SPECIAL JOINT NEWSLETTER FROM FINOHTA AND SBU

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The typical homo sapiens would appear to be a healthy man – at least, when it comes to studying the effects of health technologies. For decades, clinical trials recruited mostly adult Caucasian males, randomizing them to courses of real or fake pills or different types of operations. Benevolently, the men agreed to return for dozens of blood tests, exercise tests, or whatever was needed to advance our understanding of the effects of these technologies on health.

Women have been excluded from such studies for many good reasons. The cyclical hormone production of adult females interferes with many other physiological functions, causing awkward variations in measurements. Similarly, elderly persons and people with chronic diseases have been excluded from studies due to variations in metabolism.

Studies that looked at the effects of drugs on people with asthma, hypertension and other diseases used to reject persons with other chronic health problems. Children have rarely been recruited in trials for obvious reasons. So thank you, healthy white males, for providing all the data!

The difficulty begins when we look at actual patients. Few of them are healthy males; children, women, and the elderly also become ill and need medicines, operations, and other interventions. Can we safely apply technologies to these atypical human beings, too? How should we translate results from middle-aged men to infants, or to frail senior citizens, who may already be using three prescription drugs a day?

In the Health Technology Assessment database at the University of York (www.crd.york.ac.uk), a search for the words “elderly or old” resulted in only 158 hits among 7500 HTA reports. Often these featured dementia, osteoporosis, or geriatric care. “Child or children” returned links to 461 technology assessments on, for example, infections, vaccinations, and sleep disorders.

For these important population groups, we see surprisingly few reports: less than 10% of all HTAs are interested in age groups other than adults. It is difficult, of course, to assess technologies without primary research data. But even without the data, decisions still have to be made.

The national HTA units in Sweden and Finland have conducted a number of health technology assessments on children and the elderly; examples of these provide some reasons why there are so few studies. The international HTA community would be wise to focus more on issues relevant to the young and the old.

Above all, we of working age should call for good research on the effect of technologies on those that are close to us and vulnerable: the generations before and after us.

Marjukka Mäkelä
Professor, Director of Finohta
According to a survey in 2002, more than a dozen different fetal screening procedures were used in Finland. Each municipality could independently decide on its own screening program. Most offered a nuchal translucency measurement for chromosomal screening, but only a few municipalities combined this with serum markers. In addition, most hospitals offered invasive diagnostic procedures to "older" mothers, where "old" varied from 35 to 40 years of age.

Due to this wide variation, the Finnish organization for gynaecologists and local health decision makers requested a health technology assessment. The Ministry of Health also needed a thorough assessment to be used as a basis for policy decisions. Ethical issues and the costs of the various screening methods were also considered.

Although the expert group identified and evaluated several effective screening methods, some critical questions still required consideration before a national decision on fetal screening could be made. Equitable access and the quality of screening had to be ensured. Most importantly, a comprehensive public discussion on the justification of screening and its consequences was needed.

The Screening Committee at the Ministry of Health emphasized that the goal of prenatal screening was to allow parents to take informed decisions about the pregnancy. These decisions range from achieving optimal care during pregnancy and following birth, to the termination of a pregnancy due to fetal abnormalities.

It was considered important to involve all stakeholders in an open seminar in 2005. A lively public discussion also spread to the printed media, and after a year the Screening Committee was able to suggest a unified screening program with three options for all parents.

The Ministry of Health sent the draft program for comments to health decision makers, professionals, ethicists and patient organizations. The screening program could have been implemented through a recommendation or code of practice, but after weighing up the alternatives, the Ministry decided to regulate the screening program for fetal abnormalities through a statute in 2006. All municipalities must adopt the program by 2010.

Training under way
In the face of this wide variation in practice, the Ministry wanted to ensure the adoption of joint fetal screening through comprehensive training. Finohta was mandated to inform hospital regions about the new statute and prepare educational materials. To help parents, two brochures were produced: one for all in early pregnancy, and another one to be given out if an abnormality is suspected.

Two seminars were held for regional trainers and training...
Material was prepared in support of professionals in maternity care. Materials are available through the web in Finnish, Swedish, and English; the hospital districts will train their own regions.

Most importantly, expectant parents must be well informed of the screening program, and they must know that participation is completely voluntary. Parents need to understand which types of abnormalities may be identified. Facing such a finding, they need support in taking the difficult decision to continue or terminate the pregnancy.

Law as a by-product
Neither the national Screening Committee nor the Ministry had originally planned for a statute on screening. However, the broad acceptance of the prenatal screening program and a strong need to monitor its results eventually led to the conclusion that a statute is the only possibility for ensuring a unified and justified screening program.

Ella Kuula

Contents of the Prenatal Screening Program in Brief

(i) general ultrasound during weeks 10 to 14 of gestation: length of gestation, plurality, size of fetus.

(ii) screening for chromosomal abnormalities: (a) OR (b):

(a) maternal serum markers (PAPP-A and \(\beta\)-HCG) during weeks 8–11 AND nuchal translucency measurement during weeks 10–12 in connection with the general ultrasound.

(b) maternal serum markers (AFP, estriol and \(\beta\)-HCG) during weeks 14–15.

In addition: women over 40 can be offered placental biopsy or amniocentesis.

(iii) screening for structural abnormalities during weeks 18–21 via ultrasound if parents consider termination of pregnancy due to identified severe fetal malformation as an option. If termination is not an option, the structural ultrasound will not be performed before week 24.


Materials on the web in English: <finohta.stakes.fi/FI/sikioseulonnat/perheille/index2.htm> Click “in English” in the table.

See also the SBU article in this newsletter, page SE/12.
Glaucoma is a chronic progressive optic neuropathy with a highly variable course. In most patients, the disease progresses slowly and can be further delayed using medication and surgery. Visual disturbances appear on average 30 to 40 years after the onset of glaucoma in patients under treatment.

Glaucoma treatments decrease intraocular pressure. However, only half of patients display ocular hypertension. The effectiveness of treatment for glaucoma patients with normal tension remains unclear.

Fininhta conducted a modeling of glaucoma screening at five-year intervals for Finnish people aged 50–79. Persons receiving glaucoma medication were included in order to con-

MODELING STUDY:

The Cost Effectiveness of Glaucoma Screening

The prevalence of glaucoma increases with age, affecting 1.5% of those aged 50+. More than half of people with glaucoma are unaware of their disease, which can rapidly lead to a serious visual disability and full blindness at its worst.
firm their diagnoses. The visual ability and quality of life of the screen-positives were compared with patients whose glaucoma had been detected opportunistically.

**Diagnosing is difficult**

Glaucoma is often detected only when patients’ visual ability has decayed so much that they seek medical care. On the other hand, less than half of the people currently treated for glaucoma really do have the disease. The number of suspected glaucoma cases is six times higher than that for manifest glaucoma, and treatment is administered for many suspected cases of glaucoma.

Poor targeting of treatment indicates that diagnosing glaucoma is difficult. The sensitivity, specificity and reproducibility of diagnostic tests are low. A reliable diagnosis requires several tests and retesting; this practice is currently not implemented in Finland.

New glaucoma drugs increase the costs of treatment significantly. In spite of this, few economic studies and no cost-utility analyses have been conducted. Previous cost-effectiveness studies have produced inconsistent results.

**Simulation for optimal care**

The researchers used a Markov model, covering the entire glaucoma care pathway and including various clinical outcomes. The screening involved the measurement of intraocular pressure, autorefraction, fundus imaging and automatic visual field examination. In screen-positive cases, the same tests were repeated on a later occasion. In the follow-up of diagnosed glaucoma patients, tonometry was performed twice a year and the other tests once every two years.

The treatment was targeted at patients with diagnosed glaucoma only. The main outcome measures were: number of cases, years of severe disability avoided, quality-adjusted life years (QALYs) gained and direct healthcare as well as non-healthcare costs.

The screening arm was compared to the current opportunistic case-finding in Finland. Clearly, this system has not ensured equality for glaucoma patients. Two thirds of ophthalmologist consultations are in the private sector, so little is known about their content. Data on reimbursements for glaucoma medication and eye examinations were gathered from the registers of the Social Insurance Institution.

**Screening the old is effective**

The incremental cost of one year of avoided visual disability was 32 600 EUR compared with current glaucoma treatment practices. One QALY gained cost 9 023 EUR, using a 5% discount rate. Screening one million people every five years during a 20-year period would generate incremental expenses of 30 million EUR, lead to 3 360 incremental QALYs and result in 930 years of avoided visual disability for 701 persons.

The modeling suggests that glaucoma screening could be a cost-effective strategy in Finland, especially in the older age groups. The cases currently undiagnosed could be provided with treatment and expensive medication could be discontinued for the numerous people with ocular hypertension but no risk of developing glaucoma. For people aged 75 to 79 screening would be both more effective and less costly than the current opportunistic identification of glaucoma in 80% of simulated cases.

Iris Pasternack

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**Cost-Utility Analysis**

Cost-utility analyses examine effectiveness in terms of quality-adjusted life years (QALYs). The length of life in years is multiplied by a coefficient reflecting the quality of life. The coefficient is 1 for a perfectly healthy life, while the weakening of visual or physical ability or any other factor affecting the quality of life generates a reduced coefficient closer to zero.


See also the article by SBU in this newsletter, page 5E9.
Few HTAs on Rehabilitation

Rehabilitation is a priority area for Finohta in health technology assessment (HTA). An obvious lack of such knowledge was found in an analysis of the prevalence and content of HTA studies concerning the impact and cost-efficiency of rehabilitation.
Rehabilitation aims to promote functioning, independent living, well-being and employability. Compared with treatment, rehabilitation can be seen as a process that involves and affects patients and their immediate circle to a greater degree. However, the boundary between treatment and rehabilitation is often blurred. Therefore, concepts and classifications need to be clarified. High-quality rehabilitation is individualised, community-oriented, and respects people’s privacy.

All HTA reports published by the International Network of Agencies for Health Technology Assessment (INAHTA) from January 2005 to January 2006 were gathered up for a Finohta review from the HTA Database of the University of York. Studies were included in the review if they met the following criteria:
• The intervention aimed to enhance the individual’s life management, resources and functioning.
• The outcome variables were linked with the individual’s activities and participation as specified in the WHO International Classification of Functioning (www.who.int/classifications/icf/en)

18 reports
Reports were excluded where the intervention consisted of drug treatment, surgery or individual therapy with somatic outcome variables only.
A search in the HTA database found 467 studies. According to the titles 52 possible rehabilitation studies were identified. The final review material included 18 reports assessing rehabilitation. The National Coordinating Centre for Health Technology Assessment (NCCHTA) was the INAHTA member unit with the greatest number of rehabilitation assessment reports. Four of the 18 reports were from NCCHTA.

**Little on assistive technology**
Several reports assessed the outcomes of psychological interventions by multi-professional teams or interventions affecting health behaviour. The effectiveness of stroke units had also been assessed. Only a few reports dealt with the impact of physical rehabilitation and assistive technology.

International HTA units publish surprisingly few assessment reports on the impact and cost-efficiency of rehabilitation. Many reports described the multi-professional aspects of rehabilitation quite sparsely.

The HTA on cognitive training illustrates the difficulty of summarising study results.

Hannu Alaranta
Antti Malmivaara

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**The Challenge of Assessing Rehabilitation: Cognitive Training in Dementia**

The German Agency for Health Technology Assessment, DAHTA, examined the effectiveness of cognitive training for dementia and other cognitive disorders in 2005. The literature search from 27 databases resulted in selecting 33 publications.

A study on cognitive group training for dementia used eight tests to assess memory, depression, functioning and behavioural symptoms. Group training participants achieved better results in the memory tests, but the differences were not statistically significant. Computer training failed to improve Alzheimer patients’ performance in another RCT.

Although Alzheimer patients may improve their performance in memory tests, the severity of the dementia does not change. A Cochrane review of six RCTs dealt with the light form of Alzheimer and vascular dementia. Cognitive training improved performance, but the results were not statistically significant.

A randomised controlled trial on mild cognitive impairment showed that the intervention group had better results in the recall of word lists, but no other differences were observed. In another study, of healthy older people, cognitive training seemed to maintain mental flexibility and performance. By contrast, little evidence exists on training in the early and severe forms of dementia.

In summary, every third study reported improvement in cognitive performance, but it remains unclear why some studies showed a clear positive response while others did not. Training methods were extremely varied, making it difficult to assess what factors contributed to the positive responses.

Hannu Alaranta
Antti Malmivaara

How to Prevent GBS in Newborns

Group B streptococcal (GBS) infection is a relatively rare perinatal disease. The GBS bacterium rarely causes symptoms in pregnant women, but their babies can become infected during birth and develop a severe disease.

Perinatal GBS infection affects infants under seven days old. In Finland, the annual number of early-onset GBS disease cases was between 32 and 38 in 1995–2000, increasing to 58 in 2005. Most infected newborns recover fully, but some are disabled and 1–2 babies die every year.

Varying practices in Finland

Approximately 58 000 babies are born every year in Finland, and it is estimated that every fifth mother is a GBS carrier. Administering chemoprophylaxis to the mother intravenously during labor prevents the transmission of GBS to the newborn.

Since no consistent screening instructions have been issued and practices vary by hospital, the Ministry of Health (MOH) commissioned a study on the cost-effectiveness of potential screening models in Finland. The adoption of a consistent prevention strategy has reduced the number of perinatal GBS infection cases in several industrialized countries.

Mothers can be screened for GBS in several ways. The cost-effectiveness of three alternative screening programs has been assessed. The current strategy, in which no preventive action is taken (alternative 0), was compared with identifying high-risk births (alternative 1), taking bacterial cultures late in the gestation period (alternative 2), and taking a rapid test at the onset of labor (alternative 3).

Three alternatives

Based on alternative 1, chemoprophylaxis is offered during labor to mothers if they have a fever, experience an early labor (before week 38), or a lengthened labor. Treatment is also recommended for mothers whose previous baby was infected by GBS or who have had a GBS urinary tract infection during pregnancy.
In alternative 2, a bacterial culture is taken from the birth canal a month before the due date. The results are sent to the maternity hospital, where all GBS positive mothers are offered chemoprophylaxis at the onset of labor.

Under alternative 3, a midwife takes a sample when the mother arrives in labor, and a rapid test gives the result in 1–2 hours.

**Costs estimated**

To evaluate the cost-effectiveness of the screening programs, a decision tree has been constructed. The costs per prevented disease and per birth, and the annual health care costs for each screening program, were estimated based on the best information available and estimates provided by an expert group. The costs of suspected and identified cases of perinatal GBS disease were included in the screening models, but costs generated later by disabilities were not included.

Without screening and preventive measures, 87 perinatal GBS diseases would be diagnosed annually. Of these, 74 would recover, but 10 would be disabled and 3 would die. The 20 EUR cost per newborn arises from the diagnosis and treatment of infected newborns.

**Screening reduces infections**

All screening strategies would reduce the number of infections, disabilities and deaths (see table underneath). Rapid tests would be the most expensive. Screening late in the gestation period would have the lowest cost per disease prevented.

**Ethical issues**

As with all screening programs, participation in GBS screening is voluntary. Thus, mothers need sufficient information in order to decide whether to participate. It is also important to ensure that screening is equally available to everyone. The possible effects of chemoprophylaxis on the mothers and the newborns must be considered, too.

The Screening Committee of the Ministry of Health will discuss the HTA report in late 2008.

Sirpa-Liisa Hovi

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**Effects of screening for GBS in Finland**

(based on 58 000 births/year)

<table>
<thead>
<tr>
<th>Alternative strategy</th>
<th>0. No screening</th>
<th>1. Risk factor based</th>
<th>2. Late pregnancy sample</th>
<th>3. Intrapartum rapid test</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GBS total (n)</strong></td>
<td>87</td>
<td>67</td>
<td>27</td>
<td>28</td>
</tr>
<tr>
<td>of which</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>recovered (n)</td>
<td>74</td>
<td>57</td>
<td>23</td>
<td>24</td>
</tr>
<tr>
<td>disabled (n)</td>
<td>10</td>
<td>8</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>deaths (n)</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Costs (EUR)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>per delivery</td>
<td>19,80</td>
<td>20,40</td>
<td>27,80</td>
<td>53,10</td>
</tr>
<tr>
<td>per prevented disease</td>
<td>–</td>
<td>59,160</td>
<td>26,873</td>
<td>52,200</td>
</tr>
<tr>
<td>Whole country</td>
<td>1 148 400</td>
<td>1 183 200</td>
<td>1 612 400</td>
<td>3 079 800</td>
</tr>
</tbody>
</table>

Universal or Selective Screening for PKU in Finland?

Phenylketonuria (PKU) is a rare metabolic disorder which can lead to irreversible brain damage. Early diagnosis and a lifelong diet can prevent this disability. The estimated incidence of PKU in Finland is only 1:100 000–1:200 000. PKU is five to ten times more common in other populations.

Due to the rarity of PKU, Finland has no national program for PKU screening. The Screening Committee at the Ministry of Health requested a comparison of screening options. Specifically, the cost-effectiveness of targeted PKU screening of infants born to genetically non-Finnish parents was to be considered. The assessment is based on a previous HTA report, which has been updated with the addition of a systematic literature review, register research, and a hospital survey.

The number of infants born to immigrant parents is increasing. According to the National Birth Register and Population Information System, the percentage of infants born to immigrant parents increased from 2.3 to 3.4% in 2000–2006. Of the 58 000 babies born every year in Finland, some 2000 have both parents who are of non-Finnish origin.

It is often problematic to identify a person’s genetic background. This dilemma was tackled by identifying the first language of parents. Infants whose both parents spoke a first language other than Finnish, Swedish, or Sami were classified to have a non-Finnish genetic background.

Screening methods compared
PKU can be screened for with several methods. The Guthrie method and fluorometry are considered cost-effective in many countries, while the newer tandem mass spectrometry (MS/MS) has been found to be cost-effective only when combined with screening of at least one other metabolic disease.

The annual cost of screening PKU in infants born to genetically non-Finnish parents would add up to 96 000 EUR every year. Screening all newborns for PKU would cost 2.7 million EUR and would be more cost-effective if screening for other metabolic disorders would be included.

A survey of maternity hospitals revealed that several already screen for PKU in newborns with immigrant parents. These hospitals care for 80% of all deliveries, so most families with a higher risk of PKU are already offered screening. This spontaneous screening did find the only new case of PKU to emerge in the last 7 years, so PKU still remains very rare in Finland.

Ethical questions
The cost-effectiveness of both universal and selective PKU screening in Finland is dubious. Ethical questions also arise: How is it possible to define and identify ethnic origin? Could targeted screening of a minority group be a justifiable public health strategy? The Screening Board will consider these issues before deciding on a national screening program.

Ella Kuula

The literature search found more than one thousand articles, of which eight were accepted for inclusion in the review, representing seven studies. Three of these were controlled studies and four were follow-up studies with both baseline and follow-up data. No randomised studies were found.

Two studies examined electric powered wheelchair interventions, one rollators, one walking frames, one focused on individually adjusted wheelchairs and one on a special powered wheelchair. In one study, three different types of mobility devices were examined. All studies were relatively new, starting from 2003. Three of them had been carried out in Sweden.

Self-evident outcomes?
The outcomes of mobility devices were clinically significant in all studies. In two studies, the mobility device helped in reaching individually set activity and participation goals, and one study showed an improved ability to participate in social activities. Two studies found that the mobility device improved the quality of life. The study with the highest quality showed that an outdoor wheelchair has a significant effect on the activities, participation and quality of life of stroke patients.

Increasing need
Mobility devices are generally regarded as important. Both the UN and WHO underline their importance in increasing equal opportunities for people with disabilities. In the Nordic countries, access to mobility devices is guaranteed free of charge if the devices are expected to improve individuals’ daily lives. Sizable public funding is currently spent on such devices, and with an ageing population the need will increase. Although the outcomes of mobility devices are often self-evident, more...
high-quality research is needed to compare different alternatives.

Active use is often considered to indicate user benefits. However, benefits cannot necessarily be measured by how much a device is used, since the use is situational; even if a device is seldom used, it may efficiently meet the user’s functional needs. The principal purpose of mobility devices is to promote an individual’s activity and participation. Effects on activity and participation are therefore the most important outcome indicators of mobility devices.

**Design important**

Other important mobility device characteristics include durability, the impact of seat cushions on pressure sores, wheelchairs’ maneuvering and their turning angle. Outcomes research is particularly challenging, since the use of a mobility device is an ongoing process influenced by the user, the mobility device, the environment and services received.

A wheelchair, for example, is not of much help if the user cannot move through doorways with it or is unable to use it alone. Another issue is whether the device breaks easily or there are long servicing times. A good outcomes study considers such factors during planning, implementation and analysis.

Future research on the effectiveness of mobility devices should focus on new devices and those where eligibility criteria and costs need to be considered with particular care.

Anna-Liisa Salminen
Outi Töytäri
Åse Brandt
Kersti Samuelsson
Antti Malmivaara

**Review Methods:**

**Seventeen Different Outcome Instruments**

Original studies and systematic reviews of mobility device interventions were searched for in seven electronic databases. Controlled studies and all types of follow-up studies that used both baseline and follow-up data were accepted.

The studies were included if the participants were over 18 years of age and needed sticks, crutches, walking frames, rollators, manual wheelchairs or powered wheelchairs (including scooters). Activity and participation were regarded as primary outcomes, and frequency of use, mobility, the need for assistance, user satisfaction, quality of life and adverse effects as secondary outcomes.

The seven studies used 17 different instruments and scales to measure mobility device outcomes. EuroQol 5D (EQ-5D) and Individually Prioritised Problems Assessment (IPPA) were the only ones used in several studies.

Only one of the studies was of a high methodological quality. The descriptive information on interventions and mobility devices was inadequate in every study. Numerous shortcomings limited the usability of the results while interventions and outcome indicators also varied among the studies. No general conclusions can be drawn as to the impact of mobility device interventions on user activity and participation. Conclusions can only be based on individual studies.
Explore the Global Health Evidence Community

Focus on

Finding reliable evidence on what works in health care and health promotion is easier today than ever before. Users of health evidence now benefit from... share the results of health technology assessments and systematic reviews. Here are a few examples of such collaboration.

Connecting organizations involved in HTA, the European network for Health Technology Assessment, EUnetHTA, facilitates cross-border collaboration by focusing on existing networks as reviews which is published quarterly as the Cochrane Library. Currently, there are 3,500 Cochrane reviews. The Cochrane Collaboration is an international not-for-profit organization that produces and disseminates up-to-date systematic reviews about the effects of healthcare, including new and changing health technologies. Its members identify, assess, and make evidence-based recommendations that are widely used and accepted by healthcare professionals who volunteer to work in Cochrane Review Groups.

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The EUnetHTA project started in 2006, supported by a grant from the European Commission. EUnetHTA involves 63 organizations from 31 countries, with the secretariat hosted by Denmark's National Board of Health. Currently, the network has 47 members in 24 countries. The Swedish Council on Technology Assessment in Health Care hosts the secretariat. The HTA database is hosted by the Centre for Reviews and Dissemination (CRD) and is produced in collaboration with the INAHTA Secretariat, based at SBU, Sweden. CRD is a department of the University of York and is part of the National Institute for Health Research.

The HTA database is located at: www.eunethta.net. You can read INAHTA briefs – summaries of recent reports from member agencies – on INAHTA's website, www.york.ac.uk/inst/crd. The Cochrane Collaboration is an international not-for-profit organization that produces and disseminates up-to-date systematic reviews about the effects of healthcare, including new and changing health technologies. Its members identify, assess, and make evidence-based recommendations that are widely used and accepted by healthcare professionals who volunteer to work in Cochrane Review Groups.

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Explore the Global Health Evidence Community

Finding Reliable Evidence on What Works in Health Care and Health Promotion is Easier

2008. Conference to be held in Paris on November 20:
- Stakeholder Open Forum and learn more about HTA’s future in Europe: ‘a con-necting network that delivers.’
- The HTA database is hosted by the Swedish Co-operative Research Unit and produced via the European Commission Framework Programme 6. The HTA database is located at: www.inahta.org.
- Focus on health and disease prevention
- The HTA database is located at: www.inahta.org. The website also presents an English glossary of health technology terms and a tool-box of supportive materials from several organizations.

The Health Evidence Network (HEN) is an international not-for-profit organization that produces and disseminates up-to-date systematic reviews about the effects of health care, technologies. Its members identify, select, assess, and translate evidence that includes research findings and other knowledge. Information is retrieved from websites, databases, documents, and national and international organizations and institutions.

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Focus on Health Evidence.

Here are a few examples of means and systematic reviews.

- of health technology assessments
- of health technology assessments, and economic evaluations, as well as summaries of Cochrane reviews available in Cochrane databases which have become known internationally as a source of high-quality, reliable health information. Guideline makers and HTA units increasingly make use of Cochrane reviews.

www.euroscan.bham.ac.uk

www.cochrane.org

Swedish CORD is a department of the University of York and is part of the National Institute for Health Research.

www.euro.who.int/HEN

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www.euroscan.bham.ac.uk
Ear Tubes Can Help Children

A tiny tube through the eardrum can help children whose hearing is impaired by fluid in the middle ear for a prolonged time. But scientific evidence has yet to prove the benefit of ear tubes in children with recurrent, acute ear infections. This type of problem currently accounts for 1 in 5 such operations.

The benefit of inserting ear tubes in children with recurrent, acute ear infection (acute otitis media) is not scientifically confirmed. Studies show conflicting findings, and further research is needed to determine whether or not to continue using the method.

SBU's report shows that ear tubes improve hearing and quality of life for at least 9 months in children who have had fluid in the middle ear (serous otitis media) for 3 months or longer. Surgically removing the adenoid tissue behind the nose (adenoidectomy) improves hearing equally as much as inserting ear tubes, measured after 6 months. Studies do not show any additional improvement in hearing by combining the two treatment methods.

Suctioning the fluid from the ear during surgery does not affect ear tube function. Research has not shown any benefits from routine surgical removal of ear tubes that do not fall out spontaneously. Furthermore, it is unclear whether pneumococcal vaccination reduces the risk for new ear infections.

Several studies have investigated whether normal swimming and water play increase the number of new infections or discharge through the tube. These studies do not show any effects from water play. However, underwater activities were shown to increase the number of new infections.

Ear tubes are recommended in children who have impaired hearing and a subsequent reduction in quality of life. Questionnaires designed and tested for children with ear disorders can be used to improve hearing and quality of life.

Surgically removing the adenoid tissue behind the nose improves hearing as much as inserting ear tubes, measured after 6 months. Hearing, measured from 3 months, is not shown to improve further by combining ear tube treatment and adenoid tissue removal.

The review could not show that protecting the ears in water had any clinically meaningful effect on the number of displaced tubes. Using a bathing cap or earplugs during swimming and water play did not reduce the number of tube displacements.

Scientific evidence is insufficient to determine whether ear tubes are cost effective in treating ear inflammation involving fluid in the middle ear, or recurrent, acute ear infections.

SBU's CONCLUSIONS
Vertebral fractures can be extremely painful. Limited scientific evidence presented by SBU shows that bone cement, when injected into damaged vertebrae of patients with osteoporosis, provides better short-term pain relief and function than analgesic drugs alone.

A new method to treat severe pain caused by vertebral fractures, e.g., from osteoporosis, involves injecting bone cement directly into the damaged vertebra. The method is called percutaneous vertebroplasty (PVP).

In reviewing the research on this method, SBU found limited scientific evidence that PVP is superior to conventional methods when not provided acceptable pain relief. However, PVP is considered an alternative treatment option for patients with severe back pain from vertebral compression fractures. Though PVP can provide faster pain relief, increase functional capacity, and enhance quality of life, complications leading to symptoms occur in 3% to 4% of all procedures, but serious complications are uncommon.

**RESEARCH GAPS**

SBU discovered several gaps in research. The long-term effects and risks of PVP have not been fully investigated. Potentially, PVP could increase the risk for new compression in adjacent vertebrae, but research has not confirmed this. Furthermore, it is unclear whether PVP helps patients with vertebral fractures from causes other than osteoporosis.

**HIGH-QUALITY STUDIES**

SBU emphasizes the need for randomized and blinded trials to reduce the risk of overestimating the treatment effects. High-quality observational studies with prolonged follow-up, for example, national registries, are necessary to determine long-term effects of PVP and compare outcomes with other treatment options.

Currently, PVP is considered for severe cases where conventional methods have not provided acceptable pain relief. Without pain relief, these patients find it difficult to remain mobile and maintain their independence. Without pain relief, patients with severe back pain may experience significant distress and reduced quality of life.
The test results will bring some expectant parents face-to-face with difficult questions and choices—demanding good communication with healthcare providers. Most studies point to deficiencies on this front. Expectant parents are not receiving what they need to make well-informed decisions.

To improve information, SBU has produced a leaflet in Swedish for women and couples who ask for more information on fetal diagnosis. However, the ethical questions raised by the new technologies have no simple answers—so the debate continues.

**EARLY FETAL DIAGNOSIS**

A combined test of ultrasound nuchal translucency measurement and maternal serum biochemistry (biochemical screening) in early pregnancy (10–14 gestational weeks), along with maternal age, is the clinically evaluated method of assessing the probability of fetal Down syndrome that gives the best balance between the percentage of detected cases and false-positive results. (1)

All of the methods (nuchal translucency measurement, maternal serum biochemistry in the second trimester, and the combined test) for assessing the probability of fetal Down syndrome and detecting cases and false-positive results (1) detected cases and false-positive results. (1) are the best balance between the percentage of detected cases and false-positive results. (1) of Down syndrome that gives the best balance between the percentage of Down syndrome detected and false-positive results. (1) The combined test of ultrasound nuchal translucency measurement and maternal serum biochemistry in early pregnancy is the clinically evaluated method of assessing the probability of fetal Down syndrome that gives the best balance between the percentage of detected cases and false-positive results. (1)
Early Prenatal Diagnosis

Raisers Ethical Issues

The option for fetal diagnosis of the most common chromosomal abnormalities is offered routinely. The Swedish National Council on Medical Ethics states that the combined test is preferable to age indication, and “the combined test does not threaten human dignity as long as it is made clear that both the combined test and the genetic prenatal diagnosis is an offer that the woman can accept or decline at her own discretion.”

However, the new combined screening test is controversial. In September 2007, SBU concluded that the combined test is superior to relying on maternal age alone, which until now has been the most common indicator used in Sweden. Taking maternal blood samples increases the risk of miscarriage, but the combined test exposes fewer fetuses to the risks of amniocentesis or sampling of placenta cells for chromosome analysis.

The combined tests detect the highest number of cases with the highest number of cases, but the combined test is also associated with a higher rate of false indications for Down syndrome. Because of its sensitivity and ability to provide specific information about the fetus, the combined approach is superior to other screening methods for Down syndrome, according to SBU’s assessment.

The combined test is offered routinely to mothers over 35 years of age. However, some local politicians want to stop the test – or at least wait. Their fear is that more women and couples will make erroneous decisions to abort fetuses with Down syndrome.

“Does it make sense to provide this freely and to always let the woman decide for herself?” asks Monica Selin of the Christian Democrats party, Stockholm County Council, in an interview for the Swedish medical weekly, Dagens Medicin. “I am prepared to review this legislation, even if it means a step backwards,” she says.

Others want to make the combined diagnostic test available as soon as possible. According to Jonas Andersson of the Liberal Party in Västra Götaland, the combined test should be available this year to women older than 35, and later to all pregnant women. “Many unnecessary amniocenteses can be avoided,” he says. “And many women want the test. Therefore we think it is right to offer the new combined screening test.”

However, the new combined screening test is controversial. In September 2007, SBU concluded that the combined test is superior to age indication, and “the combined test does not threaten human dignity as long as it is made clear that both the combined test and the genetic prenatal diagnosis is an offer that the woman can accept or decline at her own discretion.”

The latter reservation is important. SBU’s assessment shows that health services must become much better at informing expectant parents about the options for fetal diagnosis. The combined test provides a higher rate of false indications for Down syndrome. Because of its sensitivity and ability to provide specific information about the fetus, the combined approach is superior to other screening methods for Down syndrome, according to SBU’s assessment.

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This represents a dramatic change in the level of coverage, says Leif Hergils, Associate Professor at Linköping University Hospital’s ENT department, and scientific contributor to the SBU report.

He observes several reasons behind this change. In part, the timing was right since many county councils were already prepared to introduce screening, but had to arrange financing. In part, the level of coverage was greatly influenced when the metropolitan regions started their screening programs. But Leif Hergils is convinced that SBU’s report also played a role.

– The report was used in several formal decision-making processes, eg, in Stockholm County Council and in the regions of Skåne and Västra Götaland. Sweden’s association for the hearing impaired also referenced the SBU report to influence the county councils to introduce screening programs.

It is still somewhat premature to quantify the patient benefits of screening nationwide in Sweden. Comparable data are available from large British studies. Before screening was introduced early in this decade, half of the permanent hearing impairments were detected when children reached 18 months. By 2007, the corresponding age was 4 months, and those that needed hearing devices generally received them before 5 months of age.

– It would be interesting to follow up on the corresponding figures in Sweden, now when all county councils provide this service. Sweden’s registry on child hearing could be used for part of this effort, says Leif Hergils.

– We detect hearing loss earlier nowadays. It remains to be seen whether or not we can lower the age to the level indicated by the English figures.

FACTS HEARING SCREENING

The most common method used in Sweden involves measuring otoacoustic emissions (OAE). Newborns are screened by inserting a small earplug that emits a clicking sound. Healthy hair cells in a child’s ear react by transmitting a weak sound that is detected by a microphone and analyzed by computer. A normal response suggests that the inner and middle ear are functioning. The examination takes 10 to 15 minutes and causes no pain.

The test is performed at the maternity ward and can be conducted by specially trained maternity ward staff or audiometrists.

Congenital permanent hearing loss that requires habilitation is uncommon – just over 1 in 1000 among the 100 000 births annually in Sweden. Screening costs approximately 30 EUR per child, amounting to 30 million EUR annually in Sweden. The number of children born with hearing loss is estimated between 0.5 and 1 in 1000 births. Healthy hearing is important to learning and development. Early detection and habilitation improve a child’s language and communication skills. The examination can be repeated if needed.

FACTS SBU REPORT ON HEARING SCREENING

The SBU report presents scientific evidence that screening with OAE or aABR (automated auditory brainstem response) leads to early detection of congenital hearing impairment and early intervention.

Limited scientific evidence also indicates that early detection and habilitation improve a child’s language and communication skills. Comparison involves the use of traditional screening and distraction tests, eg, BOEL test.

When the report was written, data were not available to estimate the health gains of a general screening program.

SBU’s report on hearing screening was used in several formal decision-making processes. Read SBU’s summary and conclusions on www.sbu.se.
In only 3 years, general hearing screening in newborns has expanded from 5 county councils, plus a few hospitals, to nationwide coverage. Though the time was right to expand coverage, SBU’s report from 2004 also played a role. The next step is to monitor these programs to analyze the scope of patient benefits.

Screening of all newborns prior to discharge from the maternity ward helps detect hearing loss early. Habilitation—testing of hearing aids, cochlear implants for deaf children, teaching sign language, and support for families—can also be started early. These were SBU’s findings in its assessment.

Dramatic Change

At that time, 5 of Sweden’s 21 county councils and a few additional hospitals offered general screening. Within 3 years, by 2007, all county councils had decided to introduce screening programs. These findings helped promote hearing loss early detection programs. In only 3 years, general hearing screening in newborns was expanded from 5 county councils, plus a few hospitals, to nationwide coverage.
Reducing pressure in the eye slows deterioration in the field of vision in glaucoma patients. Treatment to reduce intraocular pressure also reduces the risk that patients with elevated eye pressure will develop glaucoma, but this requires a reduction of 20%. No effect has been shown at more moderate reductions. In both instances, a new SBU assessment shows that scientific evidence is limited. However, studies have reached contradictory findings, making it impossible to tell whether one type of treatment to relieve eye pressure—drugs, lasers, or surgery—is more effective than any other type. Questions concerning which method can best treat a particular group of patients are not sufficiently studied, according to the report.

A survey of current health services, conducted by SBU in conjunction with the review, found that pharmaceutical costs, the number of laser treatments, and the number of surgical interventions have increased in recent years. The survey revealed that in 2006, the county council providing the most operations (per 100,000 population >70 years of age) to reduce intraocular pressure provided nearly 40 times more operations than the county council providing the least. Drug and laser use also varies among the county councils. SBU has not analyzed whether this indicates that patients are undertreated or overtreated, but highlights this as an important question for further research.

**FACTS NIDCAP**

Annually in Sweden, 2600 children are born prior to gestational week 37. Approximately 750 of these infants are born prior to gestational week 33.

Today, more lives can be saved. But during early infancy problems can arise in the central nervous system, eyes, or lungs. In the long term, performance at school and behavior can be affected in some children.

NIDCAP involves observing an infant's behavior every seventh to tenth day, in accordance with a special schedule. Observations take place before, during, and after a caregiving activity, e.g., changing a diaper or shifting position. Information on respiration, color, stomach/bowels, muscle movement, face, alertness, and attention are noted. Also noted are the infant's position, the interventions performed, and sensory input in the environment.

A specific care plan is designed, based on an assessment of how the infant reacts and the situations in which it shows signs of seeking or avoiding contact.

Interventions in the care plan may involve the environment in the room, incubator, or bed, assistance with self-regulation (positioning, sucking and griping devices, eye protection), timing and coordination of healthcare activities and daily rhythm, and the transition between different activities. The care plan is updated successively.

A recent SBU assessment supports the need for a more evidence-based approach to the matter, of special requirements appropriate to the maturity of its nervous system.

A recent SBU assessment found limited scientific evidence showing that NIDCAP promotes cognitive and motor development in preterm infants. This conclusion is based on 6 randomized controlled trials involving 250 children. Most of the trials are small, and some include many variables. The longest trial followed children for just over 5 years.

In every study showing differences between the treatment and comparison groups, the outcomes are consistently better in the NIDCAP group. This finding applies mainly to cognitive and psychomotor development. The evidence base, which is limited, also suggests a reduced need for respiratory support.

SPECIAL REQUIREMENTS

NIDCAP requires specially trained staff and continual observation of the infant's behavior. The cost to train a certified NIDCAP observer is estimated at approximately 4600 EUR plus the costs for work leave and travel. For an infant born after gestational week 27, the cost for 10 behavioral observations is estimated at 575 EUR.

To date, no studies have weighed the effects against the costs.

**See also the article by Finohta in this newsletter, page FI/6**
NIDCAP is a new method designed to stimulate preterm infants. Limited scientific evidence supports its positive effects on child development. But securing reliable results on the method’s benefits would require larger and longer studies with a narrower focus, concludes SBU.

Previously, reflexes and inherited patterns were thought to control most actions in preterm infants. This perspective has changed. Attention now centers on the infant’s ability to interact with his environment. This focus has led to the introduction of methods to promote bonding and breast feeding, neurological development, and other aspects of infant care.

One of these methods is the Neonatal Individualized Developmental Care and Assessment Program (NIDCAP). It aims to stimulate each infant at a level appropriate to his abilities. Health services have introduced various methods to promote bonding and breastfeeding. These efforts have led to the development of methods like NIDCAP, which aims to stimulate each infant at a level appropriate to his abilities.
Around 140,000 people in Sweden have some form of dementia. Two out of three have Alzheimer’s disease, 10% have vascular dementia, and 5% have frontal lobe dementia. Common characteristics in all forms of dementia include impaired memory and cognitive function due to nerve cell death. The level of consciousness is unaffected. Memory impairment is the fundamental defect. But dementia also includes one or more of the following symptoms: impairment in thinking, communicating, and orientation and impaired practical skills, i.e., greater difficulty in retaining learned skills or managing daily activities. Those affected also develop personality changes involving impaired cognition, poor judgment, aggressiveness, lack of inhibition, emotional bluntness, and lack of empathy. Furthermore, anxiety, depression, suspicion, delusions, and obsessive behavior are reactions of the underlying disease.

SBU has not reviewed treatment for mild cognitive impairment (MCI) since current diagnostic methods are poor at differentiating people with MCI from those who are healthy.

FACTS ABOUT DEMENTIA

A somewhat surprising finding is that ginkgo biloba extract, a natural medicine, appears to ameliorate certain symptoms. But its effect beyond 6 months is not established.

The cost effectiveness of medication, i.e., how the treatment effects of the various drugs compare to their cost, cannot be assessed, according to SBU. The same applies to the cost effectiveness of various treatment programs.

The report also emphasizes that certain drugs are shown to impair cognitive function and are inappropriate for treating people with dementia. These include benzodiazepines and earlier drugs used to treat psychosis and depression.

INCREASE MORTALITY

Some evidence suggests that certain atypical antipsychotic drugs, i.e., newer medications to treat psychosis, which have been tested on behavioral symptoms in dementia, could increase mortality.
SBU’s report on dementia clarifies the need to train caregivers to provide the most appropriate care to people with dementia. SBU also shows that diagnostics can be improved and that Alzheimer’s drugs can provide some benefit for people with mild or moderate Alzheimer’s disease, but the effects of medication must be monitored and reappraised in each patient.

**Trained Staff Needed**
SBU’s review of the entire body of research available in this field also highlights the need for well-trained staff to assure the delivery of appropriate health and social services for people with dementia. In Sweden, the municipalities deliver the greatest share of dementia-related care.

– Care must be based on a strong, ethical approach, says Professor Måns Rosén, SBU’s Executive Director. This requires giving municipal caregivers and family members the support and education needed to deal with the disease.

– Caregivers need more training on how to interact with people suffering from dementia on how to interact with the disease. One must learn to understand and address the needs of people with dementia.

**Find the Person Behind the Disease**
Without special training, caregivers might easily misinterpret a grasping reflex as "pinching", or yelling as provocation. Through education and more open discourse on dementia-related disorders, people’s attitudes become less negative.

– Not until people with dementia are treated as capable individuals will their remaining abilities become clear to us, says Måns Rosén. Lars-Olof Wahlund is Professor of Geriatrics at Karolinska Institutet and one of the experts behind the SBU report. Today, we have no methods that are particularly good at detecting dementia early, he says. The SBU report shows that current tests often trigger false alarms. This fact, along with the narrow range of treatment options, means that mass screening has no scientific support, says Lars-Olof Wahlund.

Instead, the objective is to help the patients and families that seek care. Andersen Wimo, Adjunct Professor at the Alzheimer’s Disease Research Center, Karolinska Institutet, also worked on the report.

– Treatment focuses primarily on trying to slow the progression of the disease, says Andersen Wimo. There are no curative interventions.

**Moderately Strong Evidence**
Moderately strong scientific evidence suggests that cholinesterase inhibitors affect Alzheimer’s symptoms. Studies lasting up to one year show that this group of drugs has a positive effect on intellectual and general functional capacity in some people with mild to moderately severe Alzheimer’s disease. However, many of these patients experience side effects such as nausea and dizziness.

In more severe Alzheimer’s disease, there is some evidence that memantine can have some effects on cognition, but the evidence is not strong enough to recommend its use. Lars-Olof Wahlund is the lead author of the SBU report on dementia, which clarifies the need to train caregivers to provide the most appropriate care to people with dementia.

**Scientific and Practical Solutions**
SBU Science & Practice – HTAI 2008

**References**
- SBU’s report on dementia
- Alzheimer’s Disease Research Center, Karolinska Institutet
- Måns Rosén, SBU’s Executive Director
- Lars-Olof Wahlund, Professor of Geriatrics, Karolinska Institutet
- Andersen Wimo, Adjunct Professor, Alzheimer’s Disease Research Center, Karolinska Institutet

**For More Information**
- SBU’s report on dementia
- Alzheimer’s Disease Research Center, Karolinska Institutet
- Måns Rosén, SBU’s Executive Director
- Lars-Olof Wahlund, Professor of Geriatrics, Karolinska Institutet
- Andersen Wimo, Adjunct Professor, Alzheimer’s Disease Research Center, Karolinska Institutet
Today's vaccines target only 2 of at least 13 viruses that cause cervical cancer. General childhood immunization would offer some protection against cell abnormalities. But benefits in terms of cancer rates and years of immunity are not known, shows a new SBU report.

Research has not shown how childhood immunization programs for human papilloma virus (HPV) 16 and 18, if introduced today, would affect future morbidity and mortality from cervical cancer. However, findings show that current vaccines can prevent certain pronounced cell abnormalities in vaccinated subjects, at least within the timeframe studied. In some cases, the cell changes develop into cancer.

**SHORT FOLLOWUP**

SBU has reviewed the body of scientific research published on the topic, and SBU’s assessment forms the basis for Sweden’s National Board of Health and Welfare in its decision regarding a general HPV immunization program.

A strong scientific evidence shows that current HPV vaccines prevent cell changes from HPV 16 and 18 among young women who have not yet been infected. Studies followed these women for an average of 3 years; a relatively short period considering that protection is intended to last for decades.

The SBU report emphasizes that general immunization does not replace organized gynecological checkups for cell changes in vaccinated women. One reason is that vaccines target only 2 of at least 13 HPV types associated with cervical cancer. The prevalence of HPV 16 and 18 in Sweden is not known.

A general immunization program to vaccinate girls against HPV 16 and 18 would cost an estimated 22 million EUR annually. If a booster dose were necessary, the annual cost would reach 28 million EUR.

Introducing a general HPV immunization program would require systematic followup of the effects, safety, and cost effectiveness of all preventive interventions against cervical cancer. Benefits uncertain, since the medical effects remain somewhat uncertain, estimates of cost effectiveness also remain uncertain.

No followups have been published on the effects or safety of the vaccines beyond 5 years. Hence, the need for systematic followup of the vaccine program against cervical cancer.

**BENEFITS UNCERTAIN**

Since the medical benefits remain uncertain, estimates of cost effectiveness also remain uncertain. No followups have been published on the effects or safety of the vaccines beyond 5 years.
Strong SBU evidence indicates that a new drug, ranibizumab (Lucentis®), slows the loss of visual acuity in patients with age-related macular degeneration. According to a recent SBU report, the drug can even improve vision in some patients. But the estimated cost is high.

Patients with age-related changes in the macula, ie, wet macular degeneration, lose part or all of their central visual acuity and reading vision. This loss can take less than 6 months and often affects both eyes, although vision in the second eye can deteriorate later. Without treatment, these patients face a slow and often progressive decline in their visual function.

**EYE INJECTION**

Ranibizumab injected into the vitreous body of the eye slows degeneration. Patients retain greater visual acuity than with standard treatment (ie, photodynamic therapy), or placebo (simulated injections). Strong evidence supports this, but treatment is expensive. An ophthalmologist must give each injection in a sterile environment – costing over 1400 EUR, whereof the drug cost alone is 1100 EUR. If the health services were to give one injection per month to every patient with wet macular degeneration, assuming that treatment could be terminated after 2 years, the annual cost would reach 140 million EUR per year.

Offering the drug to everyone who could benefit from it would also require more ophthalmologists and specially trained ophthalmology nurses.

**LACKING KNOWLEDGE**

The report shows knowledge is lacking on whether patients can terminate treatment once started, or if the injections must continue for a prolonged – even lifelong – period to be effective. It is also unclear whether injections would be effective if given less frequently than once per month. Hence, the method’s long-term cost-effectiveness cannot be determined.

Several county councils have already introduced the drug. But its use varies across Sweden. Several clinics have already started providing this treatment, although they are uncertain how it should be financed. Some treat patients affected in one eye. Others treat patients only after vision in the second eye has begun to deteriorate. Some clinics have few or no restrictions on treatment.

**Ranibizumab**

Ranibizumab prevents formation of new vessels by affecting VEGF (vascular endothelial growth factor). Treatment should begin as soon as possible after the patient’s vision is impaired. It is notCurative. The vessels are brittle and can leak proteins, the vessels form broken and in the retina the neovascular vessels form broken and in the retina. Ranibizumab is often used with laser photocoagulation, although the latter treatment is far more effective.

Several different types of AMD are found. The most common type is neovascular age-related macular degeneration (AMD) which is the most common cause of severe vision loss in people over 60 years of age.

**FACTS MACULAR DEGENERATION**

SBU SCIENCE & PRACTICE – HTAI 2008

**VISION**

Useful but Costly Treatment

Puts Focus on Budget

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**Johanna Thorell**

Age-related macular degeneration (AMD) is the most common cause of severe vision loss in people over 60 years of age. Several different types of AMD are found. The most common type is neovascular age-related macular degeneration (AMD) which is the most common cause of severe vision loss in people over 60 years of age.
The results must be made public and thoroughly assessed for the tough decisions that inevitably need to be made. Making a decision to reject an expensive intervention is difficult for decision-makers. They urgently need evidence to inform their priority setting – in other words, they have an acute need for health technologies to inform the public.

SBU recently assessed another new intervention option: bilateral cochlear implantation in children. The cost-effectiveness of bilateral cochlear implants and our increased longevity have added to the burden of disease. Meanwhile, new and promising – but expensive – technologies increase the opportunities to improve the health of populations. Needs and opportunities alike raise important political questions. What can society afford? Who should pay? Can we achieve equity and balance?

From my point of view, decision-makers have to accept that they are not in charge of the decisions that society will inevitably have to make. They must put greater emphasis on evaluation of health interventions – comprehensive assessments of benefits, risks, costs, and ethical and economic considerations. It is essential that patient groups and relevant authorities understand how the decision-making process works and the factors behind it. SBU noted that no studies had addressed the cost-effectiveness of bilateral cochlear implantation in children. SBU’s assessment of bilateral cochlear implants made without knowing the specific long-term annual costs exceed 22 million EUR. Decisions are difficult for decision-makers. They urgently need evidence to inform their priority setting – in other words, they have an acute need for health technologies to inform the public.

In 2009, the treatment costs are massive – the drug ranibizumab could benefit 5000 eyes in Sweden – runibizumab for neovascular age-related macular degeneration. This new method could greatly improve vision in many elderly people. Although several months, the cost would be higher (at least 80 000 EUR). SBU noted that no studies had addressed the cost-effectiveness of bilateral cochlear implantation in children. SBU’s assessment of bilateral cochlear implants.
SEPTEMBER 2008

HEALTHY SKEPTICISM

Many investigations have uncovered examples of unacceptable research methods and
unsound research outcomes. When different authors produce different results, it
is easy to become convinced that the results are genuine. As an example, a Danish
study of being influenced by comparative effectiveness researchers showed that
17% of published articles contained duplicate data, but do not cite the original study.

Since different authors produce different results, it is difficult to decide who
is right and who is wrong. Misleading findings are therefore difficult to detect. In
particular, the drug's effect is underestimated if the dose is too low. Conversely, if the
dose is too high, the drug's effect is overestimated.

The conclusion is not that
HEALTHY SKEPTICISM

research is a complicated process that many studies are needed to improve health
substantially from those special interests. However, we need not be
skepticism.

We must question whether all of this research is defensible – particularly in
ethically and economically justifiable – with major roles played by researchers and
independent sponsors of studies. A documented example concerns the use of
medication for many years, even though patients treated for other conditions showed no
improvement.

We need a dose that is even more beneficial than our knowledge about long-term effects will never increase.

Purchase

Effectiveness

Buying

There are many issues that can strengthen or weaken with time –
shorter studies do not apply the results.

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improvement.

We need a dose that is even more beneficial than our knowledge about long-term effects will never increase.
Robust, comparative treatment studies are strikingly absent in scientific publications. Yet, irrelevant or misleading articles on individual treatments—usually drugs—are plentiful. Studies should focus more heavily on patient needs, not on special interests.

Healthcare providers need to know which treatment options offer the best outcomes in mortality, morbidity, and quality of life at the lowest possible risk and cost. But much of the research is not designed to provide such information.

Many drug studies pose questions that are irrelevant in routine clinical practice, or they are designed in ways that fail to provide meaningful answers. Such research serves the interests of the researcher, university, or corporation more than the interests of the patient.