functional capacity is measured before and after the intervention and, at the end, conclusions are reached on whether differences were detected between groups and the size of the potential difference.

Can a randomised experimental design successfully produce a reliable estimate of the impact of care? Various biases can undermine the reliability of final results during the implementation of a trial, and it is therefore essential that researchers rigorously report the entire course of the research process.

INTERNATIONAL CRITERIA FOR TRIALS

In 1996, an international group of researchers published guidelines on how to report randomised controlled trials, under the title of the CONSORT statement (Consolidated Standards of Reporting Trials). The CONSORT statement includes a trial flow diagram and a checklist with 22 items. It provides clear instructions on the contents of the main sections of research papers, i.e. abstract, introduction, methods, results and discussion. The purpose of the statement is to facilitate and harmonise the trial reports.

Currently, many leading scientific journals require researchers to adhere meticulously to the CONSORT criteria before sending a research article to their editorial staff.

CRITICAL REVIEW OF REPORTING PHYSICAL THERAPY

For more complex trials, the significance of clear, high-quality reporting becomes all the more important. Physiotherapeutic interventions for children with cerebral palsy (CP) are typically highly diverse in form and multifactorial.

The new Finohta review assesses the quality of reporting of interventions used in physical therapy for children with CP, by examining the compliance of 15 RCTs by means of 33 questions derived from the CONSORT statement.

The studied research papers provided a straightforward answer to approximately every other CONSORT question. For many RCTs, reliability, validity and applicability were left open to conjecture. However, appropriate and clear reporting would have been possible.

OBJECTIVES REPORTED CLEARLY

The assessment also revealed some relatively well-reported RCTs, with seven research reports fulfilling at least half of the CONSORT questions.

The reporting was observed to be clearest in introductions where the objectives, participants and circumstances of the trial’s implementation were defined. For eight RCTs, the description provided
was sufficient, including e.g. the participants’ type of CP and baseline data for the primary outcome measure. In general, only a brief description of the therapeutic methods or their intensity was given.

Half of the physiotherapeutic trials reported how the quality of measurements was ensured, and nearly all presented a description of the statistical methods used. Eight RCTs included ancillary analyses, e.g. by subgroups, but it remained unclear whether they were conducted in order to obtain specific results or whether they had been pre-specified in the trial protocol.

All publications lacked a flow diagram with a clear presentation of the different trial phases, and it was left up to the reader to search for this from the text and tables.

Most of the RCTs gave a thoroughgoing report of the number of participants in different groups and the difference between groups. Only two RCTs presented confidence intervals for inter-group differences.

MOST SHORTCOMINGS IN METHOD DESCRIPTION

According to the Finohta review, the most prominent shortcomings in the reporting quality of randomised physiotherapeutic trials were related to research methods. Often, the randomisation process and blinding to group assignment were left totally unmentioned.

Only four RCTs included power calculations to allow estimation of the number of participants required to detect differences between groups. Five RCTs defined the primary outcome measures. A total of 51 different outcome measures, only half of them validated, were used in the RCTs.

When analysing the results, it is important to know whether the participants were actually evaluated in the groups to which they were originally assigned. On the basis of the number of patients stated in the reports, this was estimated to have occurred in at least one third of the trials.

While masking an intervention is generally very difficult for physiotherapeutic trials since therapists and patients know how the care is given, masking of those assessing the outcomes remains possible. Nevertheless, only two RCTs described how the success of masking was ensured. Furthermore, only a few RCTs reported the children’s other activities during the intervention and whether the therapy caused any adverse effects to the children.

HIGH-QUALITY REPORTING ENSURES APPLICABILITY

Weak and unclear reporting reduces the usability of research data and complicates the assessment of trials’ scientific quality. The trial itself may have been carefully conducted. However, many trial reports failed to describe clearly several items related to validity and applicability. High quality reporting is possible, though. Those funding research and researchers should therefore take account of the following key message: Demand the use of CONSORT criteria, in order to improve the quality of research. Doing so would provide the interested parties with a greater possibility to apply valuable research data.

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The CONSORT statement is available online at www.consort-statement.org.
Use of quality-adjusted life years for assessing the effectiveness of health care

A key indicator of the effectiveness of health care is the Quality-Adjusted Life Year, QALY, which is also useful when making decisions on the allocation of resources.

Society is continuously investing resources in health care, but evidence of the effectiveness of treatment often remains insufficient. Decisions can be made on a fairly vague basis and without defining how interventions will affect quality of life as perceived by the patients themselves.

In particular, data allowing the comparison of the effectiveness of various interventions across different medical specialties has been scarce, and most comparative studies use only disease-specific outcome measures.

In addition to longevity, the quality of life is important. Recent years have seen the emergence of measures taking account of patient preferences in the evaluation of treatment results. The Quality-Adjusted Life Year, QALY, expresses the effectiveness of health care while taking account of both length and quality of life.

In Great Britain, the National Institute of Health and Clinical Excellence (NICE) uses the QALY as its principal measure of health outcomes, and the Medline database provides thousands of references with the search term QALY.

72 ARTICLES UNDER CLOSER REVIEW

The recent Finohta report 29 is based on a systematic review with literature searches from five databases conducted in May 2004. Studies whose health-related quality of life (HRQoL) was measured using a generic instrument allowing the calculation of QALYs or assessed by a direct valuation method before and after the intervention, were eligible for the review.

The review’s searches identified 4,878 publications, of which 3,882 represented primary research. Based on abstracts, a total of 624 articles were selected for closer inspection. Only 72 articles (related to 70 separate studies) evaluated the treatment outcome based on a before-and-after design using patients’ self-reports and an HRQoL instrument allowing the calculation of QALYs.

The studies were analysed and descriptions were gathered of their clinical specialty, intervention, aim, study population, the analysis method used, the economic evaluation perspective, cost data used, results concerning HRQoL assessment, number of and cost per QALYs.
gained by intervention, the quality of the study and any methodological or other limitations.

PHARMACOLOGICAL THERAPY AND SURGICAL PROCEDURES MOST RESEARCHED

Of the articles, 71 per cent had been published in specialty journals, 20 per cent in general medical journals and 8 per cent in journals mainly devoted to health economics, health technology assessment or health care administration. One study included had been published as a dissertation. Only three articles were written using a language other than English.

Thirty-one per cent of the studies were mainly concerned with pharmacological therapy and 26 per cent with surgical interventions. The rest were related to various types of conservative treatment, rehabilitation, diagnostic imaging and secondary prevention.

The interventions studied covered a broad range from transplantation surgery to spa-exercise therapy. The most commonly studied interventions were treatment of coronary heart disease, total hip arthroplasty and cochlear implants.

The evidence grade was evaluated by considering both the study design and its implementation. Approximately half of the articles were based on randomised controlled trials (RCTs), while comparative design was often also used in other studies.

Hearing is a sense which can be medically restored. This is possible by surgically implanting a permanent hearing device, a cochlear implant, in the inner ear. Cochlear surgery can be performed on either a child born deaf or on an adult who became deaf after learning to speak.

Finohta’s report, *Quality-Adjusted Life Years for the Estimation of Effectiveness of Health Care*, includes four studies on the impact of cochlear implants. Two of these assessed the intervention’s impact on the health-related quality of life (HRQoL) on child patients and the other two on adults.

Measuring the HRQoL is more difficult in children than in adults. HRQoL instruments used for adults are not suitable for children and, furthermore, very small children are unable to assess the quality of their own lives. Frequently, research must therefore resort to assessments by children’s parents or health care professionals, although these are not always very reliable.

Research results suggest that cochlear implants enhance children’s health-related quality of life. For example, a study conducted by Wong et al revealed that cochlear implantation had positive effects on speech, ordinary bodily functions, depression and anxiety in addition to hearing.

Cochlear implants are a good example of technology with little impact on survival but with a considerable one on the patients’ quality of life. The study by Cheng et al. showed that for children born deaf, the HRQoL index, measured using the HUI instrument, increased by no less than 0.39 units (on a scale from 0 to 1). Cochlear implants were also considered reasonable in proportion to their costs, since the cost of one quality-adjusted life year amounted to 5 197 USD (approximately 4 000 EUR). When indirect costs, such as the special needs of the hearing impaired at school, were included in the calculation, cochlear implants were deemed to produce net savings to society.

Three studies viewed cochlear surgery as a procedure acceptable to society, when the obtained change in HRQoL was proportioned to the procedure’s cost. One study did not address the issue of acceptability.

The cost-effectiveness of treatment for the severely hearing impaired is a very important theme for research, not only because of the cochlear implant’s relatively high price but also because it is subject to continuing controversy. In such circumstances, patients’ self-reported estimates on a method’s effectiveness are downright indispensable.

**REFERENCES**


**IJTAHC article award to Finland**


The evidence grade was evaluated by considering both the study design and its implementation. Approximately half of the articles were based on randomised controlled trials (RCTs), while comparative design was often also used in other studies.
Half of the studies were deemed to be of good quality and none of poor quality. Four studies were based on economic modelling.

**QALY DIFFERENCES UP TO A MILLION EUROS**

The most popular QALY outcome measure used was the EQ-5D instrument. The reported average number of QALYs varied widely depending on the intervention studied and on the number of years over which the QALY gain was extrapolated.

Of the articles included in the review, 86 percent involved an economic evaluation. While the average cost per QALY showed great variation from less than one thousand to over a million euros, nearly half of the studies viewed the intervention to be cost-effective in terms of its acceptability to society.

**THE BEST OUTCOME EXPERTS: PATIENTS**

In most of the excluded studies, quality of life data was obtained from poorly defined sources or based on estimates by healthcare professionals. Professionals are certainly aware of the clinical nature of a disease and the burden it can cause on a patient. But can they really – never having experienced the disease themselves – judge the quality of life encountered by their patients?

Studies based on real information obtained from patients are of much more value to a decision-maker pondering the allocation of resources than studies based on professionals’ estimates.

The Finohta review’s literature search also identified studies in which quality of life had been studied based on a proper before-and-after design, but which did not include the term, QALY. The calculation of QALYs would have been possible, but as QALYs were not mentioned, these studies were not eligible for the review. It is possible that studies in which the effect of an intervention on health-related quality of life is absent or minimal are more likely not to report QALYs than those with positive results.

**INFORMATION ON EFFECTIVENESS OF SCREENING ALSO REQUIRED**

When health care professionals and decision makers allocate limited health care resources, they need information on the benefits of different interventions and their possibilities to generate well-being.

Research results with the treatment outcome expressed as QALYs enable comparability between different treatment methods in decision-making.

The systematic Finohta review excluded studies related to prevention and screening, since they focus on different types of research questions. Although such studies would benefit from using QALY as an outcome measure in terms of comparability, measuring the HRQoL using a similar design as for the treatment of diseases is seldom feasible. Consequently, Finohta has drawn up preliminary plans for a project producing a comprehensive summary of research data concerning the impact and cost-effectiveness of screening and preventive methods.

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The review has also been published as an original article (limited version without appendices) in the International Journal of Technology Assessment in Health Care 2006;22(2):235–41.
The Ohtanen database proudly presents:

**Summaries of foreign assessments**

For almost a year, Finohta has been dedicating efforts to creating an online service intended for health care decision makers and professionals, including summaries of foreign assessment reports in Finnish. The pilot version of the Ohtanen database is now available.

Finohta is actively following publications by HTA agencies based in other countries. The relevance of the HTA reports identified during this mapping process is roughly assessed by Finohta’s literature committee. Finnish summaries, with a maximum length of 8 000 characters, are then drawn up on the assessment reports. Reports concerning current or otherwise important issues take priority in the production schedule.

The summaries are uploaded to a database freely accessible to all. For each report, the Ohtanen database contains not only the prepared summary, but also the following information:

- Report name in the original language and in Finnish
- Publishing unit and publication year
- Health technology being assessed
- Disease or other health problem discussed in the report
- Assessment method
- The languages of the report and its abstract
- URLs of the report and its abstract
- Related specialities
- Keywords

The original message of the foreign report is retained as accurately as possible, which means that the summaries will neither include overt interpretations by the summary’s author nor Finohta. However, if the summary’s author/s wish to comment on the reports, they can do so in a designated comment field.

The quality of original reports will not be systematically assessed, since this would require far greater effort. It is therefore the responsibility of the reader – at least for the time being – to estimate the suitability of a foreign report as support material for decision-making in Finland.

The reader should also view the original report using a link located in Ohtanen’s summary page. By viewing the original report, the reader can obtain a better understanding of the reliability of the assessment and its applicability to different situations.

Due to the high number of assessment reports produced, not all of them can be summarised in Finnish for the time being. However, we have the future objective of including at least the basic data of as many reports as possible in Ohtanen.

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**Prompt information search**

When more summaries are added to the Ohtanen database, the role of search features will become more important. Complementary descriptions of the reports’ contents will be added by the summaries’ authors, making the summaries commensurate in structure. This will facilitate searching and improve search results.

The report contents are described using various classifications, e.g. medical speciality, report type, technology type and assessment method. Keywords complementing the summary are also included, in order to ensure that authors and readers use the same vocabulary consistently. Keywords in Ohtanen are mainly based on the FinMeSH vocabulary (Finnish Medical Subject Headings), produced by Duodecim Medical Publications Ltd. The FinMeSH vocabulary comprises Finnish translations of the MeSH vocabulary generally used in medical databases.

The basic search in Ohtanen allows the use of one or several words as search criteria. You can also use truncated searches with an asterisk, e.g. “heart or heart”. The search will be targeted at the report name, summary content, keywords describing the report and the reports’ original reference data. Search results can be narrowed down by the publishing HTA agency, publication year or specialty.

The user will obtain a list of search results with the possibility either to open a single summary or select several summaries for viewing and printing as a single text. The summary also contains a link to the original report and its abstract as well as to their English data of as many reports as possible in Ohtanen.

KRISTIAN LAMPE
LEENA RAUSTIA

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The Ohtanen database is available to all, free of charge. You can try out the new online database at http://lib.stakes.fi/ohtanen.
A rapid review completed at the right time

Horn and bells giving way in hearing screening

Finolta’s rapid review was consulted when maternity hospitals decided upon screening methods for newborn hearing.

At the beginning of 2005, several maternity hospitals asked Finolta to examine the new methods developed for screening newborn hearing. We studied the characteristics of screening methods based on otoacoustic emission (OAE) and auditory brainstem response (ABR). The review was completed in the spring of 2005 and sent to all maternity hospitals, auditory units and centres, and hospital districts.

Finolta’s rapid review concluded that the new screening methods were effective but that the small sample sizes weakened the reliability of results1. According to the evidence presented, the otoacoustic emission was slightly more sensitive than auditory brainstem response (98% vs. 94%), but the specificity of ABR was better than that of OAE (98% vs. 87%).

Our estimate of the maximum number of children to be sent annually for further examination in Finland was 670, if the screening objective is to diagnose moderate or severe hearing loss in both ears and to begin treatment by the age of 6 months. If the objective also includes the diagnosis of unilateral hearing loss, up to 2200 children may be referred for further examination. These figures show how changes of method and the definition of the screening threshold affect the need for further examination and the burden of hearing examination units.

In May 2006, we studied the impact of Finolta’s review on decisions to change screening methods. Of Finland’s 32 maternity hospitals, 24 (75 per cent) responded to the online survey. A total of 13 hospitals had switched to a new method and seven of these hospitals had done so before 2005. Seven hospitals used the OAE method, five used an OAE/ABR combination device and one used OAE and OAE/ABR methods. With the exception of one hospital, infants with a deviating response for both ears were referred for further examination.

A traditional horn or bell was used in nine hospitals, of which six were considering switching to a new method. Two hospitals used both traditional and new screening methods in parallel, and both hospitals planned switching completely to a new technology.

HOW WELL DID WE REACH USERS?
Hospitals planning to adopt or having adopted a new technology in 2005–2006 were asked about the factors affecting their selection of screening method. Eleven hospitals answered this additional question. The most important factor affecting decision-making was the experiences of other maternity hospitals; 10 hospitals stated this had an important or very important influence on their decision. Scientific articles were considered nearly as important. Six hospitals stated that Finolta’s rapid review had an important or very important influence on method selection. Only two hospitals stated that Finolta’s review had not influenced decision-making, but in these hospitals, the review had not been read. Only two hospitals estimated that piloting the device and manufacturer’s information had an important or very important influence on decision-making.

Fifteen respondents (63 per cent) stated that they had read the rapid review. Opinions on the new publication were highly positive. All but one respondent agreed fully or to some extent with the statement that the review contained all of the essential facts and was reliable. Good feedback was received on the text’s comprehensibility, while the visual aspect of the publication in particular was considered successful.

ULLA SAALASTI-KOSKINEN MARJUKKA MÄKELÄ ILONA AUTTI-RÄMÖ

REFERENCE
Health technology assessment extended to Tampere Satellite Office

Finohta has established a permanent foothold in Tampere, as a STAKES satellite office officially began operating there in December 2006. Assessing the effectiveness and impact of health technologies plays a central part in the operations of this new expert organisation.

The creation of STAKES satellite offices is in line with the Government’s regionalisation programme. In 2005, STAKES founded a satellite office in Jyväskylä and in March 2006 in Vaasa. The Tampere satellite office will co-operate actively with the Pirkannaa Hospital District, the City of Tampere and the University of Tampere. This office employs 12 STAKES staff, of which eight are Finohta employees.

Finohta staff in Tampere are particularly involved in the assessment and development of technologies in the framework of the national MUMM programme (Managed Uptake of Medical Methods). The MUMM Programme Manager is Dr. Minna Kaila, Adjunct Professor, and she is also the contact person for Finohta’s Tampere Office.

Contact information for Finohta’s Tampere Office is on the backpage of Impakti Newsletter.

Dissertation on the results of the MIKSTRA programme

The results of the MIKSTRA programme were published as a thesis of Common infections in Finnish primary health care. According to the new PhD Ulla-Maija Rautakorpi, fewer and fewer unjustified antibiotics are being prescribed in Finland.

Approximately half of the antibiotic treatment prescribed for respiratory tract infections was fully or almost in compliance with treatment guidelines in 1998–2002, while in one fifth of the cases other than a first-line drug was selected without justification. In another 20% antibiotic was prescribed for infections where they are not recommended. Treatment practices were modified by the educational intervention at health centres.

Although the diagnosis and treatment practices of infection patients are, in some aspects, well in line with the recommendations, there is still room for improvement. For example, most general practices lacked a device for tympanometry, which is recommended for ensuring the diagnosis of otitis media.

Ulla-Maija Rautakorpi has been the Project Manager of the MIKSTRA Programme since 1998.

Fewer unjustified antibiotics are being prescribed in Finland.

Changing the use of antimicrobials has required dissemination of information on recommendations among professionals as well as amongst the general population. National Current Care guidelines, based on evidence, were prepared in collaboration with the Finnish Medical Society Duodecim and associations of medical specialists.


Report on foetal screening opened over 100,000 times

The report Maternal ultrasound and serum screening in the detection of structural and chromosomal abnormalities is Finohta’s most frequently ordered and downloaded publication. The online report has been opened over 100,000 times. This issue has aroused much public discussion and a national statute to unify the screening methods has recently been given.

Finohta publishes reports and reviews both in printed and online versions. Last year we published two assessment reports: Use of quality adjusted life years for the estimation of effectiveness of health care: A Systematic Literature Review and The effects of extending the use of mammography screening.

QALYs in screening studies under review

Finohta is assessing primary health economic studies which are related to screening and using Quality-Adjusted Life Years (QALY) as an outcome measure. The working group has reviewed approximately 600 abstracts and will proceed to full text articles (numbering approximately 180).

Studies selected for the systematic literature review will be described and classifications will be made based on e.g. the health economic analysis method used, the medical speciality, the health-related quality of life instrument used for the calculation of QALYs, the interpretation of cost-effectiveness results, and the quality of the study.

The literature search was conducted from the Medline, Embase, CINAHL, SCI and Cochrane databases. Ms. Pirjo Räsänen, Researcher is responsible for the project.
**Finnish Cochrane Centre in Finohta**

The operating region of the Nordic Cochrane Centre based in Copenhagen includes the Nordic countries, the Baltic countries and Russia. Its satellite office, the Finnish Branch of the Nordic Cochrane Centre, was founded in 1995 and is today located in Finohta.

Finland has also another Cochrane unit, the Cochrane Occupational Health Field located in the Finnish Institute of Occupational Health. Nearly 90 Finns are registered in the Cochrane Collaboration’s online information system, Archie, and network meetings are organised at STAKES once or twice a year. The Finnish Cochrane experts have participated in review groups focusing on e.g. inflammatory diseases, mental health, musculoskeletal diseases, odontology and occupational health.

Several Finnish medical journals are included in the Cochrane handsearch, and over 700 randomised trials published in Finnish journals have been added to the CENTRAL database.

*The Nordic Cochrane Centre* http://www.cochrane.dk
*The Finnish Cochrane Branch* http://finohta.stakes.fi/EN

**Effectiveness of rehabilitation seldom studied**

International HTA units publish a surprisingly small number of reports assessing the effectiveness and cost-effectiveness of rehabilitation. Based on a study by Finohta, the reports on rehabilitation contain usually only a modest multiprofessional dimension. The focus has been on effectiveness of psychological or psychiatric, multiprofessional or behavioural interventions. Reports on the effectiveness of vocational rehabilitation and assistive devices were very scarce. The INAHTA database published in 2005 was screened independently by the two authors. Titles of 467 reports were screened. Of these, 52 reports were accepted for further evaluation. Finally, based on full text data, 18 (3.9%) reports were accepted to the final group of HTA rehabilitation reports.

Since rehabilitation is one of Finohta’s priority areas, we are currently considering closer monitoring of assessment reports related to the effectiveness and cost-effectiveness of rehabilitation. The aim is to promote international information to Finnish health care decision-makers. This Finohta review was conducted by Antti Malmivuora, Senior Medical Officer, and Hannu Alaranta, Chief Physician (Käpylä Rehabilitation Centre of the Finnish Association of People with Mobility Disabilities).

**Estonian postmenopausal hormone therapy trial published**

The Estonian Postmenopausal Hormone Therapy trial (EPHT) is a four-arm trial, with two arms in a blinded substudy with active hormone treatment (HT) and a matched placebo, and two arms in a non-blinded substudy with open-label HT and no intervention. Women aged 50–64 in the trial were recruited randomly and sent a postal questionnaire. In the pilot study, 2,000 randomly selected women aged 45–64 were asked their opinions on menopause and preferences on HT by means of questionnaires sent in 1998.

Women’s decision-making on whether to participate in both the pilot and main trial was examined using the notes from the recruitment process for the trial in 1999–2001, and from the one-year follow-up questionnaires for the recruited women. To study Estonian physicians’ preferences for HT, a survey of a random sample of 500 Estonian gynaecologists and general practitioners was carried out in 2000.

Women did not have strong preference for HT and only 3% of the studied women reported current HT use. Physicians’ preference for HT was stronger than women’s, and they would recommend HT more often than women would want. Gynaecologists had more favourable attitudes than general practitioners; gynaecologists would routinely prescribe HT for all women at menopause with no contraindication.

The recruitment rate was 30% higher in the non-blind substudy than in the blind mainly due to women’s varying decisions to come to the recruitment examination. The number of women who were defined as ineligible by physicians at the examination and were excluded was larger than the number of women with predetermined reasons for exclusions. 1,823 women signed the informed consent, 5% of the whole sample population.

Finnohta, the Finnish Office for Health Technology Assessment, was established in 1995 and is a part of the National Research and Development Centre for Welfare and Health, STAKES.

Our mission is to promote the use of proper evidence-based technologies in the Finnish health care system in order to enhance the effectiveness and impact of health care. Finnohta employs over 30 professionals in the fields of assessment research, methodology and communications. The priority areas for our assessment are rehabilitation and screening. Our journal, Impakti, our reports, the Ohtanen database and our website constitute our most important communications channels. Our staff is assisted by permanent consultants, the Scientific Committee on Health Technology Assessment and the Advisory Board of Health Technology Assessment. Furthermore, Finnohta hosts the Finnish Branch of the Nordic Cochrane Centre. The head of Finnohta is research professor Marjukka Mäkelä, a general practitioner by her first training and a clinical epidemiologist.

GUIDING PRINCIPLES

Independence Finnohta produces, summarises and disseminates information in a neutral manner and Finnohta’s assessments adopt the perspective of the whole of society.

Reliability The topics for assessment are selected, data is collected and assessed systematically, reliably, reproducibly and transparently in collaboration with experts in the field. Our working method is multidisciplinary and, in addition to studying effectiveness and costs, includes ethical and social aspects and issues related to the organization of services.

Support for major decisions Our main target group is local, regional and national health care decision-makers. In our selection of topics, we emphasise issues related to health policy questions.

Usability The assessment results are written to be understandable for educated lay people and also published in international scientific journals. The information is available through several channels for easy reach by the end users.

Collaboration We co-operate flexibly with other producers and disseminators of evidence-based information nationally and internationally. Overlapping efforts are avoided through frequent contacts and suitable structures.

Methodological support Finnohta promotes the assessment of health technologies by providing support for projects and methodological training, particularly for systematic reviews and trainer training.
The Finnish Office for Health Technology Assessment produces information to support decision-making.

The mission of FinOhta is to promote the use of proper evidence-based technology in Finnish health care in order to enhance the effectiveness and impact of health care.

The Office was established in 1995. It is based in the National Research and Development Centre for Welfare and Health, STAKES.

The principles underlying our activities are:

- Independence
- Reliability
- Supporting significant decision-making
- Usability
- Collaboration
- Methodological support

**FinOHTA**

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**XV Cochrane Colloquium in Brasil**

The 15th Cochrane Colloquium, to be held in Sao Paulo, in 23rd–27th October 2007, will gather more than 700 health professionals, health information professionals, librarians, scientific journal editors, policy makers and managers. Participants coming from over 70 countries will discuss about “Health evidence-based to all” and “Outcomes based on patients’ preferences”. More information at www.colloquiumbrasil.info.

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**The 4th Annual Meeting of Health Technology Assessment international (HTAi) will take place 16th–20th June 2007, in Barcelona. This meeting as a unique opportunity to bring HTA and Public Health closer together. Researchers, practitioners and decision makers can benefit from interaction and knowledge sharing. More information at www.htai.org.**