INAHTA Briefs

INAHTA

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INAHTA Briefs

The series, *INAHTA Briefs,* is a forum for member agencies to present brief and structured overviews of recently published reports. *INAHTA Briefs* are published regularly and are available free-of-charge at www.inahta.org. Information presented in the INAHTA Briefs is developed and submitted by the member agencies. This publication series would not be possible without the members' ongoing commitment and support.

The views expressed in each overview are those of the authors alone and do not necessarily reflect the position of INAHTA.

INAHTA asks readers to direct your personal medical and health questions to your family physician. Information found in INAHTA publications should not be used as a substitute for consulting with your doctor.

INAHTA
c/o SBU
PO Box 5650, Tyrgatan 7
SE-114 86 Stockholm, Sweden

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Diagnostic procedures/screening continues »

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Lise Lund Håheim, Anita Lyngstadaas, Ellen M Nilsen, Liv Merete Reinar et al, NOKC, Norway

Susanna Axelsson, Mona Britton, Agneta Pettersson, and Nina Rehnqvist, SBU, Sweden

Paul Taylor, CHIME, Royal Free and University College Medical School, UK

Jos Kleijnen, CRD, UK

Elizabeth Robinson, Keele University, UK

Sube Banerjee, King's College London, UK

Maria Woloshynowych, Imperial College London, UK

Christopher Fowler, The Royal London Hospital, UK

Jon Shenfine, Royal Victoria Infirmary, UK

Heather Epps, Tadworth Children's Trust, UK

Adrian Grant and Brenda Wilson, University of Aberdeen, UK

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Introduction

The International Network of Agencies for Health Technology Assessment (INAHTA) is a global network linking 45 non-profit, governmental institutions from 22 countries (2006).

INAHTA was established in 1993 with the aim

- To accelerate exchange and collaboration among HTA agencies
- To promote information sharing and comparison
- To prevent unnecessary duplication of activities.

The mission of INAHTA is

"To provide a forum for the identification and pursuit of interests common to health technology assessment agencies."

The INAHTA membership is open to any organization which

- Assesses technology in health care
- Is a non-profit organization
- Relates to a regional or national government
- Receives at least 50% of its funding from public sources.

The Network stretches from the USA, Canada, and Latin America to Europe, Australia, and New Zealand. The Secretariat is located at SBU in Sweden.

Further information on INAHTA is available at **www.inahta.org**

Title	**Treatment of Depression**
Agency	**SBU, The Swedish Council on Technology Assessment in Health Care** PO Box 5650, SE-114 86 Stockholm, Sweden; Tel: +46 8 412 32 00, Fax: +46 8 411 32 60; info@sbu.se
Reference	SBU Report 166, 2004. ISBN: Volume 1 91-87890-87-9, Volume 2 91-87890-88-7, Volume 3 91-87890-94-1. Summary and Conclusions in English, and full text report in Swedish are available on www.sbu.se

Aim

To investigate the evidence for methods of treating depression. Economic aspects were considered.

Conclusions and results

Partial list:

- The treatment goal should be full recovery. This can be accomplished for most patients, provided that the various treatments are applied systematically.
- Many antidepressive drugs and several psychotherapies have well documented effects in treating adults.
- Treatment effects are similar for all antidepressive drugs in treating mild and moderate depression.
- Several psychotherapies are as effective as tricyclic antidepressants and are probably as effective as SSRIs in acute treatment of mild and moderate depression.
- The risk for relapse is high unless treatment is continued at least for 6 months after the disappearance of symptoms.
- Antidepressive drugs are shown to be more effective than psychotherapies in treating dysthymia.
- There is no evidence that phototherapy is more effective than placebo in treating seasonal affective disorder.

Methods

This systematic review covers literature up to summer 2003. A protocol was developed to assess the studies. Only RCTs were included for pharmaceutical studies. Controlled studies without randomization were accepted for psychotherapies. Electronic databases were used in the primary search for literature and were supplemented by manual searches, reference lists, etc. The reviewers followed the protocol to rate the quality and internal validity of each study. The scientific evidence for each conclusion was based on the number of studies with high quality and internal validity.

Further research/reviews required

- Studies of treatment effects in the elderly (>80 years).
- Studies of long-term treatment of children and adolescents (>10 weeks); both psychotherapy and antidepressive drugs.
- Studies of maintenance treatment after successful ECT (electroconvulsant therapy).
- Studies of treatment of bipolar disorder.

Written by Agneta Pettersson, SBU, Sweden

Title **The Effectiveness and Cost Effectiveness of Medical Treatments for Smoking Cessation**

Agency **KCE, Belgian Health Care Knowledge Centre**
Résidence Palace, 10th floor, Wetstraat 155, Block A, BE-1040 Brussels, Belgium;
Tel: +32 2 287 3397, Fax: +32 2 287 3385; hta@kenniscentrum.fgov.be, www.kenniscentrum.fgov.be

Reference KCE Reports vol 1A, June 2004

Aim

To evaluate the effectiveness of medical treatments for smoking cessation by reviewing the existing literature. In addition, we reviewed the cost effectiveness of these interventions.

Conclusions and results

In Belgium, smoking prevalence is 26%. Smokers die on average 6 years earlier, and studies with longer followup report even higher loss of life years. Smoking cessation is the single most important intervention improving the health of smokers at all ages. Quitting before the age of 35 will remove nearly all health consequences of smoking.

Brief physician advice, individual and group therapies, telephone counseling, and tailored self-help materials are modestly effective in helping people to stop smoking. Nicotine replacement therapy (NRT) is also effective. Evidence on the different forms of nicotine replacement does not show a significant difference among them. Bupropion and nortryptiline both have similar significant effects on smoking cessation rates. The adverse events profiles differ, with seizures in approximately 1/1000 patients as the most serious event for bupropion, and cardiac block as the most serious for nortryptiline.

The costs and cost effectiveness of NRT and bupropion are similar, the incremental cost per quitter ranges between 1000 € and 2500 €. Costs per saved life year vary between 400 € to 13 000 €, while the costs per saved QALY vary between 1200 € and 4000 €. In most studies, NRT and bupropion are part of strategies including brief advice or counseling. The costs increase as the intensity of the advice or counseling increases. Compared to other health interventions among smokers, smoking cessation therapy is highly cost effective.

Recommendations

Non-pharmacological therapies have a modest, but significant, effect on quitting rates. As for pharmacological therapies, both NRT and bupropion are effective. Nortryptiline is an interesting alternative, but the adverse events need to be studied more in the context of smoking cessation. As all these interventions are cost effective, and the benefit of quitting is so large, therapy should be offered to all smokers, provided they are motivated to stop.

Methods

A literature review of medical databanks, HTA reports, and guidelines.

Further research/reviews required

More information is needed on the adverse events caused by bupropion and nortryptiline used for smoking cessation. Nortryptiline is an inexpensive generic product, and its cost effectiveness in smoking cessation may be several times greater than nicotine replacement therapies or bupropion. To make a more informed choice between the various therapies, more studies are needed that directly compare NRT, bupropion and nortryptiline, and the optimal intensity of counseling.

Written by Van den Bruel A, Cleemput I, Van Linden A, Schoefs D, Ramaekers D, Bonneux L, KCE, Belgium

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Issue 2005/33

Title **Introduction of Advanced Care to Pre-hospital Services in Québec**

Agency **AETMIS, Agence d'Evaluation des Technologies et des Modes d'Intervention en Santé**
2021, avenue Union, bureau 1040, Montréal, Québec, Canada H3A 2S9;
Tel: +1 514 873 2563, Fax +1 514 873 1369; aetmis@aetmis.gouv.qc.ca, www.aetmis.gouv.qc.ca

Reference Technology brief prepared for AETMIS, 2005 (AETMIS 05-01). Internet access to full text. ISBN 2-550-44471-X (Print) (French edition ISBN 2-550-44197-4); ISBN 2-550-44472-8 (PDF) (French edition ISBN 2-550-44484-1)

Aim

To review the safety, effectiveness, and efficiency of advanced pre-hospital procedures (advanced life support) in North America and the role of the chain of interventions for improving health outcomes in pre-hospital care.

Conclusions and results

Over the past few years, Québec has expanded the scope and geographic availability of primary pre-hospital emergency care (basic life support), while other provinces have moved into advanced pre-hospital care (eg, expanded drug administration, endotracheal intubation, intravenous access, and fluid resuscitation). Quebec is poised to adopt advanced pre-hospital emergency procedures.

Research evidence in this area is scarce, but indicates that the potential to save lives with advanced care is greatest for chest pain and respiratory distress. The evidence is less clear for non-traumatic cardiopulmonary arrest, and adverse effects have been noted in certain cases, eg, endotracheal intubation of young children and the treatment of trauma. Nationally and internationally, technological advances and increased training of paramedics are blurring the line between primary and advanced pre-hospital care.

Recommendations

- Limit the use of advanced care to pilot projects, with priority given to treating respiratory distress, chest pain, and cardiopulmonary arrest. Exclude advanced care for children and trauma patients at this time. Assess the effectiveness and efficiency of these pilot protocols and the organizational conditions required for their effective implementation.
- Establish a service-development plan to train emergency medical technicians and to build partnerships between pre-hospital and hospital settings.
- Enhance training for emergency medical technicians to the level of primary care paramedics as defined in the Canadian National Occupational Competency Profiles (NOCP).
- Expand the general public's training in cardiopulmonary resuscitation (CPR) and improve access to early defibrillation performed by first responders or bystanders.
- Introduce enhanced continuing education, effective medical control, quality assurance tools, and information systems for all regions in Québec.
- Horizon scanning and reasoned introduction of new procedures in pre-hospital emergency care with a significant potential for reducing mortality and morbidity.

Methods

- Comprehensive review of the scientific literature on this topic (special attention was given to the advanced pre-hospital care program in Ontario).
- Analysis of provincial, national, and international advanced care training programs and practices.
- Contextualization of scientific evidence.

Further research/reviews required

Monitor emerging evidence in pre-hospital care. Establish a research program, under the leadership of the Ministère de la Santé et des Services Sociaux (MSSS), to evaluate advanced pre-hospital care.

Written by Reiner Banken, Brigitte Côté, François de Champlain, and André Lavoie, AETMIS, Canada

Title	**Prevention of Dental Caries**
Agency	**SBU, The Swedish Council on Technology Assessment in Health Care** PO Box 5650, SE-114 86 Stockholm, Sweden; Tel: +46 8 412 32 00, Fax: +46 8 411 32 60; info@sbu.se, www.sbu.se
Reference	SBU Report 161, 2002. ISBN 91-87890-81-X. Summary and Conclusions in English, and full text report in Swedish are available on www.sbu.se

Aim

To systematically review the evidence on prevention of dental caries in children and adults and to assess the cost effectiveness of the methods.

Conclusions and results

Around 250 studies were included, covering prevention methods involving fluorides, fissure sealants, tooth cleaning, and methods of substituting sugar. Cost-effectiveness analyses were few, and most were of low quality, as were studies on groups of patients with special needs, ie, the elderly, chronically ill, disabled, and children with high caries activity.

Strong scientific evidence indicates that tooth brushing with fluoride dentifrices twice per day helps to prevent caries. Moderate evidence supports prevention programs that include fluoride. The scientific literature presents evidence of positive effects on caries prevention from fissure sealants, fluoride gel, fluoride varnish, fluoride mouthrinses, and professional tooth cleaning.

Scientific evidence shows that several methods currently in use have an effect on preventing dental caries. However, evidence is lacking on economic outcomes and effects on patients with special needs.

Methods

The report consists of a systematic review and includes one meta-analysis on fissure sealants. The MEDLINE and Cochrane Library databases from 1966 to 2001 were searched. Randomized clinical trials and controlled clinical trials with at least 2 years of followup (shorter followup was accepted for primary teeth and root surfaces) and that reported caries increment were included and appraised by protocol-defined criteria.

Further research/reviews required

Older patients may need special attention in programs to prevent caries. Patients with chronic diseases and various functional impairments need preventive interventions that are designed and evaluated according to the special problems associated with the disease. Patients with high caries activity and at a high risk for caries may also need special programs for caries prevention. Current evidence is insufficient to draw any conclusions concerning how prevention of caries should be designed for these groups. This is an important area for future research.

Written by Susanna Axelsson, SBU, Sweden

Title **Development and Validation of Methods for Assessing the Quality of Diagnostic Accuracy Studies**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2004;8(25). June 2004. www.ncchta.org/execsumm/summ825.htm

Aim

To develop a quality assessment tool for use in systematic reviews to assess the quality of primary studies of diagnostic accuracy.

Conclusions and results

The reviews identified 28 items for possible inclusion in the quality assessment tool. In the first review, the sources of bias supported by the most empirical evidence were: variation by clinical and demographic subgroups, disease prevalence/severity, partial verification bias, clinical review bias, and observer/instrument variation. There was also some evidence of bias for: effects of distorted selection of participants, absent or inappropriate reference standard, differential verification bias, and review bias. Evidence for other sources of bias was insufficient to draw conclusions regarding potential effects of these biases.

The second review found that the quality assessment tool should have the potential to be: discussed narratively, reported in a tabular summary, used in recommendations for future research, used to conduct sensitivity or regression analyses, and used as criteria for inclusion in the review or a primary analysis. A distinction should be made between high- and low-quality studies. Component analysis was identified as the best approach to incorporate quality into systematic review of diagnostic studies, and this was considered in developing the quality tool.

The third review found that only 1 item (avoidance of review bias) appeared in more than 75% of the tools, while 4 additional items (spectrum composition, population recruitment, absent or inappropriate reference standards, and verification bias) appeared in 50% to 75% of the tools. Further items appeared in fewer than 50% of the tools.

Methods

Three systematic reviews were conducted to provide an evidence base for developing the quality assessment tool:

- Review of the methodological literature on diagnostic test assessment to identify potential sources of bias.
- Systematic reviews of diagnostic tests that utilized any form of quality assessment to identify how quality was incorporated.
- Review of quality assessment tools to ascertain existing methods for assessing the quality of diagnostic studies and the evidence on which they are based.

A Delphi procedure was used to develop the quality assessment tool. This process incorporated the information yielded by the reviews. The Delphi procedure resulted in a quality assessment tool known as "QUADAS", the acronym for Quality Assessment of Diagnostic Accuracy Studies. (Please see the full monograph for further details.) A background document describes each item included in the tool and how it should be scored.

Further research/reviews required

Further work to validate the tool continues beyond the scope of this project. Further development of the tool by adding design- and topic-specific criteria has been proposed.

Written by Professor Jos Kleijnen, CRD, UK

Title **The Social Support and Family Health Study: A Randomized Controlled Trial and Economic Evaluation of Two Alternative Forms of Postnatal Support for Mothers Living in Disadvantaged Inner City Areas**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2004;8(32). Aug 2004. www.ncchta.org/execsumm/summ832.htm

Aim

To address the question of whether increased postnatal support could influence maternal and child health outcomes and to measure the impact and cost effectiveness of two alternative strategies for providing support to mothers in disadvantaged inner city areas.

Conclusions and results

The strategies studied were:

- Support Health Visitor (SHV), a program of visits from health visitors trained in supportive listening.
- Community Group Support (CGS), the services of local community support organizations.

The 731 participants were well matched in terms of socioeconomic characteristics and health and support variables. Fourteen percent of the participants were non-English speaking. Response rates at the two followup points were 90% and 82%. At both points there were no differences that could not be attributed to chance on the primary outcomes of maternal depression, child injury, or maternal smoking. Both followups revealed differences in secondary outcomes. The first followup showed a reduced use of general practitioners (GPs) by SHV children, but an increased use of NHS health visitors and social workers by mothers. The second followup showed that both CGS and SHV mothers used midwifery services less (fewer pregnancies), and that SHV mothers were less worried about their child's health and development. Uptake of the CGS intervention was low, 19% versus 94% for the SHV intervention. Satisfaction with the intervention among women in the SHV group was high. Based on the assumptions and conditions of the costing methods, the economic evaluation found no net economic cost or benefit of choosing either of the two interventions.

Recommendations

No evidence was found concerning the impact on the primary outcomes of either intervention. The SHV intervention was popular with women and was associated with improvement in some of the secondary outcomes. This suggests that greater emphasis on the social support role of health visitors could improve some measures of family well-being.

Methods

In the SHV intervention, participants were offered 1 year of monthly supportive listening home visits, starting with a visit when the baby was approximately 10 weeks old. The SHVs focused primarily on the woman and her needs, with practical support and information provided on request. The CGS intervention entailed being assigned to 1 of 8 community groups. The groups offered drop-in sessions, home visits, and/or telephone support. Their standard package of services was available to study women for 1 year.

Further research/reviews required

Future research could usefully focus on:

- combining the results of this trial and others into a systematic review of social support and its effect on health
- developing and testing other postnatal models of support that match more closely the age of the baby and the changing patterns of mothers' needs
- evaluating other strategies for mobilizing 'non-professional' support
- developing and testing more culturally specific support interventions
- developing more culturally appropriate standardized measures of health outcomes
- providing longer term followup of social support interventions
- exploring the role of social support on the delay in subsequent pregnancy.

Written by Ms Meg Wiggins, Social Science Research Unit, University of London, UK

Title **Improving the Referral Process for Familial Breast Cancer Genetic Counseling: Findings of Three Randomized Controlled Trials of Two Interventions**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(03). Feb 2005. www.ncchta.org/execsumm/summ903.htm

Aim

To evaluate two interventions (a primary care trial and a clinical trial) designed to improve management of women concerned about familial breast cancer risk.

Conclusions and results

The primary care trial compared the effects of an active, computer-supported educational strategy versus passively disseminated national guidelines, on general practitioner (GP) confidence in key skills. The trial randomized 57 practices (230 GPs) to intervention and 29 (116 GPs) to control groups. Twenty-seven (11.9%) intervention GPs from 20 (35.1%) of the practices attended one of the postgraduate education sessions. No effect of the intervention was detected on primary or secondary outcomes. Fewer than half of intervention GPs were aware of the software, and only 22 reported using it in practice, too few for meaningful analysis.

The clinic trial determined whether substituting medical geneticist assessment by nurse counselor assessment for newly referred patients was equivalent in terms of patient anxiety and a range of other outcomes. The cost effectiveness of both interventions was also examined. The participants, 289 Grampian patients (193 intervention, 96 control) and 297 Wales patients (197 intervention, 100 control) consented, were randomized, returned a baseline questionnaire, and attended the clinic. Primary analysis in both trials suggested "equivalence" in all anxiety scores, and no statistically significant differences in a range of other outcomes. "Per protocol" analysis did not alter the findings. Cost minimization analysis suggested similar costs per counseling episode. Costs were sensitive to grades of doctors substituted for and consultant time required for nurse counselor supervision, but insensitive to grade of nurse counselor, selected discount rate, or lifespan of equipment.

Recommendations

Primary care trial: No effect on GP confidence was detected. The pragmatic approach to software dissemination did not lead to high levels of awareness or uptake of the intervention. It is not possible to tell whether the lack of effect was due to the computer system itself, or because too few GPs used it.

Clinic trial: Nurse counselor intervention appeared "equivalent" to conventional cancer genetic counseling across the range of outcomes and both trial locations, suggesting some generalizability. It might be a cost-effective option for breast cancer genetic counseling, depending on the grade of doctor replaced and consultant supervision required.

Methods

Primary care trial: Cluster randomized controlled trial, with eligible general practices stratified by prior referral rate and randomized 2:1 to intervention or control groups. The intervention system was developed with GPs and disseminated using passive and active strategies. Baseline and followup outcome data were collected from GPs and patients. Concurrent economic evaluation was conducted. Analysis was by intention to treat.

Clinic trial: Two independent randomized controlled equivalence trials in different UK health service locations. Eligible, newly referred patients were randomized 2:1 to intervention (nurse counselor) or control (clinical geneticist). Patient outcome data were collected at baseline, immediately following, and 6 months after the referral episode. Data were collected from referring GPs. Primary equivalence analysis was by intention to treat, with sensitivity analysis by treatment received (per protocol). Concurrent economic evaluation was conducted.

Further research/reviews required

Primary care trial: Future evaluations must identify and address barriers to using computer based systems and clarify the relative importance of the system characteristics themselves, their integration into practice routines, and implementation strategies.

Clinic trial: Replication in other settings would provide reassurance of generalizability. Other models of nurse-based assessment, eg, in outreach clinics, should be evaluated.

Written by Dr Brenda Wilson, Department of Public Health, University of Aberdeen, UK

Title **Randomized Evaluation of Alternative Electrosurgical Modalities to Treat Bladder Outflow Obstruction in Men With Benign Prostatic Hyperplasia**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(04). Feb 2005. www.ncchta.org/execsumm/summ904.htm

Aim

To compare and evaluate the clinical and cost effectiveness of a new electrosurgical modality, transurethral vaporization of the prostate (TUVP), versus standard treatment, transurethral resection of the prostate (TURP).

Conclusions and results

TURP and TUVP were both effective in producing a clinically important reduction in the International Prostate Symptom Score (IPSS) and positive change in the IPSS Quality of Life (QoL) questions. The success rate for relief of symptoms, defined as a >5 reduction in IPSS at 6 months was 85% for TURP and 74% for TUVP. Neither the success of the treatment nor the change in aggregated IPSS differed significantly between the groups. Improvement was sustained to 24 months after treatment with no significant difference between groups. The effectiveness of both treatments was equivalent when assessed through improvement in objective measures of urinary tract function, reduction in prostate size, and the change in health questions of SF-36. There was no change from baseline for other domains of SF-36 or EuroQoL. An adverse event was defined as any undesirable experience that the patient had, whether considered procedure-related or not. The absolute incidence of adverse events was similar between the groups. The incidence of severe or prolonged bleeding was less with TUVP. TURP and TUVP are broadly equivalent in direct NHS resource use. In particular, staff costs, theatre use and capital equipment costs are the same. This study did not show any significant difference in inpatient stay or use of outpatient resources between the groups. The disposable electrodes used for TUVP are more expensive than reusable TURP electrodes.

Recommendations

TURP and TUVP are equivalently effective in improving the symptoms of benign prostatic enlargement, and the improvement lasts for at least 2 years. TUVP is associated with less morbidity due to hemorrhage than TURP. Reduced bleeding after transurethral surgery to the prostate does not significantly reduce hospital stay when patients are managed by staff accustomed to managing patients after TURP. Replacing TURP by TUVP would not produce a significant cost benefit to the NHS unless the inpatient stay could be reduced at least 1 day.

Methods

Randomization involved a sealed envelope system. Patients with symptoms and those in retention were randomized separately to ensure even distribution. They were randomized as close as possible to the time of their operation. TURP was performed and patients were managed according to the usual practice of the clinical team. TUVP was performed with the most promising available equipment using a technique described in the literature. Postoperative management after TUVP was left to the ward team, who were not necessarily informed to which treatment arm the patient had been allocated. Patients were assessed clinically, by questionnaire, and investigation at baseline, 2 months and 6 months after randomization. A postal questionnaire was sent to each patient at 2 years. For the economic evaluation, direct costs from the NHS viewpoint were collected.

Further research/reviews required

Further research is needed to determine why patients stay in hospital after transurethral surgery to the prostate and how the length of stay can be reduced. A larger observational study/audit is required to assess the incidence of infrequent adverse events after TUVP. Until the results are available, TUVP should not replace TURP in the NHS. Patients in this study should be followed to establish whether the durability of improvement is similar to 5 years and beyond.

Written by Professor Christopher Fowler, Urology Unit, The Royal London Hospital, UK

Title **A Pragmatic Randomized Controlled Trial of the Cost Effectiveness of Palliative Therapies for Patients with Inoperable Esophageal Cancer**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(05). Feb 2005. www.ncchta.org/execsumm/summ905.htm

Aim

To compare whether treatment with self-expanding metal stents (SEMS) is more cost effective than treatment with conventional modalities (non-SEMS) in patients with inoperable esophageal cancer.

Conclusions and results

This study demonstrated no overall differences in effectiveness or cost effectiveness between SEMS and non-SEMS therapies. Insertion of an 18 mm diameter SEMS led to equal effectiveness as with insertion of a 24 mm diameter SEMS. Rigid stents were associated with a significantly worse quality of swallowing following treatment and higher late morbidity than other therapies. BICAP and Ethanol Tumor Necrosis treatments were associated with poor outcomes for primary palliation. A survival advantage was demonstrated in patients receiving non-stent therapies, but these treatments were associated with significant treatment delays. No cost differences were found between therapies, with the highest contributor to cost of palliation being the length of inpatient stay. Patients demonstrated distinct but individual treatment preferences.

Recommendations

Despite underpowering, this study suggested that rigid stents and 24 mm diameter SEMS offer no advantages to either non-stent therapies or an 18 mm diameter SEMS; they should no longer be recommended for primary palliation. Subgroup analysis suggested that BICAP and Ethanol Tumor Necrosis treatments were unsuitable for primary palliation.

Methods

A multicenter, pragmatic, randomized controlled trial with health economic analysis. All patients with esophageal cancer who were deemed unsuitable for surgery in any 1 of 7 NHS hospitals were assessed for inclusion. The centers were chosen to represent a cross-section of UK hospitals in terms of facilities and staffing. Eligible patients were randomized to 1 of 4 treatment groups within 2 study arms. Research nurses assessed patients on enrollment, 1 week following treatment, and thereafter at 6 weekly intervals until death. Structured interviews to elicit patient preferences to health states and treatments were performed in a substudy to the main trial, using 1 of 2 randomly assigned techniques.

Further research/reviews required

1. A randomized controlled clinical trial of an 18 mm SEMS versus non-stent therapies with survival and quality of life endpoints.
2. An audit of palliative patient admissions to hospital to determine the reasons and need for inpatient care, with a view to implementation of cycle-associated change to reduce inpatient stay and thereby costs.
3. Audit of delays from diagnosis to palliative radiotherapy treatment with a view to implementation of cycle-associated change to reduce these delays.

Written by Mr Jon Shenfine, Northern Oesophago-Gastric Unit, Royal Victoria Infirmary, Newcastle upon Tyne, UK

Title **Impact of Computer-placed Prompts on Sensitivity and Specificity With Different Groups of Mammographic Film Readers**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(06). Feb 2005. www.ncchta.org/execsumm/summ906.htm

Aim

To determine whether computer aided detection (CAD) tools could improve the efficiency of the breast cancer screening program. Two studies used selected sets of mammograms with known outcomes to assess the impact of the R2 ImageChecker (the current market leader for CAD tools) on the sensitivity and specificity of film readers.

Conclusions and results

Main outcome measures were the mean sensitivity and specificity of film readers in two conditions: prompted (with CAD) or unprompted (without CAD). One analysis was done for sensitivity, another for specificity. For Study 1, mean sensitivity was 0.78 in both conditions (p=1.0) and mean specificity was 0.82 unprompted and 0.81 prompted (p=0.4). Hence, there is no evidence that CAD affected readers' sensitivities or specificities. The study was sufficiently powered to detect differences of less than 0.1 in sensitivity or specificity. The analyses for Study 2 were similar. Sensitivity is improved in the prompted condition (0.81 from 0.78), but the difference is not significant (p=0.10). Specificity is also improved (0.87 from 0.86); again the difference is not significant.

Economic analysis showed increased costs for computer prompting (an additional cost of £5209 per 1000 women screened compared to non-prompted) due to greater equipment costs, and no significant savings in terms of reading or assessment costs. Improvements in sensitivity and specificity are small and uncertain.

The relative cost effectiveness of computer prompting can be judged by comparing the cost per cancer detected of computer prompting with the cost per cancer detected estimated in other breast screening studies in the UK. Comparing the previous estimates of cost per cancer detected with the results from this study shows that computer prompting has a higher cost per additional cancer detected (ranging from £23 269 for study 1 to £80 587 for single reading [one radiologist with CAD] compared to double reading [1 radiologist and 1 radiographer]) than previous studies (ranging from £2168 to £7993 per additional cancer detected). The number of additional cancers detected with computer prompting is much lower than the number detected in previous studies, as reflected in the high cost per cancer detected.

Recommendations

Similar studies have assessed CAD with varying results. Our evaluation is the largest of its kind and our conclusions are likely to be robust. Prospective (but uncontrolled) trials have been published and tend to report an impact from CAD. While we recognize the limitations of studies (such as ours) based on test rollers, the methodology used in prospective trials fails to distinguish between the impact of the prompts and that of a second look at the image. Current implementations of CAD are unlikely to impact significantly on readers' decision making.

Methods

In Study 1, 50 film readers read test sets with 180 cases, whereof 60 were cancers (40 screen detected cancers and prior films from 20 false negative interval cancers). Participants viewed all cases, both with and without CAD. The second study tested the hypothesis that improved sensitivity due to CAD could be detected using a specially selected set of cases. In this study, 35 readers read 120 cases including 40 cancers selected to meet 2 criteria: correctly prompted by the R2 ImageChecker and previously missed by a film reader. The procedure for reading films was the same as in Study 1.

Further research/reviews required

The NHS should consider the approach it takes toward assessing technologies such as CAD. A fuller understanding of the impact of the prompting system requires a study of a very different type. We are conducting a prospective study with a larger group of radiologists and radiographers using double reading in a UK screening program. We believe that existing funding mechanisms for HTA seem inappropriate for rapidly changing technologies. In the case of CAD, the obvious approach would be to fund evaluations directly via NHSBSP.

Written by Dr Paul Taylor, CHIME, Royal Free and University College Medical School, London, UK

INAHTA Briefs

Issue 2005/41

Title **Issues in Data Monitoring and Interim Analysis of Trials**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(07). Mar 2005.
www.ncchta.org/execsumm/summ907.htm

Aim

To address issues about Data Monitoring Committees (DMCs) in randomized controlled trials (RCTs), ie, why and when DMCs are needed, roles and responsibilities, structure and organisation, information needs and ownership, decision making, and reporting arrangements.

Conclusions and results

Suggested criteria for determining when RCTs do not need an independent DMC include: a DMC would not make a contribution; observed differences would not prompt a protocol change (eg, early stopping); and a DMC's decisions would not likely differ from those after internal monitoring.

Roles, responsibilities, and procedures of DMCs should be agreed in advance. A template for a charter is suggested. The central role is to monitor accumulating evidence related to benefit and toxicity. DMCs for regulatory-related trials should be aware of special requirements and regulatory consequences.

Advantages were identified for larger- and smaller-sized DMCs. A DMC should be independent and multidisciplinary (at least 1 statistician and 1 clinician). Consumer and ethicist membership is controversial. The Chair is influential and likely to be most effective if experienced, understands statistical and clinical issues, and is facilitating and impartial. No evidence is available to judge approaches to training. Costs should be covered, but other rewards must be minimal and not affect decisions.

A minimum frequency of DMC meetings is usual, with the committee able to meet at shorter notice. Face-to-face meetings are preferable, but teleconferencing can be used in some situations. Both open sessions (eg, general issues such as recruitment) and closed sessions (eg, for confidential information such as interim analyses) are common.

A DMC should cover benefits and risks, and be balanced, accessible, and current. Disadvantages of 'blinded' analyses seem to outweigh advantages. Information about comparable studies should be included.

Various statistical approaches can be used. However, DMCs usually reach decisions by consensus. The general view is that DMCs should be advisory rather than executive since the trial organizers are ultimately responsible for the trial.

Recommendations

Data monitoring should be considered for all RCTs. An early DMC meeting is helpful to agree on roles, responsibilities, and operations. The proposed charter provides a structure for this. DMC membership (often 3 to 8) is chosen to optimize performance. A minimum frequency of meetings, preferably face-to-face, is usual. A DMC's primary purpose is to ensure that continuing a trial is ethical and considers both individual and collective ethics. Errors are less likely if a DMC takes a systematic approach and knows the range of recommendations open. The recommended standard name is Data Monitoring Committee (DMC).

Methods

Systematic literature reviews of DMCs and small group processes in decision making; sample surveys of reports on RCTs, recently completed and ongoing RCTs, and policies of major organizations involved in RCTs; case studies of 4 DMCs; interviews with experienced DMC members. All focused on 23 pre-stated questions.

Further research/reviews required

Areas that warrant further research include: widening DMC membership beyond clinicians, trialists, and statisticians (eg, include consumers or ethicists); initiatives to train DMC members; methods of DMC decision making, eg, voting and formal decision-making tools; *open* data monitoring; DMCs covering a portfolio of trials rather than single trials; DMC size and membership, incorporating issues of group dynamics; empirical study of the workings of DMCs and their decision making; and which trials should or should not have a DMC.

Written by Professor Adrian Grant, Health Services Research Unit, University of Aberdeen, UK

Title **Lay Public's Understanding of Equipoise and Randomization in Randomized Controlled Trials (RCTs)**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(08). Mar 2005. www.ncchta.org/execsumm/summ908.htm

Aim

1. To learn why participants in RCTs are at risk of failing to understand or remember about randomization and equipoise.
2. To investigate the background knowledge about randomization and equipoise which members of the public are likely to have if invited to participate in an RCT.
3. To explore, in the context of hypothetical trials, the effects of providing information designed to overcome barriers to understanding and recall of randomization and equipoise.

Conclusions and results

Trial participants, despite being informed, often fail to understand or remember about randomization and equipoise. Patients' expectations about treatment decisions may make it hard for them to understand information about randomization and equipoise. Hence, consent or refusal might be inadequately informed.

Investigations 1 to 6 addressed the following questions: *Do members of the public understand and accept randomization?* Most participants correctly judged which methods of allocation were random, but judged random allocation methods in RCTs to be unacceptable. *Do members of the public assume new treatments are better?* Merely describing a treatment as new was insufficient to engender a preference for it over a standard treatment. *Do they accept doctors' individual equipoise?* Around half the participants denied that a doctor could be completely unsure about the best treatment. *Do they accept doctors' suggestions of random allocation given equipoise?* Most participants judged it unacceptable for a doctor to suggest letting chance decide when uncertain of the best treatment. A research context may render randomizing less unacceptable. *Do they believe random allocation has scientific benefits?* Participants did not recognize scientific benefits of random allocation over normal treatment allocation methods. Investigations 7 to 9 examined the consequences of explaining the reasons for randomizing. In Investigation 7, a brief justification for randomization was not helpful. In Investigations 8 and 9, this brief justification and an extended explanation enabled participants to recognize the scientific benefits of random allocation. The results from Investigations 7 to 9 suggest that merely supplementing written trial information with an explanation is unlikely to be helpful. However, when people focus on the trial's aim of increasing knowledge, and process an explanation actively by answering test questions, they may be helped to understand the scientific reasons for random allocation.

Recommendations

Results highlight the disparity between assumptions underlying trial design and those the lay public may draw on if invited into an RCT. Many potential trial participants know what random allocation is, but find it unacceptable, find equipoise unbelievable, and see no reason to randomize. They are likely to have difficulty understanding and remembering trial information about randomization and equipoise. Explaining the scientific benefits of randomization may be helpful if participants can reflect on the trial's aim of advancing knowledge and think actively about the information presented.

Methods

Please refer to the NCCHTA website – via the Executive Summary link above.

Further research/reviews required

How do different forms of oral accompaniment influence participants' understanding of written trial information? We need to identify effective combinations of written and oral information. How can potential trial participants be helped to take a research perspective and thereby improve their understanding of random allocation and equipoise? Can (and should) research ethics committees expect trialists to have evaluated information leaflets on relevant patient groups? The current emphasis is on leaflets' adherence to national guidelines. An evidence based approach to leaflet construction may be valuable.

Written by Professor Elizabeth Robinson, Department of Psychology, Keele University, UK

INAHTA Briefs

Issue 2005/43

Title **Measurement of Health-Related Quality of Life for People with Dementia: Development of a New Instrument (DEMQOL) and an Evaluation of Current Methodology**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(10). Mar 2005. www.ncchta.org/execsumm/summ910.htm

Aim

To develop and validate a psychometrically rigorous measure of health-related quality of life (HRQL) for people with dementia. The measure was intended to be:

- Suitable for use in the UK.
- Available in both self- and proxy-report versions for people with dementia and their carers.
- Appropriate for use in mild/moderate and severe dementia.

Conclusions and results

The conceptual framework included 5 domains: daily activities and looking after yourself, health and well being, cognitive functioning, social relationships, and self-concept. The preliminary field test versions of DEMQOL and DEMQOL-Proxy contained 73 questions representing the 5 domains and a global question about overall quality of life. Item reduction analyses resulted in a 28-item DEMQOL and 31-item DEMQOL-Proxy. Rigorous evaluation in 2-stage field testing in 241 people with dementia and 225 carers demonstrated that in psychometric terms: 1) DEMQOL is comparable to the best available dementia-specific HRQL measures in mild-moderate dementia, but inappropriate for use in severe dementia (MMSE <10); and 2) DEMQOL-Proxy is comparable to the best available proxy measures in mild/moderate dementia and shows promise in severe dementia. Furthermore, the DEMQOL system has been validated in the UK in a large sample of people with dementia and their carers, and it provides separate measures for self and proxy report, which allows outcomes to be assessed across the wide range of severity and care in dementia.

Recommendations

The 28-item DEMQOL and 31-item DEMQOL-Proxy provide a robust method to evaluate HRQL in dementia. The new measures show comparable psychometric properties to the best available dementia-specific measures, provide both self- and proxy-report versions for people with dementia and their carers, are appropriate for use in mild/moderate dementia (MMSE ≥10), and are suitable for use in the UK. DEMQOL-Proxy also shows promise in severe dementia. As DEMQOL and DEMQOL-Proxy give different but complementary perspectives on quality of life in dementia, we recommend using both measures together. In severe dementia, only DEMQOL-Proxy should be used.

Methods

We used gold standard psychometric techniques to develop DEMQOL and DEMQOL-Proxy. First, we generated a conceptual framework from a review of the literature, qualitative interviews with people with dementia and their carers, expert opinion, and team discussion. We drafted and piloted items for each component of the conceptual framework to produce questionnaires for people with dementia (DEMQOL) and carers (DEMQOL-Proxy). We undertook 2-stage field-testing of both measures in large samples of people with dementia representing a range of severity and care arrangements. In the first field test (n=130 with dementia, n=126 carers), we eliminated items with poor psychometric performance separately for DEMQOL and DEMQOL-Proxy to produce two shorter, more scientifically robust, instruments. In the second field test, we evaluated the item-reduced questionnaires along with other validating measures (n=101 with dementia, n=99 carers) to assess acceptability, reliability, and validity.

Further research/reviews required

Further research with the DEMQOL system is needed to:

- Confirm these findings in an independent sample.
- Evaluate responsiveness.
- Investigate the feasibility of use in specific subgroups and in economic evaluation.
- Develop population norms. Additional research is needed to address the psychometric challenges of self-report in dementia and validating new dementia-specific HRQL measures.

Written by Professor Sube Banerjee, The Institute of Psychiatry, King's College London, UK

Title **Cervical Screening Programs: Can Automation Help? Evidence from Systematic Reviews, an Economic Analysis and a Simulation Modeling Exercise Applied to the UK**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(13). Mar 2005. www.ncchta.org/execsumm/summ913.htm

Aim

To assess the effectiveness and cost effectiveness of adding automated image analysis to cervical screening programs.

Conclusions and results

The predominant finding from the systematic reviews was the limited amount of rigorous primary research. None of the included studies refers to the only commercially available automated image analysis device in 2002, ie, the AutoPap Guided Screening (GS) System. The results of the studies were debatably most compatible with automated image analysis being equivalent in test performance to manual screening. Concerning process, there was evidence showing that automation leads to reductions in average slide processing times. The PRISMATIC trial reported a reduction from 10.4 to 3.9 minutes, a statistically significant and practically important difference. Economic evaluation tentatively suggested that the AutoPap GS System might be efficient. The key proviso is that credible data become available to support that the AutoPap GS System has test performance and processing times equivalent to those obtained for PAPNET.

Recommendations

The available evidence is insufficient to recommend implementation of automated image analysis systems.

Methods

Four systematic reviews were conducted according to recognized guidance. The review of *clinical effectiveness* included studies assessing reproducibility and impact on health outcomes and processes in addition to evaluations of test accuracy. A discrete event simulation model was developed, although the economic evaluation ultimately relied on a cost-minimization analysis.

Further research/reviews required

The priority for action remains further research, particularly the clinical effectiveness of the AutoPap GS System. Another priority is to assess the cost effectiveness of introducing automation alongside other approaches.

Written by Dr Chris Hyde, Department of Public Health and Epidemiology, University of Birmingham, UK

Title **Evidence for the Benefits of Telecardiology Applications: A Systematic Review**

Agency **AHFMR, Alberta Heritage Foundation for Medical Research**
Health Technology Assessment Unit, Suite 1500, 10104–103 Avenue NW, Edmonton, Alberta T5J 4A7 Canada; Tel: +1 780 423 5727, Fax: +1 780 429 3509; www.ahfmr.ab.ca

Reference HTA 34, October 2004 (English). ISBN 1-894927-04-4 (print); ISBN 1-894927-05-2 (online): www.ahfmr.ab.ca/programs.php

Aim

To review the literature assessing telecardiology in 4 areas of application: pediatric care, hospital or clinic use for adults, emergency care, and home care.

Conclusions and results

Forty-four studies met the selection criteria, and most (39 of 44) concluded that telecardiology had advantages over the alternative. However, the quality of over half of the studies was poor or poor to fair.

All but one of the studies on pediatric applications related to teletransmission of echocardiography data. Reported benefits included savings in time and cost through avoiding unnecessary referrals. Three studies were of fair quality, but the rest gave weaker evidence. Economic analyses in 6 studies were of low or very low quality.

In applications for adults, 6 of 10 studies on addressed transmission of echocardiography findings between cardiologists and primary care physicians. Benefits arose from avoiding unneeded referrals and identifying patients for urgent intervention. One study was judged to be fair, while the others had lower reliability. Two studies indicated benefits from using telecardiology in a prison and in a cardiac catheterization lab. Telemetry outside critical care units and in transmitting nuclear medicine results were deemed feasible, but the benefits were less clear.

In emergency care, 3 studies considered transmission of echocardiography data from ambulance to hospital, and found benefits from faster diagnosis and more rapid treatment. One of the studies was of good quality, while the others provided weaker evidence. A good quality study on dobutamine stress echocardiography showed benefits by avoiding unnecessary hospitalization. A fair-quality study indicated benefits from using a fax-based system for out-of-hours support.

In home care, 9 of 13 studies assessed telemonitoring of patients with heart failure. Benefits arose from reduced hospital admissions, decreased hospital stay, and lower hospital costs. Four studies were RCTs of high quality; two were judged to be fair and three were poor to fair. One of the high-quality studies contained a fair to good economic analysis. Two high-quality studies showed that home-based rehabilitation was as effective as programs in institutions. One good and one poor quality study found gains in performance in monitoring arrhythmias.

Recommendations

Despite the long history of telecardiology, most studies do not provide convincing evidence of benefit. Few recent studies of telecardiology have reported clinical or economic outcomes.

Methods

Literature databases were searched for January 1992 to September 2003. Controlled studies and case series studies of at least 20 patients reporting clinical, economic, or administrative outcomes of telecardiology were selected. Study quality was assessed and rated as: *high* (high degree of confidence in the findings); *good* (some uncertainty about the findings); *fair* (some limitations); *poor to fair* (substantial limitations); or *poor* (unacceptable uncertainty). Studies including cost or economic data were judged against accepted criteria for economic analysis.

Further research/reviews required

Most of the included studies were of poor or poor to fair quality and offer only preliminary indications of benefits and costs, requiring verification of the findings. Decision makers should note the need to follow up preliminary studies to obtain reliable outcome data for telecardiology applications.

Written by David Hailey, Arto Ohinmaa, and Risto Roine, AHFMR, Canada

Title **Trigger Point Injections for Chronic Nonmalignant Musculoskeletal Pain**

Agency **AHFMR, Alberta Heritage Foundation for Medical Research**
Health Technology Assessment Unit, Suite 1500, 10104–103 Avenue NW, Edmonton, Alberta T5J 4A7 Canada; Tel: +1 780 423 5727, Fax: +1 780 429 3509; www.ahfmr.ab.ca

Reference HTA 35, January 2005 (English). 1-894927-06-0 (print); ISBN 1-894927-07-9 (online): www.ahfmr.ab.ca/programs.php

Aim

To assess the efficacy and safety of using trigger point injection (TPI) to treat patients with chronic nonmalignant musculoskeletal pain and to determine the current status of the procedure, its feasibility in regional communities, and the clinical accreditation and training required to perform it.

Conclusions and results

Ten randomized controlled trials (RCTs) met the inclusion criteria. However, deficiencies in reporting, small sample sizes, and interstudy heterogeneity in patient population, treatment regimen, injection site, and experimental protocol precluded a definitive synthesis of the data. TPI is safe when used by clinicians with appropriate expertise. However, the evidence was inconclusive regarding its effectiveness as sole treatment for patients with chronic head, neck, and shoulder pain and whiplash syndrome. Combined use of dry needling and TPI with procaine offers no obvious clinical benefit in treating chronic craniofacial pain. The effectiveness of TPI in treating cervicogenic headache is unknown. In contrast, TPI with lidocaine may be a useful adjunct to intra-articular injection in treating joint pain caused by osteoarthritis, compared to intra-articular injection alone. There was no proof that TPI is more effective than less invasive treatments, eg, physical therapy and ultrasound, in relieving pain. Some suggest that the only advantage of injecting anesthetic into trigger points is to reduce the pain of the needling process.

Recommendations

The efficacy of TPI is uncertain since no evidence clearly shows either benefit or ineffectiveness. Generally, TPI was analyzed as a stand-alone treatment, so its effectiveness might be underestimated by analyzing it in isolation rather than in the adjunct capacity in which it is routinely used. TPI may enable exercise therapy earlier than less invasive methods do, eg, ultrasound. However, this benefit may be offset by the greater skill required to administer TPI, particularly in areas where such expertise may be scarce. Physicians should understand the importance of not relying on TPI as a sole treatment for chronic nonmalignant musculoskeletal pain. Professional bodies should consider providing a training and accreditation program for practitioners wishing to use TPI in Canada. It may be prudent to tie reimbursement to the successful completion of such training to curb potential overuse and misuse of TPI.

Methods

Data were collected on patients who underwent TPI and had nonmalignant chronic pain of musculoskeletal origin that had persisted for at least 3 months. All original, published systematic reviews or RCTs were identified by searching PubMed, EMBASE, CINAHL, Cochrane Library, Science Citation Index, AMED, BIOSIS, and the websites of health technology assessment agencies, research registers, and guidelines sites from root to September 2004. No language restriction was applied.

Further research/reviews required

Since equipoise exists among many of the potential treatments for chronic nonmalignant musculoskeletal pain, further research should focus on good quality RCTs rather than nonrandomized studies. Given the purported popularity of TPI, this research is essential to establish more realistic expectations of what the treatment can achieve in clinical practice.

Written by Ann Scott and Bing Guo, AHFMR, Canada

Title **Systematic Review of Unicompartmental Knee Arthroplasty for Unicompartmental Osteoarthritis**

Agency **ASERNIP-S, Australian Safety and Efficacy Register of New Interventional Procedures – Surgical**

PO Box 553 Stepney, Australia; Tel +61 8 8363 7513, Fax +61 8 8362 2077; college.asernip@surgeons.org

Reference ASERNIP-S Report Number 44. ISBN (0-909844-69-0).

Full text available: www.surgeons.org/asernip-s/ (publications page)

Aim

To assess the safety and efficacy of unicompartmental knee arthroplasty (UKA) compared to total knee arthroplasty (TKA) and high tibial osteotomy (HTO).

Conclusions and results

The review included 14 comparative studies (9 studies compared UKA and TKA; 6 studies compared UKA and HTO). Many of the studies had relatively small samples, substantial losses to followup, and relatively short followup. Not all studies reported all outcomes, further reducing the size of the evidence base. Knee function and postoperative pain was difficult to compare across studies due to variability in knee and pain scores. UKA appeared to be similar to TKA and HTO at 5-year followup despite considerable variability. Range of motion was significantly better in UKA compared to TKA. Overall complication rates after UKA and TKA appeared similar, although deep vein thrombosis (DVT) was reported more often after TKA than UKA. There may have been more complications after HTO than UKA; main complications reported were DVT and delayed healing or wound infections. Fewer than half of the studies reported revision and knee survival. Survival of UKA prostheses ranged from 85% to 95%, compared to survival of 90% or more for TKA prostheses. Survivorship for HTO appeared to be less than 85%. Hence, it was unclear whether there were more revisions after UKA than TKA up to 10 years after implantation, but it appeared there were fewer revisions of UKA compared to HTO.

Recommendations

The ASERNIP-S Review Group agreed on the following classifications and recommendations concerning the safety and efficacy of unicompartmental knee arthroplasty:

Evidence rating – The evidence base in this review is rated as average.

Safety – UKA is considered at least as safe as TKA and HTO.

Efficacy – In terms of function, UKA appears to be at least as efficacious as TKA and HTO. In terms of knee survival, the efficacy of UKA compared to TKA and HTO cannot be determined.

Methods

MEDLINE, EMBASE, Cochrane Library, and Current Contents were searched from inception to April 2004. The Clinical Trials Database (US), NHS CRD (UK) NHS HTA (UK), National Research Register (UK), and Current Controlled Trials (mRCT) were also searched in May 2004. Reference sections of retrieved articles yielded additional articles. Studies included for review were RTCs and nonrandomized comparative studies assessing patients treated with UKA compared with either TKA or HTO. Efficacy outcomes included knee function, pain scores, range of motion, operative time, length of stay, knee failure, and revision. Safety outcomes included complications, eg, DVT and infection. Our researcher extracted data from the studies by using standardized data extraction tables developed a priori and checked by a second researcher. Relative risks or weighted mean differences with 95% confidence intervals were calculated for some outcomes in individual RCTs.

Further research/reviews required

Current trials in progress should reduce some uncertainty surrounding the treatment of osteoarthritis in the knee. The continuing contribution of data to national joint registries will aid in validating the current trends, particularly in knee survival after UKA or TKA.

Written by Dr Tabatha Griffin et al, ASERNIP-S, Australia

Title **Laparoscopic Radical Prostatectomy**

Agency **ASERNIP-S, Australian Safety and Efficacy Register of New Interventional Procedures – Surgical**
PO Box 553 Stepney, Australia; Tel +61 8 8363 7513, Fax +61 8 8362 2077; college.asernip@surgeons.org

Reference ASERNIP-S Report Number 48. ISBN 0-909844-68-2.
Full text available: www.surgeons.org/asernip-s/ (publications page)

Aim

To compare the safety, efficacy, and costs of laparoscopic radical prostatectomy (LRP) versus open radical prostatectomy and to assess the contribution of learning curve to efficacy outcomes.

Conclusions and results

Twenty-one studies compared open and laparoscopic approaches; 13 compared transperitoneal laparoscopic radical prostatectomy (TLRP) to open radical retropubic prostatectomy (RRP), 3 compared extraperitoneal endoscopic radical prostatectomy (EERP) to open prostatectomy, and 5 compared robotic-assisted radical prostatectomy (RALRP) to open prostatectomy. Nine studies compared different laparoscopic approaches; 6 compared EERP and TLRP and 3 compared RALRP with TLRP. There were no randomized controlled trials, 10 concurrently controlled comparisons (level III-2), 17 historically controlled comparisons (level III-3), and 3 comparisons using concurrent and historical controls (level III-2/3).

Safety: No important differences appeared in the complication rate between laparoscopic and open approaches, but blood loss and transfusions were lower in laparoscopic approaches.

Efficacy: Operative times were longer for laparoscopic than open prostatectomy, but length of stay and duration of catheterization were shorter. Positive margin rates were similar, and no important differences appeared between laparoscopic and open prostatectomy when considering tumor stage or margin location. Recurrence-free survival, continence, and potency were not well reported, but did not appear to differ between the two approaches. Quality of life did not differ between TLRP and RRP in 2 studies. There were no important differences between laparoscopic approaches.

Cost and resource use were not well reported, but 3 economic models found open radical prostatectomy to be less expensive than laparoscopic prostatectomy. None of the models used a patient-relevant effectiveness outcome, eg, potency, continence, or survival, and do not provide much cost-effectiveness guidance for decision makers.

Learning curve: The effect of increasing experience could be tracked in 6 studies. As experience with the laparoscopic approaches increased, most clinical outcomes improved, but there were no clear effects on the positive margins rate or continence and potency outcomes.

Recommendations

1. A national audit of laparoscopic radical prostatectomy, including RALRP, should be instituted to monitor the introduction of the technique into the Australian healthcare system.
2. At regular intervals, hospital credentialing committees should monitor the progress of surgeons introducing LRP into practice, paying particular regard to complication rates and surgical margins during the learning phase.
3. Economic evaluations taking into consideration the Australian healthcare context should be conducted.

Methods

A systematic search of online databases (from 1996 to Dec 2004) and the Internet was undertaken, without language restriction. We included comparative studies that reported safety or efficacy outcomes of TLRP, EERP, or RALRP compared to open RRP or radical perineal prostatectomy. Comparisons between different laparoscopic approaches were included.

Further research/reviews required

Comparative data on continence, potency, and survival is insufficient. There did not appear to be any clear differences between the laparoscopic approaches. A clear learning curve for laparoscopic prostatectomy was documented which affected many clinical outcomes, but it was not possible to determine from the included studies how many laparoscopic procedures must be completed to negotiate this learning curve.

Written by Dr Rebecca Tooher et al, ASERNIP-S, Australia

Title	**Refractory Obsessive Compulsive Disorders: Conventional Treatments and Deep Brain Stimulation**
Agency	**HAS, Haute Autorité de santé/French National Authority for Health** 2, avenue du Stade de France, FR-93218 Saint-Denis La Plaine Cedex France; Tel: +33 1 55 93 71 88, Fax: +33 1 55 93 74 35; www.has-sante.fr
Reference	ANAES report. September 2005. www.anaes.fr/anaes/Publications.nsf/wEdition/AT_LFAL-6G6EXS?OpenDocument&Retour=&Chapitre=ID2

Aim

- To review treatments for obsessive compulsive disorders (OCD) and identify refractory conditions that may require deep brain stimulation (DBS).
- To assess the feasibility of DBS (used experimentally since 2002 in very severely disabled subjects).

Conclusions and results

1. *Pharmacological and psychotherapeutic treatments for OCD.* A meta-analysis and clinical trials with a good level of evidence have emphasized the efficacy of serotonin recapture inhibitors (SRI) and cognitive behavioral treatment (CBT). However, outcome is unsatisfactory in one-third of patients.
2. *Description of DBS:* Electrodes are inserted into a target area of the brain located using a stereotactic frame.
3. *Clinical trial of DBS:* One randomized controlled trial (RCT) (8 patients, evidence level 2 according to the HAS classification) and 5 case series (9 patients, evidence level 4) were identified. Different targets were used in these patients.
4. *Efficacy of DBS:* Clinical scores were improved by about 82% postoperatively (6/8 patients improved in the RCT and 8/9 in the case series). Improvement was maintained at 1 year in the RCT.
5. *Safety of DBS:* Complications included brain hemorrhage during the procedure, and weight gain and mood disorders during the postoperative period.
6. *Benefit/risk ratio of DBS:* DBS is still an emerging technology. The benefit/risk ratio cannot be assessed because of an insufficient number of comparative trials of a good level of evidence and because of a lack of long-term followup. Although few patients have been treated, results are encouraging and suggest that DBS might soon become a treatment modality for refractory patients.

Methods

Several databases were searched over the period 1984-2004 (MEDLINE, EMBASE, Pascal, Cochrane Library, National Guideline Clearinghouse, HTA Database) for relevant articles in English or French. Studies were selected on the basis of their level of evidence and design quality. The critical literature review was submitted to a multidisciplinary working group of 21 experts and to 21 peer reviewers recruited from learned societies (chosen fields: psychiatry, neurology, neurosurgery).

Further research/reviews required

The results of the French multicenter trial on DBS for OCD and that of international trials should be available next year. The most suitable target for DBS needs to be identified.

Written by Françoise Saint-Pierre and Isabelle Gautier L'Hermitte, HAS, France

INAHTA Briefs

Issue 2005/50

Title **Cost Estimation of Point of Care B-Type Natriuretic Peptide for the Diagnosis of Heart Failure in the Emergency Department: Application to Alberta**

Agency **AHFMR, Alberta Heritage Foundation for Medical Research**
Health Technology Assessment Unit, Suite 1500, 10104-103 Avenue NW, Edmonton, Alberta T5J 4A7 Canada; Tel: +1 780 423 5727, Fax: +1 780 429 3509; www.ahfmr.ab.ca

Reference IP 25, May 2005. ISBN 1-896956-09-5 (online): www.ahfmr.ab.ca/programs.php

Aim

To estimate the cost of Biosite Triage Point-of-Care BNP assay, used to rule out congestive heart failure (CHF) from other pulmonary conditions, for patients presenting in Alberta emergency departments (EDs) with acute dyspnea, but who do not have acute myocardial infarction (AMI), renal dysfunction (RD), or unstable angina (UA).

Conclusions and results

Yearly, about 5000 patients in urban settings and 1600 patients in rural settings present at EDs in Alberta with symptoms of acute dyspnea (but without AMI, RD, or UA). In urban settings, the total cost of standard diagnostic protocols was $4 507 639 per annum. Total savings from reducing the number of echocardiograms (ECHOs) and patient days was $990 543 per annum (savings from reducing patient days alone was $207 771). The total add-on cost of BNP testing was $99 998. In rural settings, the total cost of standard diagnostic protocols was $1 245 136 per annum. The total savings achieved if BNP testing reduces the number of ECHOs at an urban center was $65 442. The total add-on cost for BNP testing was $1646. The results indicate that in one year, BNP testing compared to standard diagnostic protocols could significantly reduce total costs, with greater cost implications in urban settings and in older populations with a higher prevalence of CHF.

Recommendations

The economic utility of BNP testing depends greatly on reducing the number of ECHOs. Hence, strict diagnostic protocols must be followed with clear diagnostic guidelines for physicians so that BNP is used properly. A pilot study of BNP testing may be worth pursuing to produce the information necessary for more definitive conclusions that reflect actual use in Alberta.

Methods

To estimate the cost of BNP testing, several hypothetical cost models were designed to compare potential BNP scenarios with standard clinical diagnostic protocols in Alberta. In urban settings the use of BNP could reduce the number of patients referred for echocardiography (ECHO) and hospitalization days, or reduce the number of hospitalization days alone, or have no impact (add-on cost). In rural settings, BNP could either reduce the number of patients referred to an urban center for ECHO, or have no impact. Resource costs were estimated and valued based on provincial data and available literature. Cost minimization analysis (CMA) was used to compare the costs for potential scenarios of BNP use.

Further research/reviews required

Economic considerations are secondary to health outcomes. Justification for BNP testing must be predicated on improving clinical care at reduced costs. This analysis is the first step in elucidating the potential cost implications of BNP testing in Alberta EDs. Further study should include not only treatment management and patient monitoring, but also long-term health outcomes and quality of life from a broader societal perspective.

Written by Anderson Chuck and Philip Jacobs, AHFMR, Canada

INAHTA Briefs

Issue 2005/51

Title **Laparoscopic Adjustable Gastric Banding for the Treatment of Clinically Severe (Morbid) Obesity in Adults: An Update**

Agency **AHFMR, Alberta Heritage Foundation for Medical Research**
Health Technology Assessment Unit, Suite 1500, 10104-103 Avenue NW, Edmonton, Alberta T5J 4A7, Canada; Tel: +1 780 423 5727, Fax: +1 780 429 3509; www.ahfmr.ab.ca

Reference IP 26, May 2005 (English). ISBN 1-896956-14-1 (print); ISBN 1-896956-15-X (online): www.ahfmr.ab.ca/programs.php

Aim

To examine the research on whether laparoscopic adjustable gastric banding (LAGB) is a safe and effective procedure compared with open and/or laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic vertical banded gastroplasty (LVBG), especially in the longer term (≥5 years), for adult patients with clinically severe obesity.

Conclusions and results

Three health technology assessment (HTA) reports and 18 published primary studies, including 1 randomized controlled trial (RCT) comparing LAGB with LVBG, 3 nonrandomized studies comparing LAGB with LRYGB, and 14 case series met the inclusion criteria. Results from the RCT and 2 single-center comparative studies suggested significantly shorter operating time and length of stay (LOS) with LAGB compared with LVBG or LRYGB. Short-term mortality rates after LAGB, LVBG, and LRYGB were similar. Significantly higher long-term postoperative complications and reoperations after LAGB raised safety concerns in severely obese patients. Although LOS was shorter with LAGB, late complications (reoperation) could increase hospital days. LAGB appeared to produce significant weight loss in severely obese patients. However, LAGB appeared to be less effective than LRYGB, with mean percent excess weight loss (%EWL) less than 50% at up to 2-year followup for patients with a wide range of preoperative BMIs (27 kg/m^2 to 81 kg/m^2). LAGB also appeared to be less effective than LVBG, with mean %EWL less than 50% at 3-year followup for patients with preoperative BMIs from 40 kg/m^2 to 50 kg/m^2. Two large case series showed that weight loss after LAGB gradually increased with careful band adjustment, reaching 47% to 54% EWL over 1 to 5 years after surgery. Improvements in comorbidities and quality of life (QoL) were reported inconsistently. LAGB improved certain comorbidities (eg, diabetes and hypertension) and QoL. LRYGB appeared to improve comorbidities more profoundly. RYGB patients tended to report higher scores on QoL measures than did LAGB or VBG patients. Nutritional deficiencies after bariatric surgery was a particular concern with RYGB, but most studies did not mention this outcome. Although this report intended to look at long-term (>5 years) safety and efficacy of LAGB, the weak evidence does not permit conclusions. Based on the evidence, guidelines, and position statements, all bariatric surgeries are effective in treating morbid obesity, but differ in the degree of weight loss and range of complications.

Recommendations

The evidence supports the current practice (RYGB or VBG) for treating clinically severe obese patients in Alberta. There is an opportunity to establish a registry to collect data on patient characteristics and link these data to outcome measures to answer questions of clinical safety and efficacy of various bariatric surgery techniques beyond 5 years.

Methods

Systematic reviews, HTAs, clinical guidelines, and primary studies were identified by systematically searching the Cochrane Library, National Health Service Centre for Reviews and Dissemination database (Economic Evaluation Database, HTA, Database of Abstracts of Reviews of Effects), PubMed, EMBASE, Web of Knowledge, and relevant library collections, practice guidelines, evidence based resources, and other HTA agency resources from 2000 to March 2005 (systematic reviews, HTAs, clinical guidelines) and from 2002 to March 2005 (primary studies). Searching was limited to English language, human studies in adults.

Further research/reviews required

The greatest needs are for long-term studies (with systematic surveillance and minimal loss to followup) that better define long-term weight loss, improvement in comorbidities and QoL, and complications following LAGB compared with LRYGB and LVBG. Future research needs to classify patients by their preoperative BMIs and analyze subgroup results for each class of obesity (WHO/Canada body-weight classifications). The main issue is to identify which patient group is most appropriate for which bariatric procedure.

Written by Bing Guo and Christa Harstall, AHFMR, Canada

INAHTA Briefs

Issue 2005/52

Title **Screening Mammography: A Reassessment**

Agency **AETMIS, Agence d'Evaluation des Technologies et des Modes d'Intervention en Santé**
2021, avenue Union, bureau 1040, Montréal, Québec, Canada H3A 2S9;
Tel: +1 514 873 2563, Fax: +1 514 873 1369; aetmis@aetmis.gouv.qc.ca, www.aetmis.gouv.qc.ca

Reference Technology brief prepared for AETMIS (AETMIS 05-03). Internet access to full text.
Printed version: ISBN 2-550-44486-X (French edition ISBN 2-550-44487-6);
PDF version: ISBN 2-550-44486-8 (French edition ISBN 2-550-44488-4)

Aim

Québec's Ministère de la Santé et des Services sociaux (MSSS) asked AETMIS to re-examine the quality of the scientific evidence on which the provincial mammography screening program is based and on the pertinence of extending screening to women younger than 50 years of age.

Conclusions and results

A Cochrane Collaboration Group review challenged the effectiveness of mammography screening in reducing breast cancer deaths. The AETMIS study found that most of the 8 mammography screening trials assessed had serious problems with validity. Some trials were not randomized, and most studies did not provide baseline characteristics of women in the experimental and control groups. Documentation was often poor or inconsistent. Regarding trial methodologies, the author found an inverse relationship between the quality of the study and the reduction in mortality as a result of screening. Hence, the more valid studies tend to show a smaller reduction in mortality (9%) than the weaker studies do (15%–23%). The authors hypothesize that the weak contrasts produced by these earlier studies can be explained partly by less refined equipment and techniques, single rather than double breast views and inconsistent measuring periods. No trial was designed and conducted in a way that used the full potential of modern programs that might detect tumors earlier and further reduce mortality.

Recommendations

- Existing scientific trials, despite their flaws, support mammography screening for women aged 50 years and older. Modern screening programs may achieve earlier detection and greater reductions in mortality than these earlier trials.
- Trial data do not provide scientific justification for screening women younger than 50 years of age, although screening of individual women, based on personalized risk assessment, could be of benefit.
- The following quality controls could be consistently applied to Quebec's screening program: high-quality mammographic films, double reading of films, a reading volume for radiologists that allows them to acquire and maintain the expertise needed for early detection.
- Efforts to increase participation should not overstate the benefits of mammography nor understate the risks and uncertainties.

Methods

This meta-analysis analyzed 8 screening mammography trials (conducted between 1963 and 1982) according to 3 criteria:

Relevance: Only studies that contrasted screening with no screening were included (1 study was excluded).

Validity: Each trial was scored according to the strength of contrast between the experimental and cohort groups in terms of their exposure to high-quality mammography and with regard to other validity criteria, in particular the adequacy of randomization, baseline equivalence of both cohorts, exclusion of pre-existing cancers, and followup of results.

Precision: Trial results were weighted by the inverse of their variance. Trials were ranked based on their scores on the validity scale (good or medium quality, poor quality, and flawed) and then progressively combined.

Further research/reviews required

These recommendations should be reviewed in several years when the results of the ongoing UK Age Trial become available.

Written by Wilber Deck with Ritzuko Kakumo, AETMIS, Canada

Title **HTA Molecular Diagnostics in Belgium**

Agency **KCE, Belgian Health Care Knowledge Centre**
Résidence Palace, 10th floor, Wetstraat 155, Rue de la Loi, BE-1040 Brussels, Belgium;
Tel: +32 2 287 3388, Fax: +32 2 287 3385; info@kenniscentrum.fgov.be, www.kenniscentrum.fgov.be

Reference HTA report, October 2005. KCE reports 20 A. (D2005/10.273/23)

Aim

To evaluate the transient solution whereby molecular diagnostics were introduced into the Belgian healthcare system based on funding of 18 Centers for Molecular Diagnosis (CMDs). To develop a framework to evaluate and introduce new molecular tests.

Conclusions and results

The CMDs introduced 94 molecular tests, while the yearly CMD health insurance budget remained fixed at 6.5 million Euros. Over the years, the volume of tests for microbiology (117 139 tests in 2004) and hemato-oncology (29 611 tests in 2004) has increased. Using new real-time polymerase chain reaction (PCR) technology, the cost per test decreased to an average of 33 Euros for a PCR test performed in duplicate. Most of the tests are performed using in-house PCR methods ("home-brew"), and most of these methods have not been validated. Standardization of the tests and evaluation of their clinical or diagnostic efficacy are not well documented. Non-CMD hospitals express the need for more efficient communication and a faster turn-around time for specific tests. In contrast to Europe, molecular testing kits in the US must undergo pre-market evaluation, and GMP standards are also required for components of in-house tests. The proposed model for test evaluation was applied to several molecular tests: detection, quantification in genotyping of HCV-RNA (of clinical use and cost effectiveness); PCR enterovirus in meningitis (technical accuracy insufficient); PCR t(14;18) in follicular lymphoma (at diagnosis, diagnostic performance of FISH is superior versus PCR); PCR Factor V Leiden (clinical impact has not been demonstrated unequivocally).

Recommendations

A model to evaluate (novel) molecular tests is being proposed. The model consists of a 6-point scale to judge the diagnostic efficacy of a test and several conditions to arrive at test effectiveness under routine conditions. These include appropriate requesting of tests, test quality (compulsory ISO accreditation and participation in external quality assessment programs for all tests is recommended), and service requirements (maximum turn-around time and standardized reporting). Health authorities should build the necessary expertise to evaluate individual tests. Where needed, appropriate studies to evaluate diagnostic efficacy should be financed. Microbiology tests with proven clinical utility and a large volume can be reimbursed as other laboratory tests. Rare microbiology tests are best performed at one or a few reference centers for reasons of expertise and quality. Molecular tests in hemato-oncology are best performed in laboratories that also perform the cytogenetic testing since there is a need for stepwise testing and integrated interpretation of these complex tests.

Methods

Test characteristics were documented using CMD financial reports, activity reports, reports of CMD quality assurance rounds, CMD standard operating procedures and questionnaires completed by the CMDs. Documentation on kits was received from the manufacturers. Interviews were conducted with requesting physicians in non-CMD hospitals. Databases were searched for HTAs and systematic reviews. A pilot assessment was conducted for selected tests.

Further research/reviews required

A systematic review or HTA was identified for only a small fraction of molecular tests, which limits evidence based decision making.

Written by Dr Frank Hulstaert, KCE, Belgium

Title **Integration of Hepatitis B Vaccination in the National Immunization Program in Denmark – An HTA Report**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 74 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference DACEHTA Report 2003; 3(1). Danish, English summary.
ISBN: 87-91437-05-9 (online): www.sst.dk/publ/Publ2004/hepatitis_b_180204.pdf

Aim

To evaluate the consequences of introducing hepatitis B vaccinations in the child immunization program in Denmark, this health technology assessment:

- describes the present and future epidemiology of hepatitis B in Denmark, with and without the introduction of hepatitis B immunization
- describes the different hepatitis B vaccines, including the new combined vaccines where hepatitis B vaccine is included with other vaccines given to children
- describes the protective effectiveness of hepatitis B vaccine
- evaluates parents' knowledge about hepatitis B and their acceptance of hepatitis B immunization
- evaluates the consequences for the health sector of a hepatitis B immunization program
- evaluates the financial implications for the health service.

Conclusions and results

The advantages of introducing hepatitis B vaccinations as an element in the child immunization program are that the number of cases of acute hepatitis B from the present level of 120 cases annually would probably decrease to almost zero and that approximately 20 new reported cases of chronic hepatitis B would be avoided. However, the effect will only manifest itself in approximately 15 to 20 years. After many years (minimum 40 to 50), immunization will lead to fewer deaths (less than 10 per year) resulting from chronic liver disease. Other related benefits will appear the short term. In particular, children will not need to be vaccinated in daycare centers that include children with chronic hepatitis B. Similarly, patients with chronic hepatitis B will run a smaller risk of being stigmatized. The disadvantages of introducing hepatitis B vaccinations include the financial costs, although these might be completely avoided depending on whether immunization is introduced as a supplement to existing vaccines or whether it is introduced in the form of new combined vaccines. There is also a possible risk associated with introducing an additional vaccine to the existing immunization program in terms of potentially lower up-take in the total child immunization program.

Recommendations

The working group concludes that an overall recommendation depends on the emphasis placed on the advantages and disadvantages respectively.

Methods

Literature review, structured telephone interviews with randomly chosen parents/families, organizational analysis, and health economic analyses including sensitivity analysis.

Written by Krogsgaard K et al, for DACEHTA, Denmark

Title	**Mammography Screening in the County of Funen 1993–1997. An HTA Report**
Agency	**DACEHTA, Danish Centre for Evaluation and Health Technology Assessment** National Board of Health, DK-2300 Copenhagen S, Denmark; Tel: +45 72 22 74 48, Fax: +45 72 22 74 07; www.dacehta.dk
Reference	DACEHTA Report 2004; 4(1). Danish, English summary. ISBN: 87-91437-31-8 (online): www.sst.dk/publ/Publ2004/CEMTV_mammo_fyn.pdf

Aim

To evaluate the economic and psychosocial consequences of regular mammography screening. The project was extended to include an evaluation of the radiological and clinical effects of the first two screening rounds.

Conclusions and results

Radiological and clinical effects: Potential advantages of mammography screening include a decrease in breast cancer mortality, an increase in the use of more gentle methods (eg, breast conserving surgery instead of mastectomy), avoidance of removing all lymph nodes in the axilla if the sentinel node is free of metastases, and a reduced use of adjuvant therapy. The main disadvantage of mammography screening is the risk for false-positive and false-negative test results. A conclusion is that the results from the first and second screening rounds are considerably better than expected. The participation rate is higher and the recall rate is lower. Surgical frequency is as expected. The percentage of females with breast cancer is higher, and the corresponding percentage of females with a benign disease is lower, than expected.

Psychosocial consequences: The psychological consequences from participating in a mammography screening program relate partly to the general effect of screening participation and partly to the problem of false-positive and false-negative findings. Questionnaires of the screening project in Funen found a generally high level of satisfaction with the organization of screening. Hence, for 90% of the females, the screening program does not lead to more focus on breast cancer, or a generally greater concern about cancer.

Economic consequences: Introducing mammography screening not only leads to changes in the diagnostic procedure, but it also affects the treatment of breast cancer patients through increases and cutbacks concerning different areas in the course of treatment. Overall, the results indicate that mammography screening leads to a total increase in the costs for diagnostic procedures and treatment of breast cancer. However, some of these costs are counterbalanced by savings in other areas, mainly associated with adjuvant oncological therapy and treatment for recurrent disease. However, from a societal perspective, the costs are essentially higher because the time and transportation costs for women must also be included.

Methods

The general aspects of mammography screening are addressed through a survey of the literature. The economic and psychosocial consequences of regular mammography screening are evaluated from data collected from 2 screening rounds, questionnaires, and interviews. The material is population based, comprising all females aged 50 to 69 years in the county of Funen, Denmark, treated for tumors in the breast within the time intervals specified.

Written by Dyreborg U et al, for DACEHTA, Denmark

Title **Early Home-Supported Discharge (EHSD) of Patients Suffering from Stroke – A Health Technology Assessment**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 74 48, Fax: +45 72 22 7407; www.dacehta.dk

Reference DACEHTA Report 2005; 5(1). Danish, English summary. ISBN 87-7676-044-8 (online): www.sst.dk/publ/publ2005/cemtv/hjemmetraening/hjemmetraening_apopleksi.pdf

Aim

To comprehensively and systematically assess EHSD by separately examining the technological, economic, organizational, and patient-related issues, to enable a synthesis, and to provide guidance in implementing EHSD.

Conclusions and results

- Death or referrals to an institution during followup (3–12 months) are reduced from 27.6% to 16.2%, with OR (Odds Ratio) 0.59 and NNT=9 (Number Needed to Treat). Referral to an institution has OR=0.52 and NNT=14.
- About 45% of all newly diagnosed stroke patients might benefit from EHSD.
- An economic evaluation related to Danish conditions is based on 3 saved bed days, a reduction of 4 percentage points in referrals to an institution during the first 12 months, and an average of 10 home training sessions. This is calculated as an average net saving of 800 Euro per patient, exclusive of a QALY effect of 0.04 priced as 400 Euro.
- The effect of EHSD is related to 2 psychological processes: (1) patients have a special motivation to return as quickly as possible to their homes and usual social relationships, and (2) training at home improves the capacity for coping.

Recommendations

Despite the socioeconomic net saving and the qualitative improvements, a potential financial barrier exists between the healthcare and social sectors. To overcome this constraint, a flexible model is outlined whereby the hospitals are partially compensated for their expenses for sending out therapists.

It is recommended that EHSD be planned and coordinated by a multidisciplinary hospital team comprised, at minimum, of physiotherapists, occupational therapists, and nurses.

To facilitate interprofessional collaboration, it is recommended to use an appropriate functional measure, eg, the Functional Independence Measure (FIM) and a plan for goals and rehabilitation.

Methods

This HTA is based on a MEDLINE literature search for randomized controlled trials (RCTs) on early supported discharge or home rehabilitation of stroke patients, supplemented by a series of patient interviews from an implementation project. The meta-analysis of outcomes from EHSD trials includes 6 RCTs from 5 countries (994 patients). Economic evaluation is designed as a cost-benefit analysis based on the average variable costs, savings, and benefits during the first 12 months after admission to hospital. A seminar with reviews from invited specialists was held to synthesize the partial investigations. Two external peer reviewers appointed by DACEHTA, and anonymous to the author, assessed the final report.

Further research/reviews required

More research in the development of *therapeutic empathy* relevant to an individualized rehabilitation scheme, such as EHSD, is recommended.

Written by Larsen T, for DACEHTA, Denmark

Title	**Lower Urinary Tract Symptoms – Epidemiology and Results from LUTS Project Funen on Implementation of a Clinical Guideline in General Practice**
Agency	**DACEHTA, Danish Centre for Evaluation and Health Technology Assessment** National Board of Health, DK-2300 Copenhagen S, Denmark; Tel: +45 72 22 74 48, Fax: +45 72 22 74 07; www.dacehta.dk
Reference	DACEHTA Report 2005; 5(2). Danish, English summary. ISBN 87-7676-003-0 (online): www.sst.dk/publ/publ2005/CEMTV/LUTS_rapp/luts_finrap_net.pdf

Aim

To determine the prevalence of LUTS (Lower Urinary Tract Symptoms) among men in Denmark, to investigate variations in clinical practice, and to investigate the effect of implementing a clinical guideline.

Conclusions and results

- LUTS are widespread among elderly men (212 000 Danish men are estimated to have urinary symptoms that potentially require treatment), which implies that identification, examination, and treatment in general practice is important to ensure that hospital departments are not unnecessarily overburdened with patients who might just as well be examined and treated in general practice.
- Changing clinical practice and applying the results of scientific studies in clinical practice is difficult and takes time.

Recommendations

The development and implementation of guidelines should be accompanied by considering the extent to which resources devoted to development and implementation are counterbalanced by resource savings from improving clinical practice and whether this improves patients' health-related quality of life.

Methods

- Epidemiological analysis based on survey data from the Danish Council of Prostate Diseases.
- Questionnaire and interview surveys designed as controlled, before-after studies. Patient pathway analysis.

Further research/reviews required

The effectiveness and patient impact of different implementation strategies need to be analyzed.

Written by Olsen J, Vondeling H, and Jensen G (ed), for DACEHTA, Denmark

Title **Colon Examination with CT Colonography – A Health Technology Assessment**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 74 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference DACEHTA Report 2005; 5(3). Danish, English summary. ISBN 87-7676-083-2 (online): www.sst.dk/publ/publ2005/CEMTV/CT_kolo_rapport/CTkolo_rapport.pdf

Aim

To evaluate how to perform CT colonography (diagnostic performance including interobserver variation and learning curve), to assess the marginal costs of CT colonography compared to conventional colonoscopy, and to assess patient discomfort and preferences compared to colonoscopy.

Conclusions and results

CT colonography is a minimally invasive colon examination to detect space-occupying lesions in the colon. This report focuses on Danish conditions and represents a prospective health technology assessment (HTA) performed at a university hospital and a regional hospital. The sensitivity of CT colonography for lesions ≥6/5 mm was 81%/66% compared to 87%/93% for colonoscopy. The quality of the examination differed considerably depending on the observer, which underlines the need to train and test radiologists who perform CT colonography. The patients found CT colonography significantly less painful, less uncomfortable, less humiliating, and less stressful than colonoscopy.

CT colonography proved to be cheaper than colonoscopy. The additional cost that is presently paid for the greater effectiveness of colonoscopy compared with CT colonography is between 1399 and 8872 Danish kroner (DKK) per additional lesion detected. It was not possible to identify major improvements in the sensitivity and specificity during the course of evaluation of the first 100 investigations by 2 independent observers.

Recommendations

CT colonography has a place in the Danish healthcare service, but should not generally replace colonoscopy. CT colonography should replace double-contrast barium enema in case of incomplete colonoscopy and should be considered as the primary diagnostic tool in patients in whom the risk of incomplete colonoscopy is considered to be high or in patients in whom colonoscopy with anesthesia is indicated. Only radiologists familiar with CT colonoscopy should perform the examination.

Methods

The results are based on prospectively collected data from observer-blinded studies at a university hospital and a regional hospital. The data were collected from January 1999 to May 2002 in an outpatient population with a high incidence of colorectal pathology. The results are compared to the international literature.

Further research/reviews required

Results obtained in routine clinical practice rather in a research setting are needed.

Written by Pedersen BG, Arnesen RB, Poulsen PB, Adamsen S, Hansen OH, and Laurberg S, for DACEHTA, Denmark

Title **Nutritional Care of Medical Patients – A Health Technology Assessment**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, PO Box 1881, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 74 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference DACEHTA Report 2005; 5(4). Danish, English summary. ISBN 87-7676-102-9
(online): www.sst.dk/publ/publ2005/CEMTV/ernaeringspleje/ernaeringspleje_final.pdf

Aim

To identify and focus attention on problems in nutritional care of medical inpatients and to propose changes to ensure that the nutritional care they receive is optimal.

Conclusions and results

In Denmark, 1 in 3 admissions are to a medical department. Often, the patients are elderly, undernourished, and at risk for becoming even more undernourished during hospitalization. If the patient weakens, the risks for bedsores, phlebitis, and infections increase. This assessment was inspired by the apparent disparity between our knowledge of the importance of nutritional care in the patient's recovery and the common failure to incorporate nutritional care in treatment.

There is considerable potential to increase the intake of nourishment within the current nutritional care provided to medical inpatients through, eg, enhanced dialogue among professional groups and between nursing staff and the patients, a clear division of responsibilities in nutritional care, and the range of foods offered. Optimizing nutritional care is estimated to reduce the average hospital stay and save 143.6 million Danish kroner (DKK) annually. The primary aim in optimizing nutritional care should be to improve patient care and treatment, not primarily to achieve cost savings. The benefits are two-fold: patients experience improved quality, and this will probably have a positive effect on operation of the medical departments.

Recommendations

A standard formula cannot improve nutritional care at the individual hospital, eg, since each hospital works in its own way and nutritional care depends on many groups. A conscious decision by management to prioritize nutritional care in association with long-term planning and implementation is of fundamental importance. Lacking this, it is difficult to ensure permanent, optimized nutritional care at all levels.

Methods

Nutritional care at medical departments in 3 Danish hospitals was investigated by interviewing the professional groups and 75 inpatients. Practice was compared with the official Danish dietary recommendations for ill persons. The analysis identified factors – from the perspectives of professional groups and patients – that promote or inhibit optimal nutritional care. Historical aspects of nutritional care were studied by collecting historical source material and interviewing senior nurses. Official measures and national policy discussions were also elucidated through relevant source material. A systematic literature search was used to investigate the technology and the economic aspects. Data on current activities were collected for a health economic analysis to determine the potential savings at the local and national levels.

Further research/reviews required

The wider perspective in the nutritional care of medical patients is to apply existing knowledge in a coordinated and systematic manner. The main research and development needs concern implementation in hospitals. This would enable knowledge to be implemented in practice and provide an important precondition to ensure that optimal nutritional care of medical patients becomes permanent in Danish hospitals.

Written by Lassen KØ, Olsen J, Grinderslev E, Melchiorsen H, Kruse F, and Bjerrum M, for DACEHTA, Denmark

Title **Hospice Without Walls – A Health Technology Assessment of a Palliative Network**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 74 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference DACEHTA Report 2005; 5(5). Danish, English summary. ISBN 87-7676-122-3 (online): www.sst.dk/publ/Publ2005/CEMTV/Hospice/Hospice.pdf

Aim

To illustrate the consequences of a network-based organization such as "Hospice Without Walls" compared to a more sectorized approach.

Conclusions and results

What consequences does a palliative network such as Hospice Without Walls have on pain treatment, palliative care, patients, organizations, staff, and economic factors, eg, in areas like Skanderborg and Odder municipalities in Denmark? Concerning the technology relevant to Hospice Without Walls, the project indicates that pain management of terminal patients has become more potent and, consequently, is expected to provide faster pain palliation. Furthermore, the focus on palliative symptoms and problems has increased. The greatest changes resulting from establishment of Hospice Without Walls seem to be found within the organization. Hospice Without Walls has been well received by the different partners and staff groups within the hospital and the primary care sectors. A main reason for this generally positive acceptance is that Hospice Without Walls is based on existing structures and frameworks. However, disparities between cultures and practices have appeared in cross-sectorial cooperation – especially between hospitals and GPs. According to the relatives (used as proxy in a retrospective survey after the death of a patient) the patients and their families have been nearly exclusively positive toward Hospice Without Walls. Ninety-two percent of the relatives report that it has provided "very good" or "good" help. The expectation in establishing Hospice Without Walls was that it would have economic benefits by lowering hospital costs through fewer and shorter inpatient stays. However, based on a marginal cost analysis, this HTA has demonstrated that this does not seem to be the case. On the contrary, it involves an increase in costs, although this increase is limited.

Recommendations

The positive experiences and elements from Hospice Without Walls may be used in other Danish counties with the primary focus being on palliation at a highly specialized level. Focus should be on coherent patient sequences for terminal patients and their families and a fulfillment of the wishes that patients may have in their final phase of life.

Methods

Data collection methods such as systematic journal reviews, case sequence descriptions, literature reviews, postal surveys, individual and focus group interviews, and cost analyses have been applied in this health technology assessment.

Written by Poulsen PB, Rajani N, Hornemann A, and Kolbye A, for DACEHTA, Denmark

Title **Medical Versus Surgical Termination of Pregnancy – A Health Technology Assessment**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, PO Box 1881, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 74 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference DACEHTA Report 2005; 5(6). Danish, English summary. ISBN 87-7676-183-5
(online): www.sst.dk/publ/Publ2005/CEMTV/Med_kir_abort/med_vs_kir_abort.pdf

Aim

To evaluate whether the introduction of medical abortion was the right decision or whether this decision should be revised.

Conclusions and results

There is strong evidence to support that the primary success rate (complete abortions with no need for later surgical intervention) is higher after surgical (98%) than after medical abortion (95%). There is moderate evidence to support a higher rate of antibiotic prescriptions based on verified or suspected infections after surgical (8–12%) compared to medical abortion (1–5%). Based on moderate evidence, side effects (abdominal pain, nausea, diarrhea, and dizziness) are more intense and last longer after medical versus surgical abortion. Moderate evidence supports that more women are satisfied with the surgical procedure (90–95%) than the medical procedure (75–80%). More women would also choose the same method of termination again after a surgical than after a medical procedure (85–94% vs 55–95%). Based on moderate evidence, more women are satisfied after choosing the medical method of termination themselves (82%) than if the method is determined by randomization (68%).

The medical regimen (mifepristone 200 mg + misoprostol 0.8 mg) with followup including a blood sample at the hospital and a clinical checkup by a general practitioner, is more cost effective than surgical abortion under general anesthesia. From the hospital's perspective, medical abortion at home is more cost effective than medical abortion in the hospital, but less cost effective from a societal perspective. Organizations that offer both medical and surgical abortion procedures are probably less efficient compared to organizations that offer only one of the procedures.

Recommendations

The higher risk of infection, or suspected infection, related to a surgical procedure is assumed to be associated with reduced fertility in the future. However this association has not been directly investigated. If this assumption is proven, the medical procedure is recommended as the optimal abortion procedure, since most of the women undergoing termination of pregnancy wish to become pregnant later in life.

Methods

Systematic review, partly randomized study comparing medical and surgical abortion, cost analysis.

Further research/reviews required

The higher risk for infection/suspected infection related to a surgical procedure and its association with reduced fertility needs to be investigated.

Written by Rørbye C, Nilas L, Juul Larsen R, Kildemoes HW, and Folkersen J, for DACEHTA, Denmark

INAHTA Briefs

Issue 2005/62

Title **Endovascular Treatment of Carotid Stenosis**

Agency **KCE, Belgian Health Care Knowledge Centre**
Résidence Palace, 10th floor, Wetstraat 155, Block A, BE-1040 Brussels, Belgium;
Tel: +32 2 287 3397, Fax: +32 2 287 3385; hta@kenniscentrum.fgov.be, www.kenniscentrum.fgov.be

Reference Bonneux L, Cleemput I, Ramaekers D. April 2005.
KCE Reports vol 13A. Ref D2004/10.273/09.
www.centredexpertise.fgov.be/documents/D20051027309.pdf

Aim

To evaluate the clinical effectiveness and cost effectiveness of protected carotid stenting (PCAS) as compared to carotid endarterectomy (CEA) for patients with carotid stenosis.

Conclusions and results

Evidence on the performance of PCAS in the short term and long term is insufficient to make any other statement than that PCAS is a promising emerging technology, and more expensive than CEA. Most published literature is based on clinical trials or observational studies in centers of clinical excellence. Surgeons in clinical trials are usually rigorously screened before they can participate in the trial and usually have an above-average level of experience with the procedure. Patients also are carefully selected for trials and are generally not representative of the entire patient population for whom the technology is likely to be used. If the procedure becomes widely available without clear guidance or conditions for its use, the outcomes will deteriorate. The economic literature review showed that PCAS is not cost effective relative to CEA. Additional costs for the stents and cerebral protection devices do not outweigh the short-term savings associated with shorter lengths of stay nor the slightly fewer short-term complications. However, outcomes and costs will inevitably change if the technology becomes more widely used as the technology advances and operators gain experience with the procedure. Both changes have implications for the effectiveness and costs of the technology.

Recommendations

- PCAS should be made available to patients that are at high risk for stroke, but are poor candidates for surgery. Information on these interventions should be registered prospectively.
- Experimental use of PCAS in other patients should be limited to ongoing randomized clinical trials (RCTs) comparing PCAS with CEA, eg, the ICSS trial.
- Experimentation with PCAS outside clinical trials is ethically and economically difficult to justify.
- Treatment decisions should be made by vascular teams, consisting of at least one surgeon, radiologist, or neurologist (or a geriatrician replacing the neurologist). Centers should have sufficient experience (sufficient number of carotid interventions) and maintain sufficient experience.
- Registration of the outcomes of all carotid interventions should be improved.
- CEA remains the standard treatment. Exceptions should be motivated.

Methods

A literature search on the clinical and cost effectiveness of PCAS is supplemented with information from experts. Rapidly evolving technology is less amenable to the standard methodology of systematic literature review. Besides technological changes, the clinical conditions are important for the outcome of the intervention, ie, skill of the interventionist, preference of the surgeon or radiologist for one intervention or another, excellence of the center, and the choice of device. These considerations guide the interpretation of the literature on PCAS. Three external validators with international expertise in this domain validated the scientific report.

Further research/reviews required

This report will need to be updated after publication of the results of the major RCTs comparing CEA with PCAS. Ethical committees should define the conditions for introducing expensive emerging technology.

Written by Luc Bonneux, Irina Cleemput, and Dirk Ramaekers, KCE, Belgium

Title	**HTA Positron Emission Tomography in Belgium**
Agency	**KCE, Belgian Health Care Knowledge Centre** Résidence Palace, 10th floor, Wetstraat 155, Block A, BE-1040 Brussels Belgium; Tel: +32 2 287 3397, Fax: +32 2 287 3385; hta@kenniscentrum.fgov.be, www.kenniscentrum.fgov.be
Reference	Cleemput I, Dargent G, Poelmans J, Camberlin C, Van den Bruel A, Ramaekers D. October 2005. KCE Reports vol 22A. Ref D2005/10.273/29. www.kenniscentrum.fgov.be/documents/D20051027329.pdf

Aim

- To evaluate the clinical utility and cost effectiveness of PET for different indications.
- To describe PET in Belgium, including regulation, utilization, and costs and to compare Belgium with other western countries.
- To formulate recommendations for organizing and financing PET services in Belgium.

Conclusions and results

The evidence of improved clinical patient outcome of PET is limited to a few indications. The most solid evidence for clinical effectiveness was found for the initial staging of non-small cell lung carcinoma (NSCLC) and for detecting and localizing recurrence of colorectal cancer. For other indications, there is only evidence about the sensitivity and specificity of PET compared to other diagnostic methods.

Compared to many Western countries, Belgium has the most PET scanners and the highest annual throughput. Belgium has 13 approved PET scanners (1.26/million population) and probably several non-approved units are still in operation. About 20 000 PET scans are done per year (about 12 000 are for reimbursed indications). The high number of scanners, and overcapacity, in Belgium cannot be justified based on scientific evidence or demographic data. Based on indications for which PET has proven therapeutic impact, 3 PET scanners would be sufficient in Belgium. A more lenient approach leads to an estimate of no more than 10 scanners. (The full report also presents the arguments to maintain overcapacity.) The financing system should stimulate the efficient use of PET scanners. Indications for which PET imaging is reimbursed under the current reimbursement scheme in Belgium appear to be similar to the indications found in our review. For possible future expansion of reimbursed indications, the impact on therapeutic management and patient outcomes should be considered.

Recommendations

- A legal framework is needed for outsourcing fluorodeoxyglucose (FDG) production to non-commercial, academic PET centers with a cyclotron on-site.
- The fee per dose of FDG delivered is lower than the price charged for FDG by the companies with a marketing authorization in Belgium. Reimbursement of FDG should be in line with requirements imposed by the government.
- Maintaining or creating an overcapacity for the sake of uncertain future benefit is not only costly, but also not useful given the ongoing technological advancement in this field.
- Full use of existing (over)capacity and efficient use of healthcare resources are not compatible in the context of PET. Full capacity use of all approved PET scanners implies higher costs that are not proportional to possible improvements in therapeutic planning or patient outcome.
- Healthcare policy makers need to make a tradeoff between efficiency (implying the closure of some PET scanners) and other policy objectives, eg, ensuring accessibility to PET services.
- If the option of maintaining overcapacity of PET is chosen, there is an important opportunity for research with PET in Belgium. As public resources will be used, this research must have clear objectives that are relevant for society. If financial resources for research come from the healthcare budget, this should be publicly transparent and should not overlap with other financial streams toward hospitals for research.

Further research/reviews required

The KCE recommends an update of this study in a few years.

Written by Cleemput I, Dargent G, Poelmans J, Camberlin C, Van den bruel A, and Ramaekers D, KCE, Belgium

Title	**HTA Elective Endovascular Treatment of Abdominal Aortic Aneurysms**
Agency	**KCE, Belgian Health Care Knowledge Centre** Résidence Palace, 10th floor, Wetstraat 155, Block A, BE-1040 Brussels, Belgium; Tel: +32 2 287 3397, Fax: +32 2 287 3385; hta@kenniscentrum.fgov.be, www.kenniscentrum.fgov.be
Reference	Bonneux L, Cleemput I, Vrijens F, Vanoverloop J, Galloo P, Ramaekers D. 2005. KCE Reports vol 23B. Ref D/2005/10.273/33. www.centredexpertise.fgov.be/fr/Publications.html

Aim

To review the evidence concerning clinical effectiveness and cost effectiveness of elective endovascular treatment (EVAR) of abdominal aortic aneurysms (AAA) compared to watchful waiting and open surgery. To evaluate the introduction of endovascular technology in Belgium based on EUROSTAR registry data.

Conclusions and results

Clinical effectiveness: For patients with aneurysms <5.5 cm, watchful waiting is the preferred treatment. For patients with aneurysms ≥5.5 cm and fit for surgery, EVAR has better short-term results, but worse long-term results. For patients with aneurysms ≥5.5 cm and unfit for surgery, pending further evidence, EVAR increases the risk of morbidity and interventions, without decreasing mortality.

Cost effectiveness: EVAR is not cost effective compared to open surgery, but is nevertheless a promising technology. To be a cost-effective option, the costs for the device must decrease, the indication setting for EVAR must improve, and the long-term reintervention rates must decrease.

Introduction in Belgium: Many more centers than anticipated recruited patients, and many centers reported low volumes. A numerical association was found between the volume of a hospital and short-term mortality (+50% in centers with fewer than 20 patients). Hospitalization costs averaged 11 500 Euros for EVAR, and 7900 Euros for open repair.

Recommendations

1. EVAR should be used only in patients fit for surgery and for aneurysms that are sufficiently large (>5.5 cm, or >5.0 cm with associated risk factors).
2. "AAA repair", with open surgery or EVAR, should be reimbursed at comparable prices, regardless of the technology used.
3. To guarantee a sufficient volume of interventions, only a limited number of vascular centers with tertiary care should offer EVAR.

Methods

The clinical and economic literature on EVAR (compared to open surgery and watchful waiting) was systematically reviewed. A meta-analysis of the comparison of EVAR versus open surgery was also conducted. Analyses were performed on the EUROSTAR registry database for all patients treated with EVAR in Belgium. Claims data were used to estimate the cost of endovascular repair in Belgium. External experts provided input to the scientific report, and 3 validators validated the scientific content of the report.

Further research/reviews required

This work has shown the need for global reflection concerning the introduction of emerging technology in the healthcare system. This reflection will be the subject of a future KCE project.

Written by Bonneux L, Cleemput I, Vrijens F, Vanoverloop J, Galloo P, and Ramaekers D, KCE, Belgium

Title **Malocclusions and Orthodontic Treatment in a Health Perspective**

Agency **SBU, The Swedish Council on Technology Assessment in Health Care**
PO Box 5650, SE-114 86 Stockholm, Sweden;
Tel: +46 8 412 32 00, Fax: +46 8 411 32 60; info@sbu.se, www.sbu.se

Reference SBU Report 176, 2005. ISBN: 91-85413-06-2.
Summary in English and complete report in Swedish are available on www.sbu.se

Aim

To investigate the evidence on the risks and consequences of different orthodontic treatment methods versus no orthodontic treatment, the effects on oral and psychosocial health, whether the outcome of orthodontic treatment is long lasting, and whether validated devices (eg, indices) are available to assess treatment need. Economic aspects were considered.

Conclusions and results

Patients with a large overjet have a higher incidence of trauma to the anterior teeth of the maxilla. Also, if the maxillary canines are incorrectly positioned in the jawbone before their eruption, the risk is greater that they will damage the roots of the front teeth as they emerge. Caries prevalence in people with occlusal deviations is the same as in people with a normal bite. Evidence is insufficient to draw conclusions on a correlation between specific untreated malocclusions and symptomatic temporomandibular joint disorders. A correlation between moderate malocclusions and negative effects on the self-image of 11- to 14-year-olds has not been found, although adults with untreated malocclusions express more dissatisfaction with the appearance of their bite than adults without malocclusions. Scientific evidence is insufficient to draw conclusions about the validity of morphological priority indices. Treatment of crowding aligns the dental arch, and treatment of large overjet with fixed appliances (Herbst[1]) normalizes the occlusion. Relapses occur, but cannot be predicted at the individual level. Common complications of orthodontic treatment are pain and root resorptions[2]. Side effects such as temporomandibular joint disorders (TMD) have not been demonstrated in connection with orthodontic treatment.

Methods

Electronic databases were used in the primary search for literature dating back to 1966. The findings of a study had to be applicable to the questions posed by the report, ie, appropriate outcome measures, followup period, and study design. The reviewers rated the quality and internal validity of each study. The scientific evidence for each conclusion was rated based on the quality and internal validity of the studies.

Further research/reviews required

Studies on indications and assessments (decisions) for orthodontic treatment, followup of treatment results, the significance of malocclusions for quality of life, and studies in the field of health economics are needed.

[1] Braces that hold the mandible in a forward position via a telescoping mechanism.

[2] Gradual dissolution of tooth roots.

Written by Susanna Axelsson, SBU, Sweden

Title	**Treatment of Anxiety Disorders**
Agency	**SBU, The Swedish Council on Technology Assessment in Health Care** PO Box 5650, SE-114 86 Stockholm, Sweden; Tel: +46 8 412 32 00, Fax: +46 8 411 32 60; info@sbu.se, www.sbu.se
Reference	SBU Report 171, 2005. ISBN: vol 1 91-87890-98-4, vol 2 91-85413-05-4. Summary and conclusions in English, and full text report in Swedish are available on www.sbu.se

Aim

To investigate the evidence on treatments available for anxiety disorders. Economic aspects were considered.

Conclusions and results

(partial list)

- Effective treatment options are available for all anxiety disorders. Apart from specific phobias, the effects of pharmacological and psychological treatments are only moderate. Symptoms are alleviated, but full remission is seldom accomplished. With few exceptions, symptoms recur when treatment is completed.
- Socioeconomic costs – primarily in terms of lower productivity and greater ill health, raised death rates, and increased need for somatic care (treatment of physical symptoms) – are high. The cost effectiveness of various treatment options has not been determined.
- Scientific evidence is insufficient for comparing either the efficacy or cost effectiveness of different treatments.
- Some benzodiazepines are shown to be effective in treating certain anxiety disorders. However, it is well established that the drugs cause significant problems in terms of side effects, dependence, or exacerbation of symptoms after a certain period of treatment.
- No study has unequivocally explained why anxiety disorders are associated with raised death rates. Long-term studies on how to reduce raised death rates through some form of intervention are lacking.
- There are too few studies of relevant quality on psychodynamic therapy to evaluate its effect.

Methods

This was a systematic review covering literature up to 2005. A protocol was developed to assess the studies. Regarding pharmaceutical studies, only randomized controlled trials were included. Regarding psychotherapies, we accepted studies where the control group was on a waiting list. Electronic databases were used in the primary search for literature and supplemented by manual searches, reference lists, etc. Reviewers followed the protocol to rate the quality and internal validity of each study. Scientific evidence for each conclusion was based on the number of studies with high quality and internal validity.

Further research/reviews required

(partial list)

- Studies on the effect of combining antidepressant drugs and psychotherapy.
- Studies of diagnosis, treatment, and other services in primary care.
- Studies evaluating the effects on treatment in patients with comorbidities.

Written by Agneta Pettersson, SBU, Sweden

Title **Validity of Methods for Predicting Violence in the Community by Psychiatric Patients – A Systematic Literature Review**

Agency **SBU, The Swedish Council on Technology Assessment in Health Care**
PO Box 5650, SE-114 86 Stockholm, Sweden;
Tel: +46 8 412 32 00, Fax: +46 8 411 32 60; info@sbu.se, www.sbu.se

Reference SBU Report 175. Summary and conclusions in English, and full text report in Swedish, are available on www.sbu.se

Aim

To evaluate the evidence for methods used to predict the risk of psychiatric patients committing violent acts in the community.

Conclusions and results

(partial list)

- Moderately strong evidence shows that violence can be predicted with a validity significantly better than chance in male patients.
- There is weak (low) evidence of validity in risk assessments of female patients, and no evidence of validity in risk assessments of patients belonging to ethnic minority groups.
- Predictive validity was generally found to be moderate, with at best 70% to 75% accuracy in classification.
- No evidence was found for short-term risk predictions pertaining to risk of violence in the community within days, weeks, or months.
- No evidence was found that clinical judgment and instruments (eg, HCR-20 and VRAG) differ in terms of validity.

Methods

This was a systematic review covering literature between 1970 and February 2005. A protocol was developed to assess the studies. The primary search for literature involved electronic databases, supplemented by manual searches, reference lists, etc. Reviewers followed the protocol to rate the quality and internal validity of each study. Scientific evidence for each conclusion was based on the number of studies with high quality and internal validity.

Further research/reviews required

(partial list)

- Well-designed studies with prospective followup, representative for Sweden.
- Large studies allowing for analysis of the relatively few cases of violent acts, performed within hours or days after the assessment.
- Research to find assessment methods that are applicable to women.

Written by Agneta Pettersson, SBU, Sweden

INAHTA Briefs

Issue 2006/01

Title **Surgical Treatment of Morbid Obesity: An Update**

Agency **AETMIS, Agence d'Evaluation des Technologies et des Modes d'Intervention en Santé**
2021, avenue Union, bureau 1040, Montréal, Québec, Canada H3A 2S9;
Tel: +1 514 873 2563, Fax: +1 514 873 1369; aetmis@aetmis.gouv.qc.ca, www.aetmis.gouv.qc.ca

Reference Technology brief AETMIS 05-04. Translated from an official French publication titled *Le traitement chirurgical de l'obésité morbide: mise á jour*. Internet access to full text.
Printed version: ISBN 2-550-45724-2; PDF: ISBN 2-550-45725-0

Aim

To update a 1998 report on the surgical treatment of morbid obesity and to re-examine the efficacy, cost, and risk for complications of surgical procedures used to treat morbid obesity.

Conclusions and results

Obesity is defined as a body mass index (BMI) of 30 kg/m^2. *Morbid obesity* refers to a BMI of 40 kg/m^2, or 35 kg/m^2 if associated with comorbidities. Between 1978 and 2004, obesity rose in the Canadian population from 13.8% to 23.1% (21.8% in Québec), while morbid obesity rose from 0.9% to 2.7%. In 1997, 2.4% of Canada's total medical costs, or $1.8 billion, were attributable to adult obesity. Since a multidimensional approach (education, counseling, etc.) is not effective in treating morbid obesity, bariatric (ie, weight loss) surgery is considered the only treatment. The following techniques were studied:

- *Vertical banded gastroplasty* (VBG) has lost favor as a stand-alone method due to lower than expected weight loss. Combined with RYGB, VBG yields good long-term results.
- *Roux-en-Y gastric bypass* (RYGB) is considered the gold standard in weight-loss surgery, and is the most common method.
- *Biopancreatic diversion with duodenal switch* (BPD-DS) is no longer considered experimental due to positive results. Some suggest it is appropriate for super-obese patients.
- *Laparoscopic RYGB and VGB* reduce hospital stays and decrease, or eliminate, complications associated with open surgery. Surgeons must train in the best conditions to master the approach.

Surgical treatment of morbid obesity appears to be cost effective. The positive effects of weight loss appear to compensate for the costs of surgery, complications, followup, and plastic surgery. Evidence indicates that hybrid techniques that combine gastric restriction and intestinal malabsorption are superior to those designed only to restrict gastric capacity. Research shows that after 1 year of followup, laparoscopic RYGB achieves the same outcomes as the open version.

Recommendations

- Develop a plan to define and respond fairly to the need for bariatric surgery in Québec.
- Provide the conditions (patient-selection, facilities, multidisciplinary teams, etc) to ensure that Québec hospitals can offer high-quality bariatric treatment for patients most in need.
- Establish a registry on morbid obesity to assess needs and best clinical practices.

Methods

Scientific articles and health technology assessment reports published since 1998 were reviewed (most were retrospective case series). The outcome measures for the analysis were: clinical efficacy (weight loss); safety (complications); comorbidity (reduction or not of associated conditions); consumption of health goods or services; and efficiency (cost-utility ratios).

Further research/reviews required

- Ongoing evaluation of current surgical procedures and new approaches based on registry data.
- Confirmation, by longer-term economic studies, of the early assessment that hybrid techniques are superior.

Written by Raouf Hassen-Khodja and Jean-Marie R Lance, AETMIS, Canada

Title **ADHD – Attention Deficit Hyperactivity Disorder in Girls. A Survey of the Scientific Literature**

Agency **SBU, The Swedish Council on Technology Assessment in Health Care**
PO Box 5650, SE-114 86 Stockholm, Sweden;
Tel: +46 8 412 32 00, Fax: +46 8 411 32 60; info@sbu.se, www.sbu.se

Reference SBU Report 174, 2005. ISBN 91-85413-02-x.
Complete report in Swedish is available on www.sbu.se

Aim

To map and analyze the scientific literature concerning girls with certain psychiatric disturbances, particularly ADHD.

Conclusions and results

1. Girls with ADHD suffer from the same degree of functional disturbances as boys with ADHD. These girls have poorer performance at school, have difficulties in planning and organizing everyday life, and experience conflicts with other children.
2. ADHD in girls is associated with an increased risk for depression and anxiety disorders compared to girls without ADHD and boys with ADHD. Oppositional defiant disorder and conductive disorder are more common than in girls without ADHD, but less common than in boys with ADHD.
3. The prevalence of ADHD in girls is not completely defined and varies in most studies from 2% to 5% in girls between 6 and 15 years of age. ADHD is 1.3 to 4.0 times more common in boys than in girls.
4. Ten years ago, boys were diagnosed 7 to 9 times more often than girls. Currently, girls constitute 20% to 25% of the ADHD population.
5. Teachers recognize more boys than girls with ADHD, whereas parents identify boys and girls to the same extent.
6. Girls are treated less frequently with pharmaceuticals or behavioral therapy than boys are.

Methods

Literature review

Further research/reviews required

- Longitudinal studies on how ADHD influences adult life.
- Specific studies on girls with ADHD with emphasis on preschool age and teenage.
- Studies concerning possible sex-specific diagnostic criteria.
- Studies on long-term effects of centrally stimulating drugs.
- Studies on effects of behavioral therapy.
- Studies on therapeutic effects on self esteem and prevention of future drug abuse.
- Studies on the interaction of female sex hormones and centrally stimulating drugs.

Written by Nina Rehnqvist, SBU, Sweden

Title **HTA Capsule Endoscopy**

Agency **KCE, Belgian Health Care Knowledge Centre**
(10th) Wetstraat 155, Rue de la Loi, BE-1040 Brussels, Belgium;
Tel: +32 2 287 33 88, Fax: +32 2 287 33 85; info@kenniscentrum.fgov.be, www.kenniscentrum.fgov.be

Reference Poelmans J, Hulstaert F, Huybrechts M, Ramaekers D. Capsule Endoscopie. January 2006. KCE reports 25 A. (D2006/10.273/01). www.kenniscentrum.fgov.be/documents/D20061027301.pdf

Aim

To evaluate the clinical efficacy and cost effectiveness of capsule endoscopy (CE) compared to other diagnostic modalities for different potential indications, eg, obscure gastrointestinal bleeding (OGIB), Crohn's disease (CD), intestinal polyposis, and Celiac disease.

Conclusions and results

Evidence of diagnostic accuracy is shown in diagnosing bleeding sources in patients with OGIB. The diagnostic yield of CE is generally higher compared to other diagnostic modalities, but patient selection bias is present in most studies. Limited data suggest that the yield of CE is highest in overt ongoing bleeding, intermediate in overt previous bleeding, and intermediate or low in occult bleeding. Capsule retention necessitating surgical or endoscopic removal occurred in 0.7% to 5.0% of the patients in a trial setting. CE failed to reach the cecum within the battery lifetime in 17% to 34% of the patients.

Studies in patients with suspected or established CD evaluated small and heterogeneous populations (CD and/or suspected CD, different previous investigations, different comparators, etc). Hence, the results cannot be generalized since it is unclear which patients would benefit from CE. Future studies should address potential fields of application and their significance. The problem of false positives should be resolved. A catalog with normal and pathological CE findings is essential. Capsule retention with CE is more likely in CD patients, even after a negative radiological evaluation. In such cases, unintended surgery may be required to remove the capsule. CE failed to reach the cecum within the battery lifetime in 17.5% of the patients. Hence, the terminal ileum, a critical segment for CD, was not visualized in these patients.

Recommendations

CE is recommended in patients with OGIB (when other previous investigations are negative). The most important risk in CE is capsule retention necessitating unintended surgical or endoscopic removal. Patients should be informed of this risk prior to CE. For reasons of volume and quality, CE in Belgium should be limited to a few centers only. The expected maximum budget for CE in Belgium for OGIB is estimated at 600 000 Euros after 5 years.

The quantity and quality of evidence is insufficient to determine the relative diagnostic performance of CE compared with other conventional tests for diagnosing patients with CD, intestinal polyposis, and Celiac disease. No conclusions can be drawn as to whether CE is an effective alternative to other tests.

Methods

A systematic literature search on the clinical and cost effectiveness of CE is supplemented with information from experts. Levels of diagnostic accuracy were applied. Three external validators with international expertise on this issue validated the scientific report.

Further research/reviews required

Further research is warranted to determine the place of CE in managing OGIB and other potential indications, eg, CD, intestinal polyposis, and celiac disease.

Written by Johan Poelmans, KCE, Belgium

Title **A Randomized Controlled Trial to Compare the Cost Effectiveness of Tricyclic Antidepressants, Selective Serotonin Reuptake Inhibitors and Lofepramine (AHEAD)**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(16). May 2005. www.ncchta.org/execsumm/summ916.htm

Aim

To determine the relative cost effectiveness of 3 classes of antidepressants: tricyclics (TCAs), selective serotonin reuptake inhibitors (SSRIs), and the tricyclic-related antidepressant lofepramine, as first choice treatments for depression in UK primary care.

Conclusions and results

The trial randomized 327 patients. Followup rates were 68% at 3 months and 52% at 1 year. Linear regression analysis revealed no significant differences between groups in number of depression-free weeks when adjusted for baseline (HAD-D). A higher proportion of patients randomized to TCAs entered the preference arm than those allocated to the other choices. Switching to another class of antidepressant in the first few weeks of treatment occurred significantly more often in the lofepramine arm and less in the preference arm. No significant differences were found between arms in mean cost per depression-free week. For values placed on an additional quality adjusted life year (QALY) of over £5000, treatment with SSRIs was likely to be the most cost-effective strategy. Tricyclics were the least likely to be cost effective as first choice of antidepressant for most values of a depression-free week or QALY respectively, but these differences were relatively modest.

Recommendations

Given the low probability of significant differences in cost effectiveness, it is appropriate to base the first choice between these 3 classes of antidepressants in primary care on doctor and patient preferences. Adopting this policy may lead to less switching of medication. Choosing lofepramine is likely to lead to a greater proportion of patients switching treatment in the first few weeks.

Methods

The study was an open label, pragmatic controlled trial with 3 randomized arms and 1 preference arm. Patients were followed for 12 months and were randomized to receive a tricyclic antidepressant, a selective serotonin reuptake inhibitor, or lofepramine. Standardized recommendations about dose and dose escalation based on the British National Formulary were issued to GPs. Cost effectiveness was based on an analysis of direct costs from an NHS perspective.

Further research/reviews required

It is difficult to see how a better study of this topic could be conducted in the primary care setting. The research agenda for managing depression in primary care should move on to address important questions such as the most appropriate threshold of severity at which to commence antidepressant medication, the effectiveness of strategies to improve recognition of depression, quality of management of identified patients, and the efficacy of interventions to improve patients' compliance with treatment.

Written by Professor Robert Peveler, University of Southampton, Royal South Hants Hospital, Southampton, UK

Title **The Investigation and Analysis of Critical Incidents and Adverse Events in Healthcare**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(19). May 2005. www.ncchta.org/execsumm/summ919.htm

Aim

To review methods of investigating and analyzing accidents and near misses in health care, supplemented by a parallel overview of methods of investigation and analysis in other settings.

Conclusions and results

All techniques could potentially be applied in any specialty or discipline related to health care. While a few studies looked solely at death as an outcome, most used a variety of outcomes including near misses. Most incidents were investigated by interviews and primary document review. All techniques included papers that identified clinical issues and attempted to assess underlying errors, causes, and contributing factors. The extent and sophistication of these attempts varied widely. Review of accident investigation methods in high-risk industries reveals techniques that are potentially useful in health care. Two techniques used in health care are of particular interest and potential: Root Cause Analysis (RCA) and Organizational Accident Causation Model (OACM). Methodological developments in other approaches, eg, group-based approaches in Significant Event Auditing (SEA), might also be transferable.

Recommendations

Our reviews demonstrate considerable potential for further development of techniques, the utilization of a wider range of techniques, and a need to validate and evaluate existing methods. This would make incident investigation more versatile and use resources more effectively.

Methods

Twelve techniques from other high-risk industries were reviewed using criteria developed for the purpose. Initial searches of healthcare databases identified 1950 potentially relevant papers. After screening the abstracts, 562 papers were obtained for further review. Further screening identified 152 papers for formal appraisal, and a further 104 contained useful background information. A formal appraisal instrument was designed, piloted, and modified until reliability was acceptable. From the 152 papers, 6 techniques were found to represent clearly definable approaches to incident investigation and analysis. We excluded techniques used in fewer than 5 peer-reviewed, published studies. All relevant papers, to a maximum of 10, were reviewed for each of the 6 techniques: Australian Incident Monitoring System (AIMS), the Critical Incident Technique, SEA, RCA, OACM, and Comparison with Standards approach.

Further research/reviews required

Further exploration of techniques used in high-risk industries, with interviews and observation of actual investigations, should prove valuable. Existing healthcare techniques would benefit from formal evaluation of their outcomes and effectiveness. Studies should examine depth of investigation and analysis, adequacy and feasibility of recommendations, and cost effectiveness. Examining the implementation of recommendations is a key issue. The principal recommendations are:

- *Define techniques and provide manuals and guidelines.* Need to develop manuals and describe methods of investigation and analysis, detailing purpose, context, and process.
- *Resources and need for training.* Healthcare professionals need training and experience in investigations. Local teams need time to report on implementing change.
- *Implement change.* Researchers and investigation teams need to give more attention to recommendations for and implementation of change. Need to link findings to prevention.
- *Integrate techniques.* Investigators of clinical incidents need 'tool-box' of approaches, ie, specific techniques for different purposes and at different stages of an investigation.

Written by Dr Maria Woloshynowych, Clinical Safety Research Unit, Imperial College London, UK

Title **The British Rheumatoid Outcome Study Group (BROSG) Randomized Controlled Trial to Compare the Effectiveness and Cost Effectiveness of Aggressive Versus Symptomatic Therapy in Established Rheumatoid Arthritis**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(34). Sept 2005. www.ncchta.org/execsumm/summ934.htm

Aim

To examine the effectiveness and cost effectiveness of symptomatic versus aggressive treatment in patients with established (>5 years disease) stable rheumatoid arthritis (RA).

Conclusions and results

Significant deterioration was found in the healthcare assessment questionnaire (HAQ) score in both arms. No significant difference was found between the treatment arms for any of the primary or secondary outcomes except for the physician global assessment (adjusted mean difference 3.76 (95% CI 0.03, 7.52)) and the OSRA disease activity component (adjusted mean difference 0.4 (95% CI 0.01, 0.71)), both favoring the aggressive treatment arm. The symptomatic arm was associated with higher costs and higher quality adjusted life years (QALYs) gained. There was a net cost of £1517 per QALY gained for the symptomatic arm. Overall symptomatic treatment is likely to be cost effective in 58% to 90% of cases. Patients with stable, established RA continue to deteriorate despite treatment.

Recommendations

The trial showed no benefit of aggressive over symptomatic treatment in these patients. Patients in the symptomatic arm were able to initiate changes in treatment when indicated. Approximately one third of current clinic attenders with RA could be managed in a shared care setting with annual review by a rheumatologist.

Methods

Consenting patients were randomized to either symptomatic or aggressive therapy. Symptomatic therapy aimed to relieve all symptoms of pain and stiffness using analgesics, nonsteroidals, traditional disease-modifying, antirheumatic therapy (DMARD), and steroids as necessary. The symptomatic arm was delivered predominantly in the community by a rheumatology nurse with annual review by a consultant rheumatologist. Aggressive therapy aimed to relieve symptoms and signs of joint inflammation and to keep the C-reactive protein (CRP) below twice the upper limit of normal. The aggressive arm was delivered in the hospital clinic. All patients completed a diary that was used in the economic analysis.

Further research/reviews required

The following questions should be addressed:

- Patients with stable, established RA might benefit from even more aggressive treatment, eg, with one of the new anti-TNF drugs.
- Patients managed in shared care might not need regular visits from a rheumatology nurse. Telephone contact might suffice.

Written by Professor Deborah Pauline Mary Symmons, ARC Epidemiology Unit, University of Manchester, UK

INAHTA Briefs

Issue 2006/07

Title **Is Hydrotherapy Cost Effective? The Costs and Outcomes of Hydrotherapy Programs Compared with Physiotherapy Land Techniques in Children with Juvenile Idiopathic Arthritis**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(39). Oct 2005. www.ncchta.org/execsumm/summ939.htm

Aim

1. To compare the effects of *combined* hydrotherapy and land physiotherapy with *land* physiotherapy alone on cost, quality of life, and disease outcome in children with juvenile idiopathic arthritis (JIA).
2. To determine the cost effectiveness of combined hydrotherapy and land physiotherapy in JIA.

Conclusions and results

Primary outcomes: Seventy-eight patients were recruited to the trial and received treatment. Two months after intervention, 47% in the *combined* group and 61% in the *land* group had improved, and 11% and 5% respectively had become worse. The difference in proportions of patients that improved in the 2 arms, with continuity correction for observed differences, was -0.11 (95% CI -0.34, 0.12). The central estimate suggests that 11% more patients benefit under land treatment. Cost-effectiveness analysis showed no significant differences in mean costs and QALYs between the two groups. The combined group had slightly lower mean costs and lower mean QALYs. Small sample size and degree of disease severity were limitations in the trial. Recruitment did not reach the original target since patients at the severe end of the disease spectrum were excluded as their management was not constant, a pharmaceutical intervention trial with similar entry criteria was run simultaneously in JIA, and some children and their parents did not want hydrotherapy withdrawn. Hence, the sample was biased toward less serious disease with data skewed toward the norm. Extrapolating these results to a wider JIA population is not advisable due to selection criteria and sample size. The findings show that physiotherapy is a safe intervention that can improve outcome in JIA, an incurable disease with limited treatment options.

Recommendations

Either treatment has the potential to benefit the child with JIA, although no clear difference was established between the efficacy or cost of the two treatments. In the absence of such evidence, it could be argued that if one treatment is more enjoyable and improves compliance with exercise, then this should be the treatment of choice. Further research would be needed to determine if the costs of building new hydrotherapy pools is justifiable or cost effective in the long term.

Methods

We devised a multicenter randomized controlled, partially blinded trial with 100 patients in a control arm receiving land physiotherapy only (land group) and 100 patients in an intervention arm receiving a combination of hydrotherapy and land physiotherapy (combined group). Patients in the land group had 16 one-hour sessions of land-based physiotherapy at a trial center over 2 weeks. They then received land physiotherapy once a week or fortnight for 2 months, as outpatients. Community physiotherapists used their clinical judgment to decide whether a patient's treatment should continue or stop, but were asked to exclude hydrotherapy until a 6-month assessment had been completed. Swimming was not excluded from patients' usual activities. Patients in the combined group had 8 one-hour sessions of hydrotherapy, and 8 one-hour sessions of land physiotherapy at a trial center over 2 weeks. They then received hydrotherapy only, once a week or fortnight for 2 months, as outpatients. The intervention protocol was standardized and all physiotherapists trained in its administration. Intervention was terminated or modified only if treatment exceeded the study protocol, medical complications occurred, surgery was required, disease flared or became unstable.

Further research/reviews required

(see Recommendations)

Written by Dr Heather Epps, Paediatric Physiotherapist & Cons in Hydrotherapy, Tadworth Children's Trust, UK

INAHTA Briefs

Issue 2006/08

Title **Randomized Controlled Trial and Cost Effectiveness Study of Targeted Screening Versus Systematic Population Screening for Atrial Fibrillation in the Over 65s: the SAFE Study**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

Reference Health Technol Assess 2005;9(40). Oct 2005. www.ncchta.org/execsumm/summ940.htm

Aim

To determine the rate of new cases of atrial fibrillation (AF) detected by various screening strategies and to evaluate the incremental cost effectiveness of the screening strategies compared to routine clinical practice in detecting AF in people aged 65 and over. Other aims were to:

- evaluate the relative cost effectiveness of screening methods for AF diagnosis
- evaluate the most cost-effective method of test interpretation
- assess different combinations of screening strategies and procedures
- calculate company prevalence and incidence of AF in people aged 65+
- evaluate the value of clinical assessment and echocardiography in risk stratification
- evaluate the implications of national AF screening and identify the optimum algorithm.

Conclusions and results

Total patients in each arm: Control 4936, Opportunistic screening 4933, Systematic screening 4933. Baseline prevalence of AF was 7.2%, with higher prevalence in males (7.8%) and patients aged 75 and over (10.3%). The control population showed higher baseline prevalence (7.9%) than either the systematic (6.9%) or opportunistic (6.9%) intervention populations. In the control population 47 new cases were detected (incidence 1.04% per year). In the opportunistic arm 243 patients without a baseline diagnosis of AF had an irregular pulse, with 177 having an ECG, yielding 31 new cases (incidence 0.69% per year). A further 44 cases were detected outside the screening program (overall incidence 1.64% per year). In the systematic arm, 2357 patients had an ECG, yielding 52 new cases (incidence 1.1% per year). Of these, 31 were detected by targeted screening and 21 by total population screening. A further 22 cases were detected outside the screening program (overall incidence 1.62% per year). Regarding ECG interpretation, computerized decision support software (CDSS) gave a sensitivity of 87.3%, a specificity of 99.1%, and a positive predictive value (PPV) of 89.5% compared to the gold standard (cardiologist reporting). GPs and practice nurses performed less well. Practice nurses from the control arm performed less well on interpretation compared to intervention practice nurses of limb lead (PPV 38.8% vs 20.8%) and single lead (PPV 37.7% vs 24.0%) ECGs. The opportunistic arm cost £337 for each extra case detected compared to the control arm, while the systematic screening arm was dominated.

Recommendations

Prevalence of AF in this population was found to be 7.2%. Incidence ranged from 1.04% to 1.64% per annum. In terms of a screening program, opportunistic screening was the only strategy that improved on routine practice, at a cost of £337 per case detected.

Methods

This was a multicenter, randomized controlled trial of patients aged 65 and over from 50 primary care centers. Selected general practices were randomly allocated to 25 intervention and 25 control practices. GPs and nurses in the intervention practices received education on the importance of AF detection and ECG interpretation. Patients in the intervention practices were randomly allocated to systematic (n=5000) or opportunistic screening (n=5000). Prospective identification of pre-existing risk factors for AF in the screened population enabled comparison between targeted screening of those at higher risk of AF and total population screening. AF detection rates in the systematic and opportunistic screening populations in intervention practices were compared to the AF detection rate in 5000 patients in the control practices. The screening period was 12 months.

Further research/reviews required

None given.

Written by Prof David Fitzmaurice, Dept of Primary Care and General Practice, University of Birmingham, UK

Title	**Effect of Oseltamivir (Tamiflu®) for the Prevention and Treatment of Influenza During an Influenza Pandemic**
Agency	**NOKC, Norwegian Knowledge Centre for the Health Services** PO Box 7004, St Olavs plass, NO-0130 Oslo, Norway; Tel: +47 23 25 50 00, Fax: +47 23 25 50 10; www.nokc.no
Reference	Report no 1/2005. ISBN 82-8121-017-6. Summary and Conclusions in English, and full-text report in Norwegian are available on www.nokc.no

Aim

- To assess the effects of the neuraminidase inhibitor oseltamivir (Tamiflu®) in preventing and treating influenza.
- To evaluate the cost effectiveness of oseltamivir, with special reference to an influenza pandemic.

Conclusions and results

Oseltamivir reduces the duration and severity of illness in previously healthy adults and children with laboratory-confirmed influenza. The frequencies of secondary complications such as bronchitis, sinusitis, otitis media, and pneumonia, in addition to antibiotic use, were also reduced in the study population. Using oseltamivir for prophylaxis provides a protective effect of 55% to 89% against laboratory-confirmed influenza in healthy adults and children. The adverse events (nausea and vomiting) of oseltamivir were transient and were mild to moderate. Oseltamivir prophylaxis for 6 weeks, covering the entire Norwegian population, implies a cost of 1900 million Norwegian kroner (NOK), whereas treatment for 5 days (attack rate 40%) implies a cost of NOK 180 million.

Methods

The report consists of a systematic review of studies published from 1980 to October 2004. Relevant databases that were searched were the Cochrane Library, Database of Abstracts of Reviews of Effectiveness (DARE), International Network of Agencies for Health Technology Assessment (INAHTA) database, National Guidelines Clearinghouse, MEDLINE and EMBASE. In total, 66 potentially relevant studies were assessed, and 15 studies and 2 sets of guidelines were included in the report.

Further research/reviews required

Studies on resistance to oseltamivir are insufficient, in particular among patients treated with oseltamivir. It is important to know if oseltamivir-resistant mutants are infectious.

Written by Ellen M Nilsen et al, NOKC, Norway

Title **Bed Sharing, Pacifier, Breastfeeding and Cot Death – Is There an Association?**

Agency **NOKC, Norwegian Knowledge Centre for the Health Services**
PO Box 7004, St Olavs plass, NO-0130 Oslo, Norway;
Tel: +47 23 25 50 00, Fax: +47 23 25 50 10; post@kunnskapssenteret.no

Reference Report no 5-2005. ISBN 82-8121-049-4, ISSN 1503-9544. Summary and conclusions in English, and full text report in Norwegian available: www.kunnskapssenteret.no

Aim

To systematically review studies that had evaluated newborns and infants and the effect of sleeping alone or in the parents' bed, pacifier use, and/or breastfeeding. Outcomes were breastfeeding rates and cot death.

Conclusions and results

Forty studies that met the inclusion criteria were included. Only a few studies compared groups that were randomly allocated to one intervention or another. Hence, it is difficult to determine causation.

Because of the limitations in study design we cannot draw any firm conclusions about the factors we investigated. There is an increased risk for cot death with bed sharing if the mother has smoked during pregnancy. It is uncertain whether the risk of cot death is reduced with breastfeeding or with pacifier use, if co-sleeping encourages breastfeeding, if bed sharing is associated with increased risk of cot death in infants older than 8 weeks of age, or if the use of pacifiers influences overall breastfeeding. It is unclear whether bed sharing with newborns less than 8 weeks of age is harmful.

Methods

We systematically searched for studies of experimental and observational design in the following databases: Cochrane Library, MIDIRS, Cinahl, EMBASE, MEDLINE and SweMed, June 2004. The search was updated in February 2005.

Further research/reviews required

More randomized controlled trials are needed to investigate whether early introduction to pacifiers interferes with breastfeeding duration or the rates of full and partial breastfeeding. It is unlikely, but not impossible, to conduct randomized trials that investigate the effects of pacifiers and bed sharing on cot death. Such studies would need a very large number of participants.

Written by Liv Merete Reinar, NOKC, Norway

INAHTA Briefs

Issue 2006/11

Title	**Transfusion Versus Alternative Treatment Modalities in Acute Bleeding**
Agency	**NOKC, Norwegian Knowledge Centre for the Health Services** PO Box 7004, St Olavs plass, NO-0130 Oslo, Norway; Tel: +47 23 25 50 00, Fax: +47 23 25 50 10; www.nokc.no
Reference	Report no 8-2005. ISBN 82-8121-053-2. Report in Norwegian and English summary: www.kunnskapssenteret.no/filer/Rapport8-05_transfusjon.pdf

Aim

- To study the role of transfusion in treating acute bleeding by assessing the evidence base for transfusion vs other options (treatment within 24 hours after onset).
- To gain an overview of the side effects associated with transfusion and the legal and ethical considerations related to hemotherapy.

Conclusions and results

Blood replacement. Albumin was not found to be more effective than colloids or crystalloids in fluid therapy for acute hemorrhage. No difference in effect was found between colloids and crystalloids.

Oxygen transport. Strong evidence shows that young, healthy individuals tolerate reduced hemoglobin concentration. At very low hemoglobin concentrations, reduced muscle power, fatigue and lightly reduced cognitive function can be observed, but this is normalized soon after retransfusion of one's own blood. No research has shown that blood-banked erythrocytes have the same effect whether used immediately or after hours of storage.

Good evidence supports restrictive use of erythrocytes in intensive care, but there are reservations in using erythrocyte concentrates containing leucocytes. Studies indicate the need for a higher threshold value of hemoglobin in treating patients with unstable angina pectoris/myocardial infarction, but evidence is inconsistent. No evidence was found for replacing transfusion of erythrocytes with artificial oxygen carriers.

Hemostasis. Good evidence shows that fibrinolytic agents reduce the need for transfusion during acute hemorrhage. There is low evidence that freshly frozen plasma/Octaplas® reduces the need for transfusions. The same applies to the use of specific coagulation factors. The future clinical use of recombinant factor VIIs is unclear. Since the results of published studies diverge, no firm conclusion about effect can be drawn. No relevant studies were found on transfusion of thrombocytes used in acute hemorrhage.

Conclusions. The evidence base for hemotherapy (except for fibrinolytic drugs that reduce the need for transfusion) is generally weak, and especially weak for the transfusion of erythrocytes and thrombocytes. The quality of transfusion products stored in blood banks is uncertain. The increasing mean age of the population and the increasing number of therapeutic options may indicate that the need for blood products will remain stable over time.

Methods

The review team systematically reviewed the published literature. Three pairs of reviewers evaluated the literature review. The assessment involved steps starting with 2438 abstracts and ending with 79 studies (81 references) approved as the evidence base. The Norwegian Board of Health provided information on legal aspects, and the report includes a statement by Jehovah's Witnesses.

The literature search included the MEDLINE, EMBASE, and Cochrane databases. No groups of patients should be excluded. The studies should include interventions to replace lost blood, ensure sufficient oxygen delivery to the tissues and drugs or other methods used to achieve good hemostasis. Outcomes were length of hospital stay, survival, complications, and use of blood products. The literature search was updated on January 13, 2005.

Further research/reviews required

It is considered a high priority for the Norwegian and international field of transfusion medicine to improve the evidence base for hemotherapy.

Written by Lise Lund Håheim, NOKC, Norway

Title **Palliation of Cancer Pain**

Agency **NOKC, Norwegian Knowledge Centre for the Health Services**
PO Box 7004, St Olavs plass, NO-0130 Oslo, Norway;
Tel: +47 23 25 50 00, Fax: +47 23 25 50 10; www.nokc.no

Reference Report no 9/2005. ISBN 82-8121-075-3, ISSN 1503-9544.

Aim

To assess the scientific evidence on the analgesic efficacy of medication and radiotherapy in palliative treatment of cancer-related pain. Also assessed were the economic, organizational, ethical, and legal aspects of these treatment methods, with particular reference to the Norwegian healthcare system.

Conclusions and results

Opioid analgesics are effective in relieving moderate to severe cancer pain. No differences in analgesic efficacy of different opioids, formulations, or routes of administration have been demonstrated. Morphine remains the drug of choice. Nonsteroid anti-inflammatory drugs (NSAIDs) are effective in relieving moderate cancer pain, and there seems to be no differences in analgesic efficacy between different drugs or when NSAIDs are combined with weak opioids. Documentation of the analgesic efficacy of paracetamol on cancer-related pain is sparse. Current data are inconclusive regarding the analgesic effect of adjuvant analgesics, palliative chemotherapy, and hormones. There is evidence to support that bisphosphonates provide a weak or moderate analgesic effect on pain from bone metastases. Intraspinal/epidural analgesics and neurolytic blockades, both invasive methods, are effective in relieving cancer pain in selected patients. External radiation therapy and radionuclides are effective in relieving cancer pain in patients with bone metastases. Single dose (unfractionated) radiation is equally effective as fractionated radiation for bone pain, but at a lower cost.

Methods

A systematic review focused on clinical evidence from studies reporting on cancer pain treatment identified through 2 evidence reports from the Agency for Healthcare Results and Quality (AHRQ, USA) published in 2001 and 2002 and 10 Cochrane reviews and additional MEDLINE-recorded studies published between 2001 and 2003 (own literature assessment). Randomized controlled trials and meta-analyses were selected. However, comparative case series were included for treatment procedures where studies of higher evidence level were lacking. The collected documentation included 300 studies. Results were summarized according to 10 treatment categories.

Further research/reviews required

This systematic review shows that although a significant body of research has been identified, available documentation has failed to produce a clear answer to key questions in the management of cancer pain, demonstrating the need for further research. Future trials should agree on common criteria for reporting of pain response.

Written by Anita Lyngstadaas, NOKC, Norway

INAHTA Briefs

Issue 2006/13

Title **The ^{13}C-Urea Breath Test for Detection of *Helicobacter pylori*: Potential Applications in Québec**

Agency **AETMIS, Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé**
2021, avenue Union, bureau 1040, Montréal, Québec, Canada H3A 2S9;
Tel: +1 514 873 2563, Fax: +1 514 873 1369; aetmis@aetmis.gouv.qc.ca, www.aetmis.gouv.qc.ca

Reference Technology brief prepared for AETMIS (AETMIS 05-05). Internet access to full text.
Printed version: ISBN 2-550-45843-5; PDF: ISBN 2-550-45844-3

Aim

To examine the different methods for detecting *Helicobacter pylori* and to assess the pertinence of increasing the use of the ^{13}C-Urea breath test in Québec.

Conclusions and results

H. pylori bacteria, which is estimated to infect the stomachs of between 20% and 40% of Canadians, plays an important role in the pathogenesis of gastroduodenal disorders such as gastritis, peptic ulcers, and gastric cancers. Invasive tests such as endoscopy with biopsies can effectively detect the bacteria, but these tests are costly and uncomfortable for the patient.

Four non-invasive tests for detecting the bacteria have attracted interest. 1) The antibody test has a good negative predictive value, but also a high rate of false-positive results. 2) The stool antigen test performs well at low cost, but interest in its use is currently dampened by doubts about patient and clinician compliance and inter-laboratory variability. 3 & 4) The ^{14}C (radioactive) and ^{13}C (non-radioactive) urea breath tests achieve virtually identical results. The literature supports the superiority of these two tests over the two other non-invasive tests.

The urea breath tests are done on samples of exhaled air before and after ingestion of urea containing specially labeled carbon. The quantity of labeled carbon in a sample of exhaled air determines the presence of active *H. pylori* infection in the stomach. The radioactive ^{14}C test has to be administered in hospitals with nuclear medicine facilities. The ^{14}C and ^{13}C tests cost approximately the same to administer (between $40 and $120 per test), but because ^{13}C is not radioactive (requiring only a mass spectrometer for sample analysis), it can be administered much more widely. The ^{13}C test has only been offered publicly in Québec since April 2005, and is not yet well known.

Recommendations

The ^{13}C-Urea breath test should be available in healthcare institutions in all regions of Quebec. Clinicians should be informed of the availability of the test and encouraged to participate in defining its optimal use.

Method

Literature search.

Further research/reviews required

All forms of testing for *H. Pylori* should be periodically re-evaluated.

Written by Lonny Erickson, AETMIS, Canada

Title **Transferring Managed Care Principles to VHA: A Summary and Discussion of the Evidence for the Effectiveness of Managed Care and Managed Care Practices**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Report, July 1996

Aim

To identify managed care principles and practices that enable the U.S. Department of Veterans Affairs (VA) to improve its efficiency and effectiveness while providing quality primary healthcare.

Conclusions and results

Three critical areas of managed care were: 1) the overall performance of managed care organizations, 2) the effectiveness of practices for changing physician behavior, and 3) interventions to increase the quality and the efficiency of primary care. Other areas addressed were the organizational structures that support primary care within managed care and the potential reductions in healthcare costs associated with health promotion and disease prevention. The results identified the following primary managed care principles: focus on primary care with the goal of improving the health of the enrolled population; aligning incentives to the well-being of the enrolled population; and practicing evidence-based clinical medicine. The managed care practices needed to implement these principles included careful selection of the numbers and types of physicians in relation to the needs of the population served, use of primary care physicians as gatekeepers, incorporation of utilization review, and management and use of education and feedback to influence physician behavior and bring about change.

Recommendations

VA has already begun to adopt managed care practices, but would benefit from addressing specific areas such as the ethical dilemmas that may be associated with managed care, effective healthcare services and delivery mechanisms, quality management, and explicit change management strategies.

Methods

A synthesis of research findings and contacts with staff- and group-model health maintenance organizations were used. Literature searches of the empirical research were conducted using databases maintained by the VA Health Services Research and Development Service Management Decision and Research Center and the National Library of Medicine. Search strategies addressed the effectiveness of managed care, specific managed care practices, and managed primary care. The synthesis relied heavily on existing systematic reviews of the analytic literature. Three high-quality systematic reviews and two of slightly lesser rigor were identified.

Further research/reviews required

Suggested areas for research are discussed in detail in the report.

Written by Karen Flynn, VATAP, USA

Title **Positron Emission Tomography: Descriptive Analysis of Experience with PET in VA and Systematic Reviews of FDG-PET as a Diagnostic Test for Cancer and Alzheimer's Disease**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Report, October 1996

Aim

To evaluate the experience of the U.S. Department of Veterans Affairs (VA) with positron emission tomography (PET) scanning and to determine whether VA should lift its purchasing moratorium and establish additional PET centers.

Conclusions and results

Researchers at VA credited PET as an important research tool. A wide range of research and clinical activities in VA PET centers remains largely uncoordinated. Research into the clinical utility of PET for the conditions selected in this review is preliminary and methodologically weak. Critical research into defining the clinical consequences of using PET for diagnosis has yet to be performed or reported.

Recommendations

The U.S. Department of Veterans Affairs should not invest in additional PET centers at this time. Rather, it should maximize the value of existing commitments, including implementing a PET registry, coordinating research efforts across VA PET centers and their academic affiliates, supporting rigorously designed studies that expand the body of PET literature and submitting currently unpublished data from studies of high methodologic quality for peer review publication.

Methods

Surveys and site visits were conducted of VA PET centers to gather data on clinical diffusion, operations, and research activities related to PET. A qualitative systematic review of published literature of PET in diagnosing selected cancers (head and neck, breast, lung, colorectal) and Alzheimer's disease was undertaken. Comprehensive literature searches were conducted using MEDLINE and other databases from 1991 through 1995, with focused hand searching of reference lists and selected literature searches from 1986 through 1991. Primary studies and systematic reviews published in English using fluorodeoxyglucose-positron emission tomography (FDG-PET) for selected indications were included and a critical appraisal framework was applied.

Further research/reviews required

See recommendations.

Written by Karen Flynn and Elizabeth Adams, VATAP, USA

Title **Shared Decision-Making Programs: A Descriptive Analysis of VA Experiences and A Systematic Review of the Evidence of Shared Decision-Making Programs for Prostate Care**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Report Number 6, July 1997

Aim

To evaluate the effectiveness and use of shared decision-making programs (SDP) for prostate disease.

Conclusions and results

A comprehensive search of the peer-reviewed published literature resulted in 3 relevant articles. These studies used SDP in benign prostatic hyperplasia (BPH), prostate specific antigen (PSA) screening, and prostate cancer. Patients with BPH who used SDP were more knowledgeable about their condition, more satisfied with the decision-making process, and showed less deterioration in their perceived general health and physical functioning than patients who received an informational brochure. In addition, patients responded favorably to SDP and reported that the program was clear, balanced, had the right amount of information, and was the right length. Patients using SDP for PSA screening were more knowledgeable about prostate cancer and screening, more likely to prefer watchful waiting, less likely to plan to have PSA screening within the next 2 years, and had less PSA screening at the next episode of care. Patients with prostate cancer who used SDP were willing to face uncertainty regarding treatment choices and actively shared in the decision-making process. The importance of patient preference in decision making was demonstrated.

Recommendations

Shared decision-making programs support patient involvement in health care, are well received by patients, and can be used with a wide range of patients.

Methods

A comprehensive literature search was conducted using MEDLINE, PREMEDLINE, HealthSTAR, EMBASE, Cinahl, and CancerLit from 1966 through 1997. Search strategies included the following terms: patient participation, decision making, shared decision making, prostate, prostatic hyperplasia, benign prostatic hyperplasia, and prostate neoplasm. The search included original research with clearly described methods published in English. Expert opinion was also obtained from representatives of the Foundation for Informed Medical Decision Making, VA providers, and researchers with extensive experience using SDP.

Further research/reviews required

Future research is needed to assess the long-term impact of SDP on the cost and quality of health care.

Written by Diana Anderson, VATAP, USA

INAHTA Briefs

Issue 2006/17

Title **Picture Archiving and Communication Systems: A Systematic Review of Published Studies of Diagnostic Accuracy, Radiology Work Processes, Outcomes of Care, and Cost**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Report, August 1997

Aim

To evaluate the clinical performance and economics of picture archiving and communications systems (PACS).

Conclusions and results

The results suggest that radiology should be the service area in which to pilot the use of information technologies to improve clinical production and efficiency. To date, PACS workstation imaging has not been demonstrated to be equivalent to conventional film for accurate primary diagnosis of all types of illnesses that present in the veteran population. The data suggest that generating, retrieving, and delivering images and starting patient treatment are performed more rapidly in a PACS environment. No study demonstrated that the use of PACS improved patient outcomes or decreased costs. It remains to be demonstrated if PACS result in more efficient clinical and production processes, or if those efficiencies translate into improved quality, increased access, or reduced cost of health care.

Recommendations

Evidence of the productivity, efficiency, or cost effectiveness of picture archiving and communications systems does not answer critical questions about this technology.

Methods

A systematic review of the literature was conducted using MEDLINE, Health Planning Administration databases, EMBASE and Current Contents Institute for Scientific Administration from 1990 through 1997. The search included the following terms: PACS, teleradiology, telemedicine, radiology, and radiology information systems. Twenty-two studies met the inclusion criteria in the following areas of study: diagnostic accuracy, process efficiency, clinical and patient outcomes, and cost savings.

Further research/reviews required

High-quality studies of the effectiveness, outcomes, and cost benefit of picture archiving and communication systems are needed. Suggested areas for research are discussed in detail in the report.

Written by Diana Anderson and Karen Flynn, VATAP, USA

Title **Stereotactic Radiosurgery for Metastases to the Brain: A Systematic Review of Effectiveness**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Report, December 1997

Aim

To evaluate the effectiveness of stereotactic radiosurgery in treating metastases to the brain.

Conclusions and results

The available data from case series suggest that stereotactic radiosurgery is a relatively safe and effective technology for definitive treatment of brain metastases in selected patients. Stereotactic radiosurgery provides greater survival benefits than traditional whole-brain radiotherapy. Stereotactic radiosurgery may be comparable to surgery plus radiation therapy in treating patients with smaller solitary metastases. Stereotactic radiosurgery can be used to treat patients whose metastases recur after traditional therapies have been tried. The patients that benefit most from stereotactic radiosurgery are highly functional patients with well-controlled systemic cancers.

Recommendations

Current evidence is insufficient to draw any definite conclusions about the effectiveness of stereotactic radiosurgery compared to standard treatment for brain metastases. No conclusions regarding optimal equipment selection, treatment parameters, or patient selection criteria can be made at this time.

Methods

Comprehensive literature searches were conducted using MEDLINE, PREMEDLINE, Health Planning and Administration, HealthSTAR, EMBASE, and Current Contents from 1991 through 1997. Search strategies used the following terms: radiosurgery or stereotactic radiosurgery combined with brain neoplasm, controlled clinical trials, meta-analysis, multicenter studies, or practice guidelines. The searches yielded 748 references of which 90 were deemed to be relevant, and their full text was reviewed. Thirteen case series met the inclusion criteria and were included in this report.

Further research/reviews required

Additional research is needed to determine the true effectiveness of using stereotactic radiosurgery in patients with metastatic brain cancer. Randomized clinical trials are currently under way.

Written by Diana Anderson and Karen Flynn, VATAP, USA

Title **Stereotactic Pallidotomy for Treatment of Parkinson's Disease**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Report, February 1998

Aim

To evaluate the effectiveness and appropriateness of stereotactic pallidotomy in treating Parkinson's disease (PD).

Conclusions and results

Six case series addressed pallidotomy without mapping and seven evaluated pallidotomy with mapping. None compared the outcomes of pallidotomy without mapping to pallidotomy with mapping. The evidence of pallidotomy with and without mapping suggested favorable clinical outcomes as measured by elimination or alleviation of dyskinesia, significant improvement in Parkinsonian signs, and higher score in activities of daily living. However, the data are insufficient to conclude that the benefits of pallidotomy in terms of safety and efficacy outweigh the risks.

Recommendations

Pallidotomy should be performed in specialized centers with expertise in neurology and neurosurgery.

Methods

Comprehensive literature searches were conducted using MEDLINE and Current Contents from 1989 through 1997. Search strategies used the term pallidotomy and the subject headings for therapeutic electrical stimulation and globus pallidus. English language studies that reported clinical outcomes for PD patients after treatment with pallidotomy were included. A comprehensive search of the peer-reviewed published literature resulted in 13 relevant case series.

Further research/reviews required

Large-scale randomized clinical trials are needed to determine the efficacy of pallidotomy.

Written by Amy Kottler and Diane Hayes, HAYES Inc, USA

Title **Endovascularly Placed Grafts for Infrarenal Abdominal Aortic Aneurysms: A Systematic Review of Published Studies of Effectiveness**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Report, May 1998

Aim

To evaluate the effectiveness of endovascularly placed grafts for the repair of aortic and carotid artery disease.

Conclusions and results

Twenty relevant studies, which were predominately case series, met inclusion criteria for review. Sixteen studies were of endovascular technologies for treating infrarenal abdominal aortic aneurysms (AAA) and constituted the main focus of the review. The resulting evidence base is methodologically inadequate for determining if endovascular repair of infrarenal AAA result in lower morbidity, mortality, and/or healthcare costs for: a) patients eligible for either endovascular repair or standard open surgical repair, b) patients ineligible for standard open surgical repair due to the presence of severe comorbid medical conditions, and c) patients who have small, asymptomatic nonexpanding AAA who are managed through watchful monitoring followed by standard open surgical repair when indicated.

Recommendations

No definitive conclusions regarding the effectiveness of endovascular graft repair of infrarenal AAA can be drawn from the existing body of evidence. The critical question regarding the potential to overutilize a minimally invasive treatment option in patients with marginal indications for surgery needs to be addressed.

Methods

Comprehensive literature searches were conducted using MEDLINE, HealthSTAR, and Current Contents from 1993 through 1998. Search strategies used the following terms: aortic aneurysm, aortic aneurysm, abdominal, carotid stenosis, stent, and minimally invasive. The searches yielded 555 articles. This review included studies on the effectiveness of endovascular repair of AAA published since 1990 in English and which used sufficient methods.

Further research/reviews required

Future research is needed to determine if endovascular repair is preferable to alternative interventions for patients eligible or ineligible for standard open surgical procedure or patients with small aneurysms.

Written by Dr Dennis A Bertram, State University of New York at Buffalo, USA

Title **Positron Emission Tomography Update: Descriptive Analysis of Experience with PET in VA and Systematic Reviews of FDG-PET as a Diagnostic Test for Cancer and Alzheimer's Disease**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Report, December 1998

Aim

To track the published literature on clinical positron emission tomography (PET) and the use of PET in the Veterans Health Administration (VHA) since 1996 to support optimal clinical use and resource allocation for provision of PET services in VA.

Conclusions and results

Recent changes in FDA regulation of PET drug products and expansion of Medicare coverage has helped fuel interest in clinical PET. VA experience confirms the importance of PET as a basic research tool and a growing interest in its diagnostic capability. Existing evidence on either traditional or modified PET as a routine diagnostic test in selected applications is preliminary and methologically flawed. Variations in study populations, imaging protocols, and methods for defining disease on PET images may limit the generalizability of findings across institutions. Systematic reviews from other agencies using similar review methods underscore the deficiencies in PET literature and the need for further clinical research.

Recommendations

Clinicians should await the results of ongoing or planned cooperative trials, including a VHA Cooperative Study of PET in managing solitary pulmonary nodules, before incorporating PET into routine diagnostic strategies. VA should maintain its moratorium on additional PET centers at this time.

Methods

Surveys were conducted of VA PET centers to gather data on clinical diffusion, operations, and research activities related to PET since 1996. A qualitative systematic review of published literature of PET in diagnosing selected cancers (head and neck, breast, lung, colorectal) and Alzheimer's disease was undertaken. Comprehensive literature searches were conducted using MEDLINE and other databases from September 1996 through July 1998, with hand searching of reference lists. Primary studies and systematic reviews published in English using fluorodeoxyglucose-positron emission tomography (FDG-PET) for selected indications were included, and a critical appraisal framework was applied.

Further research/reviews required

Rigorous prospective research is needed on the clinical consequences of PET in the routine diagnostic workup, and several cooperative studies are under way.

Written by Elizabeth Adams and Karen Flynn, VATAP, USA

Title **Treatment Options for Male Erectile Dysfunction: A Systematic Review of Published Studies of Effectiveness**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Report No 11, January 1999

Aim

To evaluate the efficacy and safety of treatment options for male erectile dysfunction, focusing on new FDA-approved therapies with the greatest resource and clinical implications for the U.S. Department of Veterans Affairs (VA).

Conclusions and results

A comprehensive search of the peer-reviewed published literature yielded studies on oral/transdermal therapies such as sildenafil (Viagra), yohimbine (Yocon, Yohimex, Aphrodyne, Erex), phentolamine (Vasomax), trazodone (Desyrel), aminophyllline+isosorbide dinitrate+co-dergocrine, buflomedil transdermal electromotive administration, intraurethral alprostadil (MUSE), intracavernous injections such as alprostadil (Caverject), phentolamine+papaverine, alprostadil+phentolamine+papaverine (Trimix), and apomorphine, a treatment under development. The results indicate that: a) educating the patient and partner about the advantages and disadvantages of commonly used treatments is important; b) most patients desire a convenient noninvasive therapy such as oral medication; c) psychosexual counseling may be helpful in patients with psychogenic erectile dysfunction; and d) vacuum constriction devices, intrauretrhal and intracavernosal vasoactive drug injection therapy, surgical implantation of a penile prosthesis and oral medications are effective treatments for primary organic erectile dysfunction.

Recommendations

VA acknowledges that vacuum constriction devices, intraurethral and intracavernosal vasoactive drug injection therapy, surgical implantation of a penile prosthesis, and oral medications are effective treatments for primary organic erectile dysfunction. Oral medications are not recommended for use without restrictions in the VA population at the present time.

Methods

Comprehensive literature searches of randomized clinical trials published in English from 1995 through 1999 were conducted using MEDLINE, HealthSTAR, EMBASE, Current Contents and Cochrane computer databases. Search strategies used the following terms; impotence and erectile dysfunction, with the following subheadings; therapy, drug therapy, surgery, and disease management. The result was combined with clinical trials, controlled trials, randomized controlled trials, meta-analyses, guidelines, academic or systematic reviews, and multicenter studies. Information was also included from patient preference studies, postmarketing reports, product inserts, and FDA MedWatch announcements.

Further research/reviews required

Suggested areas for research are discussed in detail in the report.

Wilt TJ, Fink HA, MacDonald R, Rutks IR, and Schow D,
the VA Cochrane Collaborative Review Group on Prostatic Diseases and Urologic Cancers, Minneapolis, USA

Title **Physiologic Telemonitoring in Congestive Heart Failure**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Short Report, Number 5, January 2001

Aim

To determine the effectiveness of physiologic telemonitoring in patients with congestive heart failure (CHF).

Conclusions and results

Do telephone management protocols for patients with CHF diminish hospitalizations and emergent care visits for CHF, improve patient satisfaction, and enhance patient quality of life? Six articles met the inclusion criteria. The results indicate that most patients with CHF are candidates for multidisciplinary management programs, eg, physiologic telemonitoring. Physiologic telemonitoring led to a reduction in resource use and an increased functional level in patients. In addition, patients tended to be satisfied with telemonitoring devices and their care. Within the VHA there is interest in managing patients through telemonitoring.

Recommendations

Evidence shows the feasibility of telemonitoring and its potential for clinical and economic benefits, but limitations in study design prevent drawing definitive conclusions.

Methods

Comprehensive literature searches were conducted using MEDLINE, HealthSTAR, EMBASE, Current Contents, and the Cochrane Library from 1995 to 2000. Search strategies aimed to retrieve peer-reviewed published literature using a variety of terms indicating telephone, telemetry, telemonitoring, remote monitoring, telemedicine, congestive heart failure or heart diseases, quality of life, patient satisfaction, and terms for systematic review. Citations were also obtained from INAHTA, evidence-based medicine communities, and the VA for ongoing or proposed activities involving physiologic telemonitoring. The search yielded 155 citations. Original controlled studies published in English that addressed outcomes using telemonitoring systems in the home setting were included.

Further research/reviews required

Basic research is needed to define target populations for telemedicine services and associated interventions, develop standardized tools to measure effectiveness and harm, and assess the effect of different methods of delivery and payment. Randomized clinical trials are needed to determine the relative cost effectiveness of telemedicine strategies.

Written by Elizabeth Adams, VATAP, USA

Title **Physician and Nurse Staffing in Spinal Cord Injury Care: Relation to Outcomes**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Short Report, Number 7, February 2003

Aim

To determine the number of medical staff needed to provide the best medical care for patients with spinal cord injury.

Conclusions and results

The Department of Veterans Affairs (VA) was particularly interested in the number of nurses needed in the hospital and the number of nurses and physicians needed in outpatient clinics. The number of staff needed was to be determined by outcomes important to clinicians and patients with spinal cord injury.

The review identified several studies, but only one was directly relevant to this topic. Five studies addressed care of spinal cord injury patients, but not in outpatient or extended care settings. The Veterans Health Administration (VHA) found good studies on nursing in general medical-surgical hospitals showing that patients recover better in hospitals that focus on nursing and maintain good relations between nurses and physicians. The VHA did not find evidence regarding the numbers of nurses and physicians needed in outpatient clinics that treat patients with spinal cord injury. A tool for measuring outcomes in patients with spinal cord injury was not identified.

Recommendations

Patients in general, and possibly also those with spinal cord injuries, recover better in hospitals that focus on nursing and maintain good relations between nurses and physicians. Additional information is needed to determine the numbers of nurses and physicians needed in outpatient clinics to treat patients with spinal cord injury.

Methods

The Technology Assessment Program (TAP) searched MEDLINE and EMBASE from 1966 through December 2001, the health technology assessment database, and special reports (Booz-Allen Hamilton, 2000). References provided by the VHA's Strategic Healthcare Group were included. Over 800 references were reviewed on spinal cord injuries or spinal cord trauma.

Further research/reviews required

Additional research is needed to determine the staffing needs of nurses and physicians in outpatient clinics to treat patients with spinal cord injury and identify a reliable outcome measure for patients with spinal cord injury.

Written by Karen Flynn, VATAP, USA

Title **Visual Field Testing in VA Compensation and Pension Examinations**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Short Report, Number 6, March 2003

Aim

To determine the effectiveness of the Goldmann perimeter and Humphrey Field Analyzer and their role in assessing disability or handicap, and as a result, eligibility for benefits from the Veterans Benefit Association.

Conclusions and results

The review included 91 full-text articles. Two of these articles compared the Goldmann and Humphrey perimeters for visual field defects in glaucoma. Both studies found that the automated Humphrey perimeter identified visual field defects earlier in the disease compared to the manual Goldmann perimeter. Tracking the literature from the 1970s to the present suggests that automated perimeters are replacing manual perimeters. This is not related to the functionality of either perimeter. The literature suggests complementary roles for each perimeter since each measures different proportions of the entire volume of the normal visual field. For this reason, the location within the field that is of interest in a particular patient should guide the selection of the perimeter. Since anatomy-based visual field testing assesses impairment and not disability or handicap, functional visual field indices such as the Esterman function index can be used with either manual or automated perimeters.

Recommendations

Evidence on the effectiveness of the Goldmann perimeter and Humphrey Field Analyzer suggests a complementary role for each perimeter, depending on the location of the visual field of interest. The American Medical Association (AMA) recommends the use of functional residual field indices, eg, the Esterman function index, to assess visual field disability.

Methods

Comprehensive literature searches were conducted using Dialog OneSearches of MEDLINE, EMBASE, Current Contents, Biosis and SciSearch from 1980 to February 2002. Search strategies aimed to retrieve full-text articles on perimetry (Goldmann and Humphrey) and diagnosis of visual field defects. Citations were also obtained from colleague agencies in the INAHTA community.

Further research/reviews required

Additional studies are required to determine the use of visual field testing in evaluating visual disability. Areas of additional research are discussed in the report.

Written by Karen Flynn, VATAP, USA

Title **Optical Devices for Adults with Low Vision: A Systematic Review of Published Studies of Effectiveness**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Report, May 2003

Aim

To evaluate the effectiveness of optical low vision aids for visually impaired veterans.

Conclusions and results

Eleven peer-reviewed articles met the inclusion criteria. These studies compared the performance of optical low vision devices primarily used for reading. The results indicate that reading performance with either stand-mounted or handheld closed circuit TV (CCTV) was superior to prescribed optical devices (eg, stand magnifiers, coil stand magnifiers, and microscopic lenses) for patients with age-related macular degeneration. Compared to standard rehabilitation alone, the addition of Fresnel prisms in standard rehabilitation resulted in better performance on visual perception tests, but not on activities of daily living, in post-stroke patients with homonymous hemianopia or visual neglect. CCTV was preferred to spectacle reading glasses and illuminated stand magnifiers. Prototype magnifiers were preferred to conventional devices. Sustained use of these devices in the subject's life setting, the costs and training associated with each alternative, and the link between device use and health related quality of life were unknown. The peer-reviewed literature does not yield evidence to support clinical choices about providing optical low vision devices to visually impaired patients.

Recommendations

Clinicians must use their best judgment in concert with patients' needs to determine appropriate provision of low vision devices to patients.

Methods

Comprehensive literature searches were conducted using MEDLINE, HealthSTAR, EMBASE, Current Contents, and the Cochrane Library from 1970 through 2002. Additional citations were obtained from INAHTA and evidence based medicine communities, including VA. Search strategies used terms describing low vision rehabilitation, eye diseases rehabilitation, spatial and visual perception disorders, and adult dyslexia treatment and rehabilitation. Low vision devices, tinted or filtered lenses, sensory aids, low vision enhancement systems, low vision self-help devices, ocular accommodation devices, and prisms were also researched. Devices used for reading and driving were considered. Primary studies published in English with outcome measures using commercially available devices were included.

Further research/reviews required

Future research is needed to determine the appropriate candidacy for low vision devices, suitable prescription of these devices, and outcome measures that define the quality of life in subjects with age-related visual impairment along the continuum of visual impairment and disability.

Written by Elizabeth Adams, VATAP, USA

Title **Outcomes Measurement in Schizophrenia – No 2 in a Series on Outcomes Measurement in VHA Mental Health Services**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Short Report, Number 7, September 2003

Aim

To identify outcome measurement instruments to use in tracking the progress and treatment of patients with schizophrenia.

Conclusions and results

The review identified 13 instruments that were either developed or used to measure outcomes in schizophrenia. These included the Schizophrenia Outcomes Module (SCHIZOM), the Role Functioning Scale (RFS), and the Quality of Well Being (QWB) self-administered scale. These instruments most closely align with the Veterans Health Administration (VHA) criteria for outcomes measurement. However, while the interviewer-administered version of the QWB has been tested and found to be acceptable in patients with schizophrenia, the self-administered version has not been tested or used in this patient population. The length and complexity of SCHIZOM argue against its use for routine collection of outcomes data. Other instruments that fully or closely meet the criteria for VHA use are the Lehman Quality of Life Interview, Heinrich-Hanlon-Carpenter Quality of Life Scale, Quality of Well Being scale, and the Life Skills Profile (LSP). The LSP was developed specifically for use in schizophrenia. These instruments are being evaluated to determine the most suitable instrument to follow the progress and treatment of patients with schizophrenia in the Department of Veterans Affairs (VA).

Recommendations

Additional information is needed to select one specific instrument for outcomes measurement in schizophrenia. However, the instruments currently accepted for schizophrenia are the Quality of Well Being Interviewer-Administered, Lehman Quality of Life Interview, Heinrich-Hanlon-Carpenter Quality of Life Scale, and the Life Skills Profile. There is a need for consensus on preferred approaches for use in VA.

Methods

A qualitative systematic review of the literature was undertaken. Comprehensive searches were carried out in the psychological and biomedical databases, MEDLINE, HealthSTAR, PsycINFO, Current Contents, EMBASE, the Cochrane Library, and the extensive local monograph collections of McLean Psychiatric Hospital and the Countway Library of Medicine from 1976 to 2001. Use of a comprehensive array of bibliographic search strategy terms and free text words retrieved over 1400 references, including end references, along with several highly useful books on mental health instruments and outcome evaluation. Articles that described or analyzed instruments used in treating and monitoring patients with schizophrenia were included. A list of instrument selection criteria that are relevant to VA mental health services was applied.

Further research/reviews required

Additional research is needed to determine the outcomes measurement instrument(s) best suited for schizophrenia care.

Written by Karen Flynn, VATAP, USA

Title **Optimal Temperature for Cardioplegia During Coronary Artery Bypass Grafting**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Report, Final Report, September 2003

Aim

To address the optimal temperature in cardiopulmonary bypass and cardioplegia during cardiovascular surgery, with specific attention to defining the optimal method for myocardial protection during coronary artery bypass grafting (CABG).

Conclusions and results

Variations in the optimal methods used to protect the heart from damage due to lack of oxygen during cardiovascular surgery suggests a lack of consensus among practitioners, particularly among thoracic surgeons and in VA cardiac surgery programs.

Seventeen published randomized controlled trials (one yielding 2 separate publications) met the inclusion criteria for this review. The searches also identified 3 published analyses of large databases relevant to cardioplegia temperature, 2 of which used data from randomized controlled trials. Results from these studies support the American College of Cardiology/American Heart Association (ACC/AHA) guidelines for CABG (1999).

Recommendations

The ACC/AHA guidelines for CABG (1999) state *"no strong argument can currently be made for warm versus cold and crystalloid versus blood cardioplegia"* in patients with normal left ventricular function.

Methods

The VA Technology Assessment Program (TAP) searched MEDLINE, HealthSTAR, and EMBASE databases on November 1999, June 2000, January 2001, and September 2003. The databases of the Cochrane Collaboration and the International Network of Agencies for Health Technology Assessment (INAHTA) were searched to identify existing assessments. Reference lists were examined to identify additional randomized controlled trials.

Further research/reviews required

Additional research is needed to determine the optimal temperature for cardiopulmonary bypass and cardioplegia during cardiovascular surgery. Specific attention should be given to defining the optimal method for myocardial protection during CABG.

Written by Karen Flynn, VATAP, USA

Title **Outcome Measurement in Major Depression**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Short Report, Number 8, September 2004

Aim

To identify outcomes measurement instruments to use to track the progress and treatment of patients with major depression.

Conclusions and results

This review identified 15 instruments (10 depression-specific, 5 generic) that were either developed or used for outcomes measurement in major depression. These included the Depression Outcomes Module (DOM), Zung Self Rating Depression Scale (Zung SDS), Short Form-36 item (SF-36), Hamilton Rating Scale for Depression (HAM-D), the Global Assessment of Function (GAF), Sheehan Disability Scale (SDS), and the Quality of Well Being Self-Administered (QWB-SA). The DOM, QWB-SA, and SF-36 meet all criteria for assessment. The Zung SDS and the HAM-D meet all criteria except assessment of functioning. All but the DOM assess symptom severity only. The QWB-SA and SF-36 may not be valid in a severely ill patient population. The SDS measures functional disability and meets half of the criteria. Other instruments that fully or closely meet the criteria for VHA use were the Quality of Life in Depression Scale and the PHQ-9. These instruments are being evaluated to determine the most suitable instrument to use for the progress and treatment of patients with major depression.

Recommendations

Managers at the Department of Veterans Affairs (VA) have a variety of constructs and instruments from which to choose those most suitable to their outcome measurement needs and preferences for depression care. There is a need for consensus on preferred approaches for use in VA.

Methods

A qualitative systematic review of the literature was undertaken. Comprehensive searches were carried out in the following psychological and biomedical databases; MEDLINE, HealthSTAR, PsycINFO, Current Contents, EMBASE, the Cochrane Library, and the extensive local monograph collections of McLean Psychiatric Hospital and the Countway Library of Medicine from 1976 to 2001. Use of a comprehensive array of bibliographic search strategy terms and free-text words retrieved over 1400 references, including end references, along with several highly useful books on mental health instruments and outcome evaluation. Articles that described or analyzed instruments used in treating and monitoring patients with major depression were included. A list of instrument selection criteria that are relevant to VA mental health services was applied.

Further research/reviews required

Additional research is needed to determine the outcomes measurement instrument(s) best suited for major depression.

Written by Karen Flynn, VATAP, USA

INAHTA Briefs

Issue 2006/30

Title **A Systematic Review of Clinical Predictors of Outcomes in Adults with Recent Lower Limb Amputation**

Agency **VATAP, VA Technology Assessment Program**
Office of Patient Care Services (11T), Room D4-142, 150 South Huntington Ave, Boston, MA 02130, USA;
Tel: +1 857 364 4469, Fax: +1 857 364 6587; www.va.gov/vatap

Reference VA Technology Assessment Program Short Report, February 2005

Aim

To identify clinical predictors of outcomes in adult patients with major lower limb amputation that may help direct healthcare resources toward individuals who are most likely to benefit from specific rehabilitative interventions of care.

Conclusions and results

Predictors of poor outcome were advancing age, poor compliance, phantom limb pain, and comorbid conditions. Predictors of positive outcome included the patient's general condition, preamputation functional capability, the patient's socioeconomic situation, the amputation level and covering of the stump, and the absence of stump pain. These predictors need to be confirmed and assessed in VA patients to determine the most suitable outcomes to use for veterans with major lower limb amputation.

Recommendations

Promising predictors of outcomes were identified for further study. Additional research is needed to confirm these predictors and determine which predictors are most useful in clinical practice.

Methods

A qualitative systematic review was undertaken. Comprehensive searches were conducted in MEDLINE, EMBASE, Current Contents, Science Citation Index on Dialog and the Cochrane Library from 1990 to February 2004. Bibliographic search strategy included terms for lower limb/extremity amputation and combined them with terms for rehabilitation, prognosis, recovery of function, quality of life, activities of daily living, treatment outcome, and analytic methods. These searches resulted in 581 references, of which 128 were identified as potentially relevant. Seven studies met inclusion criteria for clearly described original research, published in English, that used multivariable analysis to derive predictive factors in adult patients with lower extremity amputation.

Further research/reviews required

Additional longitudinal studies are needed to derive a comprehensive set of clinical predictors suitable for the veteran population. These predictors will be used to improve the quality of rehabilitation care for lower limb amputees.

Written by Elizabeth Adams, VATAP, USA

INAHTA Briefs

Issue 2006/31

Title **Stereotactic Radiosurgery: An Update**

Agency **AHFMR, Alberta Heritage Foundation for Medical Research**
Health Technology Assessment Unit, Suite 1500, 10104-103 Avenue NW, Edmonton, Alberta T5J 4A7, Canada; Tel: 1 780 423 5727, Fax: 1 780 429 3509; www.ahfmr.ab.ca

Reference Information Paper #12, May 2002 (English). ISBN 1-896956-56-4 (print).
Online: www.ahfmr.ab.ca/hta/

Aim

To update advice provided in a 1998 AHFMR report on stereotactic radiosurgery (SRS).

Conclusions and results

The previous AHFMR report found limitations in the scope and quality of studies on SRS. There has been little improvement in this situation. Evidence on the efficacy, effectiveness, and economic impact of SRS remains limited. No evidence shows that any one form of SRS is superior to another. Small studies give some indication of similar outcomes from the Gamma Knife® (GK) and focused linear acceleration (LINAC) versions of SRS, and that fractionated stereotactic radiotherapy (FSRT) may produce fewer complications than SRS in some situations. The GK approach is more expensive than the standard LINAC approaches or FSRT, but the costs of using recent developments in LINAC technology are unknown.

With respect to the use of SRS, evidence from the published literature suggests the following.

- *Acoustic neuroma:* SRS is useful when microsurgery would have an unacceptable risk or be refused. Long-term followup data on SRS treatment remain limited. FSRT appears to have potential as an alternative to LINAC or GK SRS.
- *Arteriovenous malformations:* Microsurgery and SRS should be regarded as complementary approaches. Surgery is preferred if the lesion can be safely excised.
- *Brain metastases:* SRS is a useful option in patients not eligible for surgery and may offer advantages in relieving neurological symptoms. SRS plus radiotherapy appears to be more effective than radiotherapy alone.
- *Brain tumors:* SRS appears to be a useful adjunctive treatment in appropriately selected patients, though its success with malignant glioma is limited. SRS is helpful when surgery is not possible or carries unacceptably high risks.
- *Parkinson's disease, epilepsy, and trigeminal neuralgia:* The role of SRS in their management is unclear.

Recommendations

SRS is an accepted treatment option for several conditions when microsurgery is not possible, and as an adjunct to surgical and other approaches. Either LINAC or GK SRS are acceptable if SRS is to be used. Placement of SRS in specialized centers and excellent quality assurance are essential. Referral of patients from Alberta for SRS treatment outside the province should be to centers of excellence experienced in managing the condition in question and take account of other treatment options.

Methods

All original studies published since the previous AHFMR report were considered. Studies reporting outcomes of SRS treatments, or other approaches to managing the same conditions being treated with SRS, on humans were identified by searching PubMed, EMBASE, CINAHL, PsycINFO, the Cochrane Library, Web of Science, EBM Reviews – ACP Journal Club, and websites of health technology assessment agencies from January 1997 to January 2002. Case series studies of fewer than 20 patients, technical descriptions of apparatus, dose calculations, imaging and treatment planning approaches, and procedural descriptions were excluded. No language restriction was applied.

Further research/reviews required

Convincing evidence of the efficacy and cost effectiveness of the new SRS options, eg, CyberKnife and FSRT, is required. There is a need to go beyond cost analysis to economic evaluation, taking appropriate account of local circumstances. As suggested in the 1998 AHFMR report, decisions on referring patients for SRS require careful consideration of history, diagnostic findings by the specialists, and information on SRS efficacy for each application.

Written by David Hailey, AHFMR, Canada

Title **Cost Estimation of Stereotactic Radiosurgery: Application to Alberta**

Agency **AHFMR, Alberta Heritage Foundation for Medical Research**
Health Technology Assessment Unit, Suite 1500, 10104-103 Avenue NW, Edmonton, Alberta T5J 4A7, Canada; Tel: 1 780 423 5727, Fax: 1 780 429 3509; www.ahfmr.ab.ca

Reference Information Paper #14, May 2003 (English). ISBN 1-896956-53-X (print); ISBN 1-896956-55-6 (online): www.ahfmr.ab.ca/hta/

Aim

To provide economic information to decision makers in Alberta Health and Wellness on the most cost-effective way to offer stereotactic radiosurgery (SRS) services to neurosurgical patients.

Conclusions and results

Cost estimates were provided for 3 main SRS technologies: Gamma Knife (GK), CyberKnife (CK), and LINAC (Novalis). An estimated 100 to 185 patients per year would be eligible for SRS, not including patients who might be referred for SRS from other provinces.

The cost model used the annuity method to distribute investment and opportunity costs over the lifetime of the equipment. A 0% interest rate and 100 patients treated annually would yield an average cost per patient of CAD 14 567 for GK, CAD 14 889 for Novalis, and CAD 16 690 for CK. Considering travel and hotel expenses, lost earnings for patient and caregiver (estimated at CAD 1600), and cost of the procedure (estimated at CAD 15 000) in Manitoba, the option of establishing a dedicated unit in Alberta is attractive. These costs are more than double if the patient is treated in the United States.

At an annual volume of 100 patients, the total healthcare cost per patient would be CAD 16 210 for Novalis, CAD 16 856 for GK, and CAD 18 187 for CK. At that operational level, healthcare resources would not be efficiently used due to excess capacity of the SRS team and equipment.

While there is no significant difference between the costs of establishing dedicated GK or Novalis units in Alberta, a CK unit would be significantly more expensive than either of these two models. A CK unit, however, could be used to treat tumors beyond the head and neck.

Recommendations

A GK-based SRS unit will become operational in Manitoba in 2003. This unit has an estimated annual capacity of 600 patients and will probably treat patients from Alberta and British Columbia (estimated cost of CAD 15 000 per patient). Quebec is also considering the purchase of a unit. If Alberta were to invest in a dedicated SRS unit, it is unclear whether Canada would have sufficient workload for 3 SRS units. Hence, if the caseload and case mix are insufficient to make the SRS business case economically sustainable, Alberta should consider other sustainable alternatives for neurosurgical patients.

Methods

Cost minimization analysis was used for cost comparisons, which assumes that the effectiveness of the assessed technologies is equal. This assumption was supported by 2 Canadian reviews, which concluded that the effectiveness of GK and Novalis did not differ significantly from each other, or from conventional microsurgery.

The SRS cost estimate was based on a hypothetical cost model, so most of the cost factors and their values were not directly measured in a real life situation. This approach was taken because there was no dedicated neurosurgical SRS unit in western Canada at the time of the analysis. It was assumed that the technologies were mainly used for neurosurgery in patients with head and neck tumors only, some of whom would be suitable for SRS.

Further research/reviews required

The field of SRS is changing rapidly, which makes the projection of caseloads in Canada difficult. Additional cost estimations that address the impact of an SRS unit in Winnipeg would be helpful.

Written by Arto Ohinmaa, IHE and University of Alberta, Canada

INAHTA Briefs

Issue 2006/33

Title **Celecoxib for the Treatment of Pain in Osteoarthritis and Rheumatoid Arthritis**

Agency **AHFMR, Alberta Heritage Foundation for Medical Research**
Health Technology Assessment Unit, Suite 1500, 10104-103 Avenue NW, Edmonton, Alberta T5J 4A7, Canada; Tel: 1 780 423 5727, Fax: 1 780 429 3509; www.ahfmr.ab.ca

Reference Information Paper #24, May 2005 (English). ISBN 1-894927-12-5 (print); ISBN 1-894927-13-3 (online): www.ahfmr.ab.ca/hta/

Aim

To determine the efficacy/effectiveness and safety of the selective cyclo-oxygenase-2 (COX-2) inhibitor celecoxib (Celebrex) for treating pain in patients with osteoarthritis (OA) and rheumatoid arthritis (RA).

Conclusions and results

Two meta-analyses of randomized controlled trials (RCTs) assessed the effectiveness and safety of celecoxib in patients with OA and RA. In terms of pain reduction and functional improvement, celecoxib was superior to placebo and equivalent to older nonsteroidal anti-inflammatory drugs (NSAIDs) (naproxen and diclofenac) in patients with RA for up to 6 months. The incidence of gastroduodenal erosions or ulcers was significantly lower after taking celecoxib for RA and OA compared with diclofenac, naproxen, and ibuprofen.

Five RCTs published since July 2002 assessed the outcomes of patients taking celecoxib for RA or OA of the knee and/or hip. In terms of pain relief, celecoxib was superior to acetaminophen and placebo, but no better than other COX-2 inhibitors (nimesulide and rofecoxib) or diclofenac for followup periods ranging from 2 weeks to 1 year. Celecoxib had a safety profile similar to that of selective and nonselective NSAIDs, whereas dyspepsia was milder with celecoxib compared to diclofenac. None of the RCTs investigated gastroduodenal erosions or ulcers. The cost of celecoxib is nearly twice that of older NSAIDs.

Recommendations

Celecoxib is as effective as older NSAIDs and other COX-2 inhibitors in managing pain. Its advantage over older NSAIDs is that it causes fewer upper gastrointestinal side effects in patients who are at risk of such problems. According to guidelines issued by the American Pain Society, celecoxib should only be used by patients at risk for upper gastrointestinal problems who do not have cardiovascular risk factors.

Health Canada recommended restrictions for the use of celecoxib beginning in April 2005. Celecoxib should not be used by patients who have had a heart attack or stroke, serious chest pain related to heart disease, or congestive heart failure. Celecoxib may increase the risk of cardiovascular events in patients who smoke or have high blood pressure, high cholesterol, or diabetes. Celecoxib should be used at the lowest possible dose and for the shortest period of time necessary.

Methods

A systematic search included PubMed, EMBASE, HealthSTAR, the Cochrane Library, Science Citation Index, and the websites of health technology assessment agencies, research registers, and guideline sites from 1998 onwards. Analysis was limited to systematic reviews on celecoxib published in English from 1998, and systematic reviews and randomized controlled studies published since July 2002. Position papers, guidance reports, and information on the regulatory status of COX-2 inhibitors were also included.

Further research/reviews required

The long-term effectiveness and safety of celecoxib relative to nonselective NSAIDs and to NSAIDs combined with drugs such as proton pump inhibitors that protect the stomach and intestine is unknown. The higher risk of adverse cardiovascular events associated with celecoxib must be explored in trials with followup periods exceeding 6 months. A robust cost-effectiveness analysis is also needed before coverage decisions can be made.

Written by Carmen Moga, Christa Harstall, and Zhiliu Tang, AHFMR, Canada

Title **Protocols for Stillbirth Investigation**

Agency **AHFMR, Alberta Heritage Foundation for Medical Research**
Health Technology Assessment Unit, Suite 1500, 10104-103 Avenue NW, Edmonton, Alberta T5J 4A7, Canada; Tel: 1 780 423 5727, Fax: 1 780 429 3509; www.ahfmr.ab.ca

Reference HTA Report #36, October 2005 (English). ISBN 1-894927-24-9 (print); ISBN 1-894827-25-7 (online): www.ahfmr.ab.ca/hta/

Aim

To identify the most appropriate investigative protocol, or protocol component, for determining the cause(s) of stillbirth, and to collate and compare protocols recommended by health authorities and obstetric and gynecological associations in Canada and worldwide.

Conclusions and results

There is no generally accepted gold standard protocol for stillbirth investigation, and it is yet to be determined which components are essential to an efficient and comprehensive investigation.

Five protocols from Canada, the USA, and Australia/New Zealand were found. They outline similar steps in stillbirth investigation: maternal and family history; maternal investigation; and stillborn infant, cord, and placental examination. All recommend a complete perinatal autopsy and cord and placenta examinations. If consent for a full autopsy cannot be obtained, a limited autopsy is recommended. The protocols differed in their recommendations on which tests to include and what components should be core or additional investigations. The Alberta protocol compared well with the other publicly available protocols.

Seven cross-sectional analytic studies assessing the value of components of stillbirth investigations met the inclusion criteria. In 5 retrospective studies, autopsy findings confirmed clinical findings in 29% to 90% of cases, and revealed a change in diagnosis in 10% to 40% of cases. Two prospective studies reported that placental examination findings were diagnostic in 23% to 47% of cases. No studies were found that compared specific protocols.

Poor evidence quality and limited data reporting permit only general conclusions. The evidence highlighted the important diagnostic contribution of fetal autopsy and placental examination in stillbirth investigations, but it is unclear which of the other components are essential. The probability of perinatal autopsy and placental examinations providing clinically significant information is directly related to the quality of the postmortem.

Recommendations

- Physicians should use the Stillborn Investigative Protocol recommended by the Alberta Medical Association in all stillbirth investigations.
- Finding ways to improve the rates of fetal autopsy and placental examination would assist the process of stillbirth investigation. It is important to encourage greater participation of clinical staff and educate parents about the value of these procedures.
- Parents considering postmortem ultrasound and magnetic resonance imaging should be counseled on the limitations of these techniques as substitutes for fetal autopsy and placental examination.

Methods

All original, published studies on using a specific protocol, test or examination to determine the cause of stillbirth were identified by searching the Cochrane Library, PubMed, EMBASE, CINAHL, HealthSTAR, Science Citation Index, BIOSIS, and websites of health technology assessment agencies, research registers, evidence-based medicine resources, and practice guidelines from January 1985 to June 2005. The medical literature was searched to identify publicly available protocols.

Further research/reviews required

Further analysis is needed to establish the critical components of an efficient and effective protocol for stillbirth investigation. This will help ensure that the timing and sequence of tests is synchronized to achieve the best use of pathology specimens within the constraints of time, resources, and access to pathology samples.

Written by Paula Corabian and Ann Scott, AHFMR, Canada

Title	**Paravertebral Blocks for Anesthesia and Analgesia**
Agency	**ASERNIP-S, Australian Safety and Efficacy Register of New Interventional Procedures – Surgical** PO Box 553 Stepney, Australia; Tel +61 8 83637513, Fax +61 8 83622077; college.asernip@surgeons.org
Reference	ASERNIP-S Report Number 47. ISBN 0-909844-70-4. Full text available: www.surgeons.org/asernip-s/ (publications page)

Aim

To make recommendations on the safety and efficacy of thoracic and lumbar paravertebral blocks.

Conclusions and results

Paravertebral blocks (PVB) for surgical anesthesia were compared to general anesthesia (GA) or other regional anesthetic techniques, while the postoperative analgesia by PVB was compared to regional blocks or analgesic drugs. The ability to draw firm conclusions was limited by the high number of indications, the diversity of outcomes, and how outcomes were measured.

For anesthesia: PVB seems to be safe and, compared to GA, substantially reduces nausea and vomiting, although PVB shows a small risk of pleural and vascular punctures and epidural spread. The PVB failure rate was no higher than 20%, and patients were more satisfied with PVB than with GA.

For analgesia: PVB appears to be about as effective as other forms of regional analgesia. The results for pain relief, nausea, and vomiting were not as clear, but PVB appeared to be as effective and safe as the comparators. There is a small risk of punctures and epidural spread, which would increase with multiple PVB procedures, eg, in treating chronic pain.

Cost: No information was available to compare the costs of PVB with GA for anesthesia, or PVB with local analgesia. However, limited data from 2 studies indicated that avoiding an overnight stay after PVB could save 500 to 1000 Australian dollars.

Evidence rating: The evidence base in this review is rated as average.

Safety and efficacy: PVB at the level of the thoracic and lumbar vertebrae are at least as safe as (1) GA and other regional anesthetic techniques for surgery, and (2) analgesic drugs and other regional blocks for postoperative analgesia.

Recommendations

Anesthetists wishing to use the PVB technique should undergo appropriate training and supervised instruction until competent, and there should be ongoing audit of their performance.

Methods

Search strategy: MEDLINE, EMBASE, the Cochrane Library, Science Citation Index, and Current Contents from inception to December 2004. The Clinical Trials Database, NHS Centre for Research and Dissemination, NHS Health Technology Assessment, National Research Register, National Institute of Health, and Meta Register of Controlled Trials were searched in December 2004.

Study selection: Randomized controlled trials, historical and/or nonrandomized comparative studies, case series, and case reports in humans of at least 18 years of age were included. Comparative studies concerned the comparative interventions, defined as GA or any other method of analgesia. Efficacy outcomes included surgical anesthesia, pain scores, and length of hospitalization. Safety outcomes included complications, eg, pneumothorax, nausea, urinary retention.

Data collection and analysis: Data were extracted by the ASERNIP-S researcher using standardized data extraction tables developed *a priori* and checked by a second researcher. Relative risks with 95% confidence intervals were calculated for some outcomes in individual RCTs.

Further research/reviews required

Additional high quality, prospective randomized controlled trials would strengthen the evidence base for PVB. Cost-effectiveness studies that address the Australian healthcare context should be considered.

Written by Ms Prema Thavaneswaran et al, ASERNIP-S, Australia

Title	**HTA Ostomy Appliances in Belgium**
Agency	**KCE, Belgian Health Care Knowledge Centre** Résidence Palace, 10th floor, Wetstraat 155, Block A, BE-1040 Brussels, Belgium; Tel: +32 2 287 3397, Fax: +32 2 287 3385
Reference	KCE Reports, 21A. Ref D/2005/10.273/27. 2005. www.centredexpertise.fgov.be/documents/D20051027327.pdf, www.centredexpertise.fgov.be/documents/D20051027328.pdf

Aim

To assess the Belgian market for ostomy appliances from the perspective of the patient and healthcare system.

Conclusions and results

Since the clinical effectiveness of ostomy appliances is sparsely documented, the cost effectiveness of ostomy appliances could not be assessed. However, a cost analysis was done to estimate the ex factory price for a standard bag and pad (single and double-sided) for colostomy and ileostomy patients. The analysis shows that the market price for the patient and health care is largely determined by the end distributor. In this context, a factor of 2.5 seems likely (ie, the purchase cost at importation is 2/5 of the total market price). An international price comparison shows that the total annual cost of ostomy products for a Belgian patient is average for the countries considered. Internationally, it appears that the Belgian regulations have little flexibility and give the ostomy therapist little official authority.

Recommendations

The recommendations of the Belgian Healthcare Knowledge Centre aim at raising flexibility in material choice, open decision making, and competitive market action to improve the benefits to patients.

Methods

A literature review was used to assess the medical effectiveness and related costs of ostomy appliances, manufacturers were asked to make available all relevant clinical studies, and a group of external scientific experts was assembled.

Production costs were estimated using the material requirements and hypotheses about the use of labor and capital. The results of these estimates are an input factor, ie, purchase costs for national distributors. An international price comparison between Belgium, Denmark, France, the Netherlands, and the United Kingdom illustrated the relative position taken by Belgium. The homogeneity of the items compared was respected as much as possible, both as regards the comparability of selected products (product name, manufacturer, material components, etc) and macroeconomic factors (purchasing power in the countries concerned, reimbursement systems, tax rates, etc). We compared the most important institutional factors (pricing, reimbursement, distribution channels, and authorized prescribers) for the 5 European countries and the Canadian province of Ontario.

The specific Belgian context was investigated by analyzing information obtained from questionnaire responses, either verbally or in writing, by the actors involved (patients, manufacturers, bandagers, and policy makers were requested to identify points for attention, especially difficulties in the current system).

Further research/reviews required

Ostomy therapists should set up prospective clinical research into factors that determine patient satisfaction.

Epidemiological base data, concerning patients in ambulatory and hospital care environments, should be collected longitudinally for Belgium.

Written by Van den Steen D, Simoens S, Vanleene V, De Maré L, Moldenaers I, Debruyne H et al, KCE, Belgium

Title **Telehealth: Clinical Guidelines and Technological Standards for Telepsychiatry**

Agency **AETMIS, Agence d'Evaluation des Technologies et des Modes d'Intervention en Santé**
2021, avenue Union, bureau 1040, Montréal, Québec, Canada H3A 2S9;
Tel: +1 514 873 2563, Fax: +1 514 873 1369; aetmis@aetmis.gouv.qc.ca, www.aetmis.gouv.qc.ca

Reference Technology brief prepared for AETMIS (AETMIS 06-01). Internet access to full text.
Printed version: ISBN 2-550-46263-7; PDF: ISBN 2-550-46264-5

Aim

To assess the practice of telepsychiatry in Quebec, and to propose clinical guidelines and technological standards for this delivery method.

Conclusions and results

This is the first of 3 reports on telehealth (ie, telepsychiatry, telerehabilitation, and telepathology). In telepsychiatry, a patient and a mental health professional, or a group of healthcare professionals, communicate in 'real-time' via video conferencing. Studies indicate that telepsychiatry can improve the continuity of psychiatric care in Quebec and is an important part of the province's new healthcare system. Clinical activities that lend themselves to telepsychiatry are patient assessment, diagnosis confirmation, medication review (nonemergency), child and adult therapy, certain psychiatric emergencies, case-study meetings, and development of clinical care plans, treatment followup, and review. Telepsychiatry is contraindicated for patients who are violent, unstable, or impulsive and those at immediate risk of suicide.

Existing economic analyses of this technology are not comprehensive. Some research indicates that the break-even point for this technology is approximately 7 consultations per week. To offset the initial investment, telepsychiatry rooms could be used for other purposes, eg, tele-education. Based on a combined-use scenario, with 14 consultations a week (2 days), each telepsychiatry unit could save the province CAD 45 000 annually. Economic analysis that considers, eg, patient satisfaction, care distribution, and accessibility is needed.

A major obstacle in this technology is patient/therapist discomfort with the distance and equipment. Hence, caregivers need training to help smooth the transition for their patients. Legislation and guidelines are needed to ensure that only legally competent patients can avail themselves of the service, that consent is obtained, and confidentiality maintained.

The report identifies two ethical issues: 1) the potential for in-person specialty services to diminish in remote locations; 2) the impact on the traditional face-to-face therapeutic relationship.

Recommendations

Clinical guidelines: To provide service that is "relatively equivalent" to conventional therapy, telepsychiatry must be supported by a central reservation system, a generic consultation tool, thorough record-keeping at primary and secondary sites, agreements on standards between the governing and delivery agencies, terms of remuneration, training of service providers, insurance for service providers, dispute resolution procedures, and coordinating staff.

Technological standards: Effective services require consulting room standards (eg, size, lighting) and equipment standards (eg, cameras, phone, fax, H.264 compression, 384-Kbps reserved-bandwidth connection).

Methods

Literature search, expert interviews, equipment testing.

Further research/reviews required

The expanded implementation of telepsychiatry should be accompanied by a rigorous ongoing assessment of cost, satisfaction, quality, and accessibility.

Written by Pineau G, Moqadem K, St-Hilaire C, Perreault R, Levac É, Hamel B, Obadia A, and Caron L, AETMIS, Canada

Title **Maternal Ultrasound and Serum Screening in the Detection of Structural and Chromosomal Abnormalities**

Agency **FinOHTA, Finnish Office for Health Technology Assessment**
STAKES, PO Box 220, FI-00531 Helsinki, Finland;
Tel: +358 9 3967 2290, Fax: +358 9 3967 2278

Reference Report 27/2005. ISBN 951-33-1796-X. ISSN 1239-6273.
Full report available at: www.stakes.fi/finohta

Aim

To systematically collect the best evidence and knowledge on the sensitivity, specificity, and possible side effects of various screening methods; to describe the ethical and psychological effects of screening for fetal abnormalities; and to analyze cost effectiveness.

Conclusions and results

Major congenital anomalies are detected in 2 to 3 out of every 100 births, of which about one third are affected by several serious anomalies or a syndrome. The effects of an anomaly on the course of pregnancy or an infant's prognosis vary widely. Screening for fetal abnormalities has major ethical and psychological consequences. Present screening practices in Finland vary from one municipality to another and do not ensure equality. We hope that the research evidence and expert knowledge presented in this report will provide a basis for fruitful health policy discussions on the targets and implementation of fetal screening. A uniform national screening system and improvements in the quality of screening are set as targets. The report provides necessary data and information.

Recommendations

A system to evaluate the quality and effect of screening for fetal abnormalities must be established. A national expert group is needed to control the quality of screening (especially education of healthcare professionals in counseling and ultrasound methods). Parents should be allowed to make a conscious, voluntary decision concerning their participation. Counseling on screening should be competent, consistent, and adequately available at each screening stage.

Methods

A systematic review was performed on the various methods for screening structural and chromosomal abnormalities. The report examines the different screening models in the context of Finnish practice, and compares their implementation and results with a situation where screening is not performed. Modeling is used to analyze the shares of abnormalities identified through screening and the costs of screening. Furthermore, the ethical and social dimensions of screening were analyzed with an expert group. The report also addresses important factors affecting the quality management of screening organizations.

Further research/reviews required

Methods to screen for structural and chromosomal abnormalities are under continuous development. To be successful, maternal screening should set clear targets for detecting fetal abnormalities. The targets may change as new treatment options emerge.

Written by Adjunct Professor Ilona Autti-Rämö, FinOHTA, Finland

Title **Percutaneous Vertebroplasty. Pain Management of Osteoporotic Vertebral Fractures**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, 67 Islands Brygge, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 75 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference Medicinsk Teknologivurdering 2004; 6(2). ISBN: 87-91437-51-2 (online): www.sst.dk/publ/Publ2004/perkutan_vertebroplastik.pdf

Aim

To contribute to an analysis and assessment of the economic and organizational consequences of introducing percutaneous vertebroplasty (PVP) as a mode of treatment that may supplement or replace conservative pain management of patients with osteoporotic vertebral fractures.

Conclusions and results

PVP is an effective and safe procedure for treating pain caused by osteoporotic vertebral fractures (80% to 90% of PVP-treated patients report total or significant pain relief). However, the documentation consists only of nonrandomized clinical trials without control groups, and patient populations are not well defined. Furthermore, no studies are available on the patients' short- or long-term functional level, rehabilitation, or quality of life following PVP treatment compared to conservative treatment.

Calculations indicate that there is no cost differential between PVP treatment and a conservative pain management pathway. However, the figures are somewhat uncertain. It is not possible to examine the cost effectiveness of PVP since there are no comparable data on the effect of PVP versus the effect of conservative pain management.

Recommendations

To determine the cost-saving potential for each individual institution it is necessary to perform more detailed local analysis, with a view toward reducing the number of bed days. The reduction should be achieved by increasing efficiency through planning, cooperation, and administration. This work should be undertaken locally and regionally/nationally in connection with the organization of the specialty service.

Methods

Analysis of the technology involved and the patient perspective is based on a systematic search and assessment of the literature. Analysis of the organizational and economic aspects is based on studies of literature, data, extracts from registers, and a sample inquiry.

Further research/reviews required

In Denmark, at least 3 randomized clinical trials in which PVP is offered as an alternative to conservative treatment are already being planned or initiated. Experiences from these trials will be crucial when it comes to determining whether and, if so, how PVP should be implemented in the Danish health service.

Written by Kjølby M, Sørensen L, Ehlers L, and Kidholm K, for DACEHTA, Denmark

Title **The Fast-Track Surgical Patient Pathway for Colon Surgery Patients – A Health Technology Assessment**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, 67 Islands Brygge, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 75 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference 2005; 5(7). ISBN: 87-7676-232-7 (online): www.sst.dk/publ/Publ2005/CEMTV/Acc_kolonkirurgi/Acc_kolonkir_patientforloeb.pdf

Aim

To examine the conditions for and the consequences of introducing fast-track colon surgery from the perspective of the technology, patient, economy, and organization.

Conclusions and results

The fast-track patient pathway for colon surgery patients results in shorter hospitalization, quicker normalization of bowel function, diminished postoperative fatigue, and quicker resumption of everyday activities. Postoperative morbidity is unaltered or better. Patient satisfaction concerning treatment for pain relief is reported to be substantially greater, but fewer patients felt ready to be discharged from the hospital.

Recommendations

The report is intended to serve as a basis for deciding whether to introduce the fast-track surgical patient pathway in other hospitals. It contains several specific recommendations on the individual modalities in the multimodal regime that forms the fast-track patient pathway.

Methods

The survey builds on literature studies, partly concerning the individual modalities and partly concerning the fast-track patient pathway in its entirety. Furthermore, comparative data have been used from two hospitals, one using and one not using the fast-track pathway, eg, as the basis for economic calculations.

Further research/reviews required

It is important to continue using rigorous research methods to document the advantages gained by the fast-track patient pathway. Further research is needed to elucidate the consequences for the patient of the fast-track pathway, including the social and economic aspects. Moreover, implications for the primary care system should be examined.

Written by Folkersen J, Andreasen J, Basse L, Jakobsen DH, and Kehlet H, for DACEHTA, Denmark

Title **Should One or Two Embryos Be Transferred in IVF? – A Health Technology Assessment**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, 67 Islands Brygge, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 75 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference Danish Health Technology Assessment 2005; 7(2). ISBN: 87-7676-208-4 (online): www.sst.dk/publ/Publ2005/CEMTV/IVF_1_2/IVF_1_or_2summary.pdf

Aim

To describe the scientific knowledge and to contribute information on the obligatory single embryo transfer (SET) policy in Denmark; to evaluate if a SET policy compared with the present double embryo transfer (DET) policy would reduce the chance of pregnancy; to identify what the attitudes of the infertile couples are to SET and fewer twin pregnancies and what the organizational and economical consequences would be.

Conclusions and results

All previous randomized studies have shown that elective single embryo transfer significantly reduces the pregnancy rate per fresh cycle. The present randomized study did not reveal any difference. Observational data from other studies have indicated that it is possible to maintain unchanged pregnancy rates following introduction of SET to selected patient groups. Previous studies and our own data on patient attitudes revealed a strong desire for twins among couples undergoing fertility treatment. An enforced single embryo transfer policy would be in conflict with patient interests and wishes.

Introduction of SET seems to necessitate employment and education of extra staff and seems to represent a change in public expenses for health care associated with in-vitro fertilization (IVF). A SET policy will create greater challenges for information and counseling concerning the choice of one or two embryos. The SET policy was not found to be more cost effective than the DET policy, which is more effective (higher clinical pregnancy rate, higher rate of delivery and children), but also more expensive (higher delivery cost and neonatal intensive care costs). The extra costs per delivery and per child born with DET do not appear to be high.

Recommendations

Respect for patient autonomy should be considered against economic aspects. Complications and long-term sequelae associated with preterm delivery derived from twin pregnancies should also be taken into account.

Methods

The project was based on the framework of health technology assessment (HTA). An analysis of the literature and a randomized study elucidated whether one or two embryos should be transferred in IVF. Patient attitudes toward this question were found through a literature search, a qualitative interview study, and by a mailed survey. The organizational consequences of introducing SET were analyzed in terms of changes in organizational processes. A health economic analysis was used to evaluate the potential economic consequences.

Written by Ingerslev HJ et al, for DACEHTA, Denmark

Title **The Use of Liquid Based Cytology (LBC) and Conventional Pap Smear (CPS) for Cervical Cancer Screening in Denmark – A Health Technology Assessment**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, 67 Islands Brygge, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 75 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference 2005; 7(3). ISBN: 87-7676-249-1 (online): www.sst.dk/publ/Publ2006/CEMTV/Cervix/Cervix.pdf

Aim

To clarify the evidence on Pap smear compared with liquid-based cytology and the status of cervical screening activities in Denmark, and to provide decision support for counties and hospitals.

Conclusions and results

In Danish pathology departments, the conventional Pap smear (CPS) has been used in systematic cervical cancer screening to prepare cell samples from the uterine cervix. In recent years, liquid based cytology (LBC) has gained ground as an alternative method, but its advantages have been disputed. In 2005, only a few Danish counties had implemented LBC, while most remained undecided. Previous reviews of the evidence on LBC have presented conflicting results.

No scientific basis was found to suggest any difference in clinical or economic effects between LBC and conventional CPS. However, other aspects of the screening program (eg, increase in participation, extension of the age limit, improvement in national homogeneity, and coordination of management) were found to be effective approaches for achieving clinical and health economic gains.

Recommendations

Instead of spending limited resources to change laboratory techniques, steps should be taken to optimize the screening program in terms of improving the coverage and management of Danish screening activities, nationally and regionally. The initial steps are being prepared.

Methods

The health technology assessment (HTA) included systematic literature-reviews on clinical effectiveness, economic modeling, evaluations of patient-related consequences, and organizational aspects based on data collected from national registers, local investigations, and by survey.

Further research/reviews required

Findings and recommendations of the HTA will be followed up by national and regional planning initiatives to optimize the screening program for cervical cancer.

Written by Kjølby M, Bech M, Bjerregaard B, Kjellberg J et al, DACEHTA, Denmark

Title **Caesarean Section on Maternal Request – A Health Technology Assessment**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, 67 Islands Brygge, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 75 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference Medicinsk Teknologivurdering 2005; 7(4). ISBN: 87-7676-250-5 (online): www.sst.dk/publ/Publ2006/CEMTV/Kejsersnit/kejsersnit.pdf

Aim

To contribute to the debate and provide input for decision making in relation to the future management of caesarean section on maternal request; to collate information and assess the benefits and risks of a planned caesarean section on maternal request in relation to a vaginal delivery.

Conclusions and results

The main conclusion of this report is that more should be done to ensure that a woman's first delivery is a positive experience. Most requests for caesarean section come from mothers who have had a bad experience in giving birth. Hence, the key point is to prevent requests for an elective caesarean by ensuring good first-time births. Another central point concerns the information given to pregnant women as a basis for their choice. Pregnant women requesting a caesarean section should be informed of the benefits and risks to themselves and to the child. They should also be informed about implications for later pregnancies and births and about the possibility to become pregnant again.

Recommendations

- Promote improvement in delivery, eg, by following the guidelines from the Danish National Board of Health.
- Attach importance to thorough and objective information given to expectant mothers.
- Attempt to persuade women to choose vaginal births. If a woman insists on caesarean section, she should be offered the procedure unless there is cause to do otherwise.

Methods

The ethical analysis is based on principles of ethics, legislation in the field, and knowledge provided by other analyses. The technological analysis is based on a systematic literature review and on registered data. The patient perspective is based on a systematic literature review. The organizational analysis is based on qualitative case studies. The economic analysis is based on a study of the literature and data from the cost register of the National Board of Health.

Further research/reviews required

Further research is needed on: how to minimize injuries associated with vaginal delivery; the vaginal delivery process itself; the women who request caesarean sections; and the consequences of choosing caesarean, considering the possible risk for complications in subsequent pregnancies.

Written by Frellsen M, Nielsen CP, Krebs L, Kjellberg J et al, DACEHTA, Denmark

INAHTA Briefs

Issue 2006/44

Title **Ward Rounds – A Health Technology Assessment Focused on Production of Knowledge**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, 67 Islands Brygge, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 75 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference Medicinsk Teknologivurdering – puljeprojekter 2006; 6(1)/DSI Rapport 2006.02.
ISBN: 87-7676-254-8 (online): www.sst.dk/publ/Publ2006/CEMTV/Stuegang/Stuegang.pdf

Aim

To illustrate the ward round as a means to produce knowledge aimed at managing diagnostic and therapeutic work; to achieve an understanding of the complex relations constituting a ward round.

Conclusions and results

Knowledge about ward rounds as a social practice is limited. The ward round has developed from being primarily educational to having multiple objectives. It is possible to create more rational work routines and more continuity in care pathways by introducing alternative formats for ward rounds. Electronic patient records (EPR) in ward rounds have had only a limited impact on new formats of the ward round.

The report presents 3 identically structured formats for ward rounds: the pre-ward round, the ward round, and the post-ward round. Differences between the formats concern whether the format of the ward round functions with daily monitoring of all patients, whether the ward round is according to requirement, and whether the ward round uses EPR or paper records.

Knowledge produced during the ward round is not a linear process from problem to solution, but a continuous exchange of knowledge among the different players involved in the ward round. Total daily time consumed by physicians and nurses for ward round activities in the 3 wards averages between 40 and 55 minutes per patient, corresponding to payroll costs between DKK 192 and 267 per patient. The time consumed varies significantly from day to day. Since many different players and interests are represented in the ward round, there is not a single, obvious way to conduct the ward round.

Recommendations

It may be appropriate to reorganize the traditional ward round for internal medicine wards by: attending to the patients according to requirement; letting patient contact in the ward round take place in private; using EPR as a tool for the administrative part of the ward round; always having a consultant present to take care of training junior doctors and to ensure quality and efficiency of medical decisions; formalizing the pre-ward round (even more) to assure that knowledge about the patients' condition is exchanged in a dialogue.

Methods

Data were collected in 3 internal medicine wards, each organizing their ward rounds differently. Observational studies, focus group interviews, individual interviews, and time registration were carried out on each ward. Written material comprising factual data on the wards in question has been collected. Literature studies have been used to illustrate the historic context of the ward round. The report outlines a relational theoretical perspective for interpreting the empirical data.

Written by Willemann M, Svendsen MN, Ankjær-Jensen A, Petersen PG, and Christensen M, DSI/DACEHTA, Denmark

Title **Cross-Sectorial Cooperation Between General Practice and Hospital – Shared Care Elucidated Using Anticoagulant Therapy (AC) as an Example**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, 67 Islands Brygge, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 75 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference Medicinsk Teknologivurdering – puljeprojekter 2006; 6(2). ISBN: 87-7676-248-3 (online): www.sst.dk/publ/publ2006/CEMTV/Shared_care/MTV_sharedcare.pdf

Aim

To present the advantages of shared care and some of the problems that can arise when cooperation is initiated for shared care.

Conclusions and results

Shared care in general: Shared care is a means of organizing treatment whereby sub-elements of the treatment are performed in a relationship of mutual interdependence between various organizations (eg, in general practice and at a hospital). Shared care is not a solution to all cooperation problems between sectors of the health service. Shared care is an appropriate means of solving problems only in situations involving mutual interdependence between sectors and can realign patient pathways that run off course due to centralization. The benefits of a shared care scheme can be attained only if several preconditions are met (eg, general treatment guidelines, patient participation, direct and mutual contact between therapists and patients).

Shared care and AC therapy: An assessment of anticoagulant (AC) therapy in Denmark reveals that it is not performed satisfactorily from a medical standpoint. Hence, shared care is a possible organizational alternative to the existing organization of AC therapy. Shared care schemes can necessitate major reorganization of treatment practice. Compared with conventional AC therapy, shared care does not have any adverse effects on self-reported state of health. Economic analysis shows that given the current premises, shared care is not more economical than other organizational forms, rather to the contrary.

Recommendations

Decisions to introduce shared care should be based on thorough analysis of the relationships involved. If mutual interdependence between participants cannot be identified, it is appropriate to choose alternatives to shared care. It is important to draw up guidelines/instructions for cooperation when planning and implementing shared care, since it is primarily informal and requires open, utilized channels of communication between the patient, the general practitioner, and the hospital physician. Direct economic savings should not be expected from shared care – to the contrary, one should expect it to be more expensive. During the establishment phase one should ensure that the current trend toward larger hospitals will tend to reduce the possibilities for direct personal contact between the patient and the general practitioner on one side and the regular shared care contact person at the hospital on the other. Shared care schemes should be regularly evaluated, and more emphasis should be placed on the indirect effects of cooperation since this is where the greatest benefit probably lies.

Methods

The project is based on; data from a systematic review, our own data from a randomized controlled trial, a model-based economic analysis, statements from experts, and a theme day involving experts interested in the subject.

Written by Holm T et al, for DACEHTA, Denmark

Title **Pain School – A Health Technology Assessment**

Agency **DACEHTA, Danish Centre for Evaluation and Health Technology Assessment**
National Board of Health, 67 Islands Brygge, DK-2300 Copenhagen S, Denmark;
Tel: +45 72 22 75 48, Fax: +45 72 22 74 07; www.dacehta.dk

Reference Medicinsk Teknologivurdering – puljeprojekter 2006; 6(3). ISBN: 87-7676-266-1
(online): www.sst.dk/publ/Publ2006/CEMTV/Smerteskole/Smerteskole.pdf

Aim

To produce a documented basis for decisions regarding the form of treatment at a Multidisciplinary Pain Centre (MPC) and its diffusion to corresponding treatment units and the primary care sector.

Conclusions and results

The study found that the effect of basic multidisciplinary treatment was prolonged with the addition of group treatment, but evidence for the independent effect of group treatment was weak. A documented, optimal length of treatment time was not found. Multidisciplinary individual pain treatment had a significant, positive effect on patients' health-related quality of life. The Pain School (PS) helped patients better understand the complexity of chronic pain, new ways of seeking treatment, and learning how to live with pain.

The PS is an endogenic technology. Still, history of the technology influences multidisciplinary individual treatment. Economic analysis could not point to any economic reason why the PS should be maintained as a part of the MPC treatment.

Whether or not the PS has an independent effect on patients' health-related quality of life and on their utilization of the healthcare system is uncertain, but group treatment maintains the effects of individual treatment for at least 6 months. Patients report that the PS contributes to greater understanding and acknowledgement. The staff credit the PS for optimizing their skills and knowledge relative to patients and their treatment.

Recommendations

Administrative and the clinical staff should thoroughly discuss the existence of the PS in its present form at the MPC. Concurrently, the MPC should carefully consider a specific physical training program for the PS, if maintained. Furthermore, until the effects are better documented, it is recommended that group treatment not be introduced in multidisciplinary treatment units without standardized psycho-education. It is recommended that PS should not spread to the primary care sector, since an isolated effect of the PS has not been demonstrated.

Methods

The study included a systematic literature search, a clinical randomized trial, an interview study, an analysis of the organization, and a financial analysis.

Further research/reviews required

Intentions to introduce comparable psycho-educative group treatments in the primary care and social sectors should not be introduced unless intervention studies with a clearly defined objective are conducted.

Written by Samuelsen S, Hansen R, Frölich S, Svendsen A, and Kloster B, for DACEHTA, Denmark

Title	**Wound Team – Organization of Treatment to Patients with Problem Wounds. A Health Technology Assessment**
Agency	**DACEHTA, Danish Centre for Evaluation and Health Technology Assessment** National Board of Health, 67 Islands Brygge, DK-2300 Copenhagen S, Denmark; Tel: +45 72 22 75 48, Fax: +45 72 22 74 07; www.dacehta.dk
Reference	Medicinsk Teknologivurdering – puljeprojekter 2006; 6(4). ISBN: 87-7676-279-3 (online): www.sst.dk/publ/Publ2006/CEMTV/Saarteam/saarteam.pdf

Aim

To study the introduction of a wound management service organized around a wound team and to assess this alternative compared with wound management organized in the traditional manner.

Conclusions and results

Only a few fixed procedures exist for surgical revision and the use of wound care products, although these products have been used for many years. The project utilizes an experienced-based combination of modern and traditional wound care products and procedures. Patients treated by the wound team experienced more rapid treatment decisions, according to the findings. Also, patients experienced less pain in connection with dressing changes and were better informed than patients treated prior to introduction of the wound team.

The wound team has upgraded the knowledge about wounds and wound management, and the project has recorded a difference between wound care administered by and without the wound team. Wound healing improved, as measured by a greater reduction in patients' wound areas (P=0.08), a greater number of patients with complete healing (P=0.04), and uniform, systematic use of modern wound care products (P=0.03).

Although an extensive health economic analysis could not be performed, it is highly probable that the wound team comprises an appropriate use of resources. By providing a structured, systematic, wound management service for patients with problem wounds, the project has shown that an important determinant of outcome is the manner in which wound management is organized.

Recommendations

Wound teams are an appropriate way to organize wound management services for patients with problem wounds. How, and the extent to which, wound teams should be organized at the individual hospital or county level depends largely on how the regional healthcare authorities have organized their hospital sector.

Methods

Based on findings from a previous health technology assessment (HTA) that wound management services in hospitals are suboptimal, the present HTA focuses on internal conditions within the hospital. The primary care sector was omitted due to a shortage of resources and time. The study was designed as an intervention study with an historical control group.

Further research/reviews required

Future studies should be designed to enable better documentation of the effects of preventative measures and to better account for changes in referral patterns.

Written by Caspersen F, Gottrup F, Mathiesen D, and Brockdorff A, for DACEHTA, Denmark

Title **Effectiveness and Safety of Endoscopic Thoracic Sympathectomy. A Systematic Review**

Agency **FinOHTA, Finnish Office for Health Technology Assessment**
STAKES, PO Box 220, FI-00531 Helsinki, Finland;
Tel: +358 9 3967 2290, Fax: +358 9 3967 2278; www.stakes.fi/finohta/

Reference FinOHTA Report 26. Stakes, Helsinki 2005. ISSN 1239-6273, ISBN 951-33-1790-0.
www.stakes.fi/finohta/raportit/026/r026f.pdf

Aim

To assess, by systematic review, the effectiveness and safety of endoscopic thoracic sympathectomy.

Conclusions and results

Endoscopic thoracic sympathectomy (ETS) aims at reducing blushing in the face and excessive sweating in the face and hands due to overactive sympathetic nerves. In ETS, the upper thoracic chain of the sympathetic nerve trunk is transected or clamped.

Methodological quality was poor in most studies. Few clinically relevant patient characteristics were reported, and only one study provided clear inclusion and exclusion criteria for patients. Five studies had uniform followup times for all patients. Three studies had mean followup times exceeding 2 years, and one study had followed all patients for at least 2 years.

Blushing and excessive sweating of hands, trunk, and feet decreased after ETS in all studies. In the absence of objective outcome measures, the results cannot be combined. Complications after ETS included hemo- or pneumothorax, Horner's syndrome, and neuralgias. Certain complications caused permanent disability. In all but two studies compensatory sweating after ETS occurred in more than half of the patients, typically on the trunk below the nipples. This caused significant disability for 3% to 15% of those who experienced it. Excessive skin dryness and gustatory sweating were also reported.

The effectiveness of ETS in alleviating sweating or facial blushing cannot be evaluated on the basis of studies without control groups. However, prospective patient series can provide valid information on the side effects of interventions. The studies in this review were seemingly prospective, although variable followup times and other inconsistencies point toward the possibility of retrospective designs.

ETS is associated with significant immediate and long-term adverse effects. Many patients also suffer from compensatory hyperhidrosis after ETS. Due to wide variation in reporting adverse effects, these effects have probably been underreported.

Recommendations

Not addressed.

Methods

Randomized controlled trials, and prospective observational studies (at least 100 patients) on ETS were searched without language restriction in MEDLINE (1966–July 2004) and the Cochrane Library (2nd quarter 2004). MeSH search terms were: hyperhidrosis, sweating, or blushing. We included papers reporting at least one outcome measure of symptoms among patients with facial blushing or sweating in the face, hands, or elsewhere (trunk or feet).

No trials were found among 195 articles retrieved. Two researchers independently selected papers based on titles and abstracts and assessed the quality of potentially eligible studies using full text versions. Fifteen prospective studies were included (see bmj.com, Web Table 1). They had recruited 5767 patients (mean 384, range 100-1312), of which 46% were male (range 26%-56%). Patients were typically young adults (mean age from 21-34 years, age range 5-72 years). Eight studies had included children below 15 years of age.

Further research/reviews required

Not addressed.

Written by Antti Malmivaara, FinOHTA, Finland

Title **The Impact of an Extension of Breast Cancer Screening. Update of FinOHTA Report 16/2000**

Agency **FinOHTA, Finnish Office for Health Technology Assessment**
National Research and Development Centre for Welfare and Health (STAKES),
PO Box 220, FI-00531 Helsinki, Finland; Tel +358 9 3967 2678, Fax +358 9 3967 2278

Reference FinOHTA Report 28, 2006. ISBN 951-33-1834-6, ISSN 1239-6273.
www.stakes.fi/finohta/e/reports/

Aim

To update the FinOHTA report from year 2000 concerning the impact of extending breast cancer screening to the group aged 60 to 69 years.

Conclusion and results

The previous FinOHTA report stated that mammography screening reduces breast cancer mortality about 25%. The updated report estimated the reduction to be somewhat less (22%). The impact of 60 to 69 years could not be estimated separately, but screening in that age group was somewhat more sensitive compared to women aged 50 to 59 years. In Finland, breast cancer screening by mammography can annually prevent around 16.5 breast cancer deaths per 100 000 women invited for screening, ie, 1 breast cancer death per 6100 women.

Mammography screening involves inequality because some municipalities also invited women aged 60 to 69 years, while screening of women aged 50 to 59 years is imposed by statute. Digital mammography is gaining a foothold as a screening method, but precise knowledge is not available concerning its reliability compared with film mammography. In some respects, women invited for screening did not receive adequate information for an informed decision. Information sent to women varied among screening centers.

Recommendations

Breast cancer screening in women aged 60 to 69 years is at least as effective as in women aged 50 to 59 years. The Ministry's working group on screening will use the report as a base in its deliberations on the need to change current screening practices, which have led to differential treatment of women in different municipalities.

Methods

The systematic literature review was updated and complemented with registry data and expert consensus. Screening centers were surveyed to determine the type of information they send to women invited for screening.

The literature was searched in May 2005 via MEDLINE, the Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials, and the Centre for Reviews and Dissemination. Articles in English, German, and Scandinavian languages from the year 2000 were accepted. Systematic reviews, new and followup randomized trials of mammography screening and screening of breast self examination (BSE) and clinical breast examination (CBE) were considered. National register studies and articles involving informed consent about participation of screening and studies of quality of life were also considered. Articles involving cost effectiveness, risk groups, care of breast cancer, and screening of women aged younger than 40 years, or older than 70 years were excluded. Two reviewers separately interpreted the articles.

Further research/reviews required

Better knowledge of digital mammography screening is needed. Few studies have been published about this new method. Cost-effectiveness studies of digital mammography are needed.

It would be interesting to know how the attendance rate of screening would change if women receive more information about screening in the invitation letter.

Written by Ulla Saalasti-Koskinen, FinOHTA, Finland

Title	**Interventions to Prevent Obesity. A Systematic Review**
Agency	**SBU, The Swedish Council on Technology Assessment in Health Care** PO Box 5650, SE-114 86 Stockholm, Sweden; Tel: +46 8 412 32 00, Fax: +46 8 411 32 60; info@sbu.se, www.sbu.se
Reference	SBU Report 173E, 2005. ISBN 91-85413-04-6. Available in Swedish and English at www.sbu.se

Aim

To evaluate the scientific evidence on the effects of interventions to prevent obesity in children/adolescents and adults.

Conclusions and results

Children/adolescents: The report includes 39 studies on 34 000 individuals. In 41% of studies and 40% of participants, prevention had a statistically significant positive effect on weight trends compared to the control groups. No negative results for intervention were found. Given the large number of studies it is improbable that random chance could skew the results in such a positive direction (p-value 0.000061). It is concluded that school-based interventions can reduce weight gain and the development of obesity in children and adolescents (Evidence Grade 1). The fact that many studies fail to demonstrate a positive effect may reflect the difficulty of achieving lifestyle changes through school-based interventions alone that do not include the home environment, free time, and the community at large.

Adults: The report includes 31 studies on 64 000 individuals. Interventions have included counseling on diets low in energy and fat and high in fiber. Most often, recommendations have been added to increase physical activity, to lower consumption of alcohol, and to stop smoking. We found that 45% of the studies reported a positive result in the intervention group as compared to controls, and it is improbable that the results occurred by chance (p-value 0.0128). It is concluded that obesity can be prevented in adults (Evidence Grade 2). The lack of effect in many studies reflects the difficulty of changing lifestyles through rather limited interventions.

Methods

Literature was searched in PubMed, Cochrane Library, and NHS EED up to May 2004 using search terms regarding overweight, obesity, and prevention. Reference lists of relevant articles and other reviews were also scrutinized. The studies had to address prevention (not treatment) and include a control group (RCT/CCT), followup of at least 12 months, and a relevant weight outcome. Study quality was assessed, and the total evidence was rated on 3-grade scale.

Further research/reviews required

Mass interventions to promote good eating habits and increased physical activity are needed. All interventions must be sustained and goal oriented. Weight trends in the population must be monitored and related to the various efforts undertaken.

Written by Mona Britton, SBU, Sweden

INAHTA Member Agencies

AETMIS
President: Dr Luc Deschênes
Contact person: Dr Véronique Déry
Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé
2021, avenue Union, bureau 1040
Montréal, Québec, H3A 2S9 **CANADA**
Tel: +1 514 873 2563, Fax: +1 514 873 1369
Email: aetmis@aetmis.gouv.qc.ca
Internet: www.aetmis.gouv.qc.ca

AETS
Director & Contact person: Dr Antonio Sarría Santamera
Agencia de Evaluación de Tecnologias Sanitarias
Instituto de Salud "Carlos III"
Calle Sinesio Delgado 6, Pab. 4
ES-28029 Madrid **SPAIN**
Tel: +34 9 1 822 2005, Fax: +34 9 1 387 7841
Email: asarria@isciii.es
Internet: www.isciii.es/htdocs/en/investigacion/Agencia_quees.jsp

AETSA
Director: Dr Purificación Gálvez Daza
Contact Person: Dr Eduardo Briones
Agencia de Evaluación de Tecnologías Sanitarias de Andalucía
Avda. de la Innovación, s/n. Edificio Arena-1
ES-41020 Sevilla **SPAIN**
Tel: +34 95 500 6638, Fax: +34 95 500 6677
Email: eduardo.briones.sspa@juntadeandalucia.es
Internet: www.juntadeandalucia.es/salud/aetsa

AHFMR
Director & Contact person: Dr Don Juzwishin
Alberta Heritage Foundation for Medical Research
10104-103 Avenue, Suite 1500
Edmonton Alberta, T5J 4A7 **CANADA**
Tel: +1 780 423 5727, Fax: +1 780 429 3509
Email: don.juzwishin@ahfmr.ab.ca
Internet: www.ahfmr.ab.ca/hta

AHRQ
Director: Ms Jean Slutsky
Contact person: Mr Martin Erlichman
Agency for Healthcare Research and Quality
Center for Outcomes & Evidence
540 Gaither Road
Rockville, MD 20850 **USA**
Tel: +1 301 427 1610, Fax: +1 301 427 1639
Email: merlichm@ahrq.gov
Internet: www.ahrq.gov

AHTA
Director: Professor Janet Hiller
Contact person: Ms Tracy Merlin
Adelaide Health Technology Assessment
Department of Public Health
Mail Drop 511, University of Adelaide
Adelaide SA 5005 **AUSTRALIA**
Tel: +61 8 8303 3575, Fax: +61 8 8223 4075
Email: tracy.merlin@adelaide.edu.au
Internet: www.public-health.adelaide.edu.au/consult/health_techn_assess.html

AVALIA-T
Director & Contact Person: Dr Teresa Cerdá Mota
Galician Agency for Health Technology Assessment
Dirección Xeral de Aseguramento e Planificación Sanitaria
Consellería de Sanidade, Xunta de Galicia, San Lázaro s/n
ES-15781 Santiago de Compostela **SPAIN**
Tel: +34 981 541831, Fax: +34 981 572 282
Email: avalia-t@sergas.es
Internet: http://avalia-t.sergas.es

ASERNIP-S
Director: Professor Guy Maddern
Contact person: Prof Guy Maddern, Ms Kerin Williams
Australian Safety and Efficacy Register of New Interventional Procedures - Surgical
PO Box 553, Stepney SA 5069 **AUSTRALIA**
Tel: +61 8 8363 7513, Fax: +61 8 8362 2077
Email: College.asernip@surgeons.org
Internet: www.surgeons.org/asernip-s

CADTH (formerly CCOHTA)
Director & Contact person: Dr Jill M Sanders
Canadian Agency for Drugs and Technologies in Health
865 Carling Avenue, Suite 600
Ottawa, ON K1S 5S8 **CANADA**
Tel: +1 613 226 2553, Fax: +1 613 226 5392
Email: jills@cadth.ca
Internet: www.cadth.ca

CAHTA
Director: Dr Joan Pons
Contact person: Mr Antoni Parada
Catalan Agency for Health Technology Assessment and Research
Esteve Terradas, 30, Recinte Parc Sanitari Pere Virgili
Edifici Mestral, 1a planta
ES-08023 Barcelona **SPAIN**
Tel: +34 93 2594200, Fax: +34 93 2594201
Email: direccio@aatrm.catsalut.net, tparada@aatrm.catsalut.net
Internet: www.aatrm.net

CEDIT
Director & Contact person: Dr Elisabeth Fery-Lemonnier
Comité d'Evaluation et de Diffusion des Innovations Technologiques
Assistance Publique Hôpitaux de Paris
3, avenue Victoria
FR-75004 Paris R.P. **FRANCE**
Tel: +33 1 40 27 18 90, Fax: +33 1 40 27 55 65
Email: elisabeth.fery-lemonnier@sap.ap-hop-paris.fr, info.cedit@sap.aphp.fr
Internet: http://cedit.aphp.fr

CENETEC
Director & Contact person: Dr Adriana Velázquez Berumen
Centro Nacional de Excelencia Tecnológica en Salud
Reforma 450 Piso 13, Colonia Juárez
Delegación Cuauhtémoc
C.P. 06600, México D.F. **MEXICO**
Tel: +52 55 5208 3939, Fax: +52 55 5207 3990
Email: cenetec@salud.gob.mx
Internet: www.cenetec.gob.mx

CMS
Director: Dr Sean Tunis
Contact person: Ms Kimberly A Long
Centers for Medicare and Medicaid Services (OCSQ)
Coverage and Analysis Group, CAG
Office of Clinical Standards and Quality
7500 Security Blvd. Mailstop C1-09-06
Baltimore, MD 21244, **USA**
Tel: +1 410 786 5702, Fax: +1 410 786 9286
Email: klong@cms.hhs.gov
Internet: www.cms.hhs.gov

CMT
Director: Professor Jan Persson
Contact person: Mr Lars Bernfort
Center for Medical Technology Assessment
Department of Health and Society
Linköpings universitet
SE-581 83 Linköping **SWEDEN**
Tel: +46 13 22 49 93, Fax: +46 13 22 49 95
Email: lars.bernfort@ihs.liu.se
Internet: www.cmt.liu.se

CRD
Associate Directors: Dr Amanda Sowden and Ms Julie Glanville
Contact person: Ms Julie Glanville
Centre for Reviews and Dissemination
University of York
York, YO10 5DD **UNITED KINGDOM**
Tel: +44 1904 321096, Fax: +44 1904 321041
Email: jmg1@york.ac.uk
Internet: www.york.ac.uk/inst/crd, www.york.ac.uk/inst/crd/crddatabases.htm

CVZ
Director: Dr P C Hermans
Contact person: Dr Albert Boer
College voor zorgverzekeringen
Postbus 320
NL-1110 AH Diemen **THE NETHERLANDS**
Tel: +31 20 797 8522, Fax: +31 20 797 8500
Email: bboer@cvz.nl
Internet: www.cvz.nl

DACEHTA
Director & Contact person: Prof Finn Børlum Kristensen
Danish Centre for Evaluation and HTA
National Board of Health
Islands Brygge 67
DK-2300 Copenhagen S **DENMARK**
Tel: +45 72 22 74 67, Fax: +45 72 22 74 07
Email: dacehta@sst.dk
Internet: www.dacehta.dk

DAHTA@DIMDI
Director: Dr Alric Rüther
Contact person: Ms Swetlana Frei
German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information
Waisenhausgasse 36-38a
DE-50676 Cologne **GERMANY**
Tel: +49 221 472 41, Fax: +49 221 4724 444
Email: dahta@dimdi.de
Internet: www.dimdi.de

DECIT-CATS
Director & Contact person: Dr Suzanne Jacob Serruya
Secretaria de Ciëncia, Tecnologia e Insumos Estratégicos
Ministerio da Saude, Departamento de Assistência Farmacêutica e Insumos Estratégicos,
Esplanada dos Ministérios,
Edifício sede; bl "G" - 8° andar - SL 834
CEP: 70058-900, Brasilia, DF **BRAZIL**
Tel: +55 61 3315 3197, Fax: +55 61 3315 3850
Email: suzanne.jacob@saude.gov.br
Internet: www.saude.gov.br/sctie

DSI
Director: Professor Jes Søgaard
Contact person: Dr Henrik Hauschildt Juhl
Danish Institute for Health Services Research
Dampfærgevej 27-29, PO Box 2595
DK-2100 Copenhagen **DENMARK**
Tel: +45 35 29 8400, Fax: +45 35 29 8499
Email: hhj@dsi.dk
Internet: www.dsi.dk

FinOHTA

Director & Contact person: Professor Marjukka Mäkelä
Finnish Office for Health Technology Assessment
STAKES
PO Box 220
FI-00531 Helsinki **FINLAND**
Tel: +358 9 3967 2290, Fax: +358 9 3967 2278
Email: marjukka.makela@stakes.fi
Internet: www.stakes.fi/finohta

GR

Acting Executive Director: Professor Wim Passchier
Contact person: Dr Gabriël ten Velden
Health Council of the Netherlands
Gezondheidsraad
Postbus 16052
NL-2500 BB Den Haag **THE NETHERLANDS**
Tel: +31 70 3407520, Fax: +31 70 3407523
Email: GHM.ten.Velden@gr.nl
Internet: www.gr.nl

HAS

Director: Mr Alain Coulomb
Contact person: Dr Sun Hae Lee Robin
Haute Autorité de santé/French National Authority for Health
2, avenue du Stade de France
FR-93218 Saint-Denis La Plaine CEDEX **FRANCE**
Tel: +33 1 55 93 71 88, Fax: +33 1 55 93 74 35
Email: sh.leerobin@has-sante.fr
Internet: www.has-sante.fr

HunHTA

Director & Contact person: Professor Dr László Gulácsi
Unit of Health Economics and Health Technology Assessment
Corvinus University Budapest
Fővám tér 8
HU-1093 Budapest **HUNGARY**
Tel: +36 1 482 5147, +36 1 482 5032, Fax: +36 1 482 5033
Email: laszlo.gulacsi@uni-corvinus.hu
Internet: http://hecon.uni-corvinus.hu

IAHS

Director: Professor Adrian Grant
Contact person: Dr Jennifer Burr
Institute of Applied Health Sciences
University of Aberdeen
c/o Department of Public Health
Medical School Buildings, Foresterhill
Aberdeen AB25 2ZD **UNITED KINGDOM**
Tel: +44 1224 5551102, Fax: +44 1224 554580
Email: j.m.burr@abdn.ac.uk

ICTAHC

Director & Contact person: Professor Joshua Shemer
Israeli Center for Technology Assessment in Health Care
The Gertner Institute, Sheba Medical Center
Tel-Hashomer 52621 **ISRAEL**
Tel: +972 3 530 3278, Fax: +972 3 635 41 36
Email: shukis@gertner.health.gov.il

IECS

Director: Professor Dr Adolfo Rubinstein
Contact person: Professor Dr Andres Pichon-Riviere
Institute for Clinical Effectiveness and Health Policy
Viamonte 2146 - 3 Piso
C1056ABH Ciudad de Buenos Aires **ARGENTINA**
Tel: +54 11 49 66 00 82, Fax: +54 11 49 53 40 58
Email: info@iecs.org.ar
Internet: www.iecs.org.ar

IHE

Director & Contact person: Professor Egon Jonsson
Institute of Health Economics
University of Alberta, Public Health Sciences
#1200, 10405 Jasper Avenue, Edmonton,
AB T5J 3N4 **CANADA**
Tel: +1 780 448 4881, Fax: +1 780 448 0018
Email: ejonsson@ihe.ca
Internet: www.ihe.ca

IMSS

Director: Dr Luis Durán-Arenas
Contact person: Mr Carlos Garrido-Solano
Mexican Institute of Social Security
Health Systems Division, Health Policy Coordination
Paseo de la Reforma Avenue #476-3er piso,
Col. Juárez, Del. Cuahutémoc, C.P. 06600, **MEXICO**, D.F.
Tel: +52 55 5553 1873, Fax: +52 55 5238 2709
Email: luis.duran@imss.gob.mx, carlos.garrido@imss.gob.mx
Internet: www.imss.gob.mx/IMSS/IMSS_SITIOS/DPM/Informacion/Tecnologia/Principal.htm

KCE

Director: Professor Dr Dirk Ramaekers
Contact person: Dr Irina Cleemput
Belgian Health Care Knowledge Centre
Résidence Palace, 10th floor, Wetstraat 155, Block A
BE-1040 Brussels **BELGIUM**
Tel: +32 2 287 3397, Fax: +32 2 287 3385
Email: hta@kenniscentrum.fgov.be
Internet: www.kenniscentrum.fgov.be

LBI@HTA (formerly ITA)

Director: Dr Claudia Wild
Contact person: Ms Beate Guba
Ludwig Boltzmann Institute for Health Technology Assessment
Garnisongasse 7/rechte Stiege Mezzanin (Top 20)
AT-1090 Vienna **AUSTRIA**
Tel: +43 1 236 8119 12, Fax: +43 1 236 8119 99
Email: claudia.wild@hta.lbg.ac.at, beate.guba@hta.lbg.ac.at
Internet: http://hta.lbg.ac.at

MAS
Head: Dr Leslie Levin
Contact person: Dr Birthe Jorgensen
Medical Advisory Secretariat
Ontario Ministry of Health and Long Term Care
56 Wellesley Street West, 8th Floor
Toronto, ON M5S 2S3 **CANADA**
Tel: +1 416 314 3999, Fax: +1 416 325 2364
Email: masinfo@moh.gov.on.ca
Internet: www.health.gov.on.ca/english/providers/program/mas/mas_mn.html

MSAC
Director & Contact person: Dr Stephen Blamey
Medical Services Advisory Committee
MDP 106, GPO Box 9848
Canberra ACT 2601 **AUSTRALIA**
Tel: +61 2 6289 6811, Fax: +61 2 6289 8799
Email: msac.secretariat@health.gov.au
Internet: www.msac.gov.au

MTU/SFOPH
Director: Dr Maya Züllig
Contact person: Mr Christoph Künzli
Swiss Federal Office of Public Health
Medical Technology Unit
Effingerstrasse 20
CH-3003 Bern **SWITZERLAND**
Tel: +41 31 322 1586, Fax: +41 31 322 7880
Email: christoph.kuenzli@bag.admin.ch
Internet: www.snhta.ch

NCCHTA
Director: Professor James Raftery
Contact person: Ms Lynn Kerridge
National Coordinating Centre for Health Technology Assessment
Mailpoint 728, Boldrewood
University of Southampton
Southampton SO16 7PX **UNITED KINDGOM**
Tel: +44 2380 595586, Fax: +44 2380 595639
Email: lk1@soton.ac.uk
Internet: www.hta.ac.uk

NHSC
Director & Contact person: Dr Claire Packer
National Horizon Scanning Center
Department of Public Health and Epidemiology
The University of Birmingham
Edgbaston, Birmingham B15 2TT
UNITED KINGDOM
Tel: +44 121 414 7831, Fax: +44 121 2269
Email: c.packer@bham.ac.uk
Internet: www.pcpoh.bham.ac.uk/publichealth/horizon

NHS QIS
Head & Contact person: Dr Harpreet S Kohli
NHS Quality Improvement Scotland
Health Services Research & Assessment Unit
Delta House, 50 West Nile Street
Glasgow G1 2NP
Scotland, **UNITED KINGDOM**
Tel: +44 141 225 6988, Fax: +44 141 221 3262
Email: harpreet.kohli@nhshealthquality.org
Internet: www.nhshealthquality.org

NOKC
Deputy Director General: Dr Berit S Mørland
Contact person: Dr Berit S Mørland, Ms Dagny Fredheim
Norwegian Knowledge Centre for the Health Services
Postbox 7004, St Olavs plass
NO-0310 Oslo **NORWAY**
Tel: +47 23 25 50 00, Fax: +47 23 25 50 10
Email: Berit.Morland@nokc.no, dagny.fredheim@nokc.no
Internet: www.nokc.no

NZHTA
Director: Dr Robert Weir
Contact person: Mrs Susan Bidwell
New Zealand Health Technology Assessment
Department of Public Health & General Practice
Christchurch School of Medicine & Health Sciences
PO Box 4345
Christchurch **NEW ZEALAND**
Tel: +64 3 364 36 75, Fax: +64 3 364 36 97
Email: susan.bidwell@chmeds.ac.nz
Internet: http://nzhta.chmeds.ac.nz

OSTEBA
Director: Mr Andoni Arcelay Salazar
Contact person: Ms Rosa Rico
Basque Office for Health Technology Assessment
Department of Health, Basque Government
Calle Donostia 1
ES-01010 Vitoria-Gasteiz **SPAIN**
Tel: +34 9 45 01 9250, Fax: +34 9 45 01 9280
Email: rosarico-osteba@ej-gv.es
Internet: www.euskadi.net/sanidad/osteba

SBU
Director: Professor Dr Nina Rehnqvist
Contact person: Ms Margareta Nordwall
Swedish Council on Technology Assessment in Health Care
PO Box 5650
SE-114 86 Stockholm **SWEDEN**
Tel: +46 8 412 32 00, Fax: +46 8 411 32 60
Email: nordwall@sbu.se
Internet: www.sbu.se

UETS

Director: Ms Elena Andradas Aragonés
Contact person: Assumpta Mauri Mas
Unidad de Evaluación de Tecnologías Sanitarias
Agencia Laín Entralgo
C/ Gran Vía, 27
ES-28013 Madrid **SPAIN**
Tel: +34-91 3089418, Fax: +34-91 3089458
Email: elena.andradas@salud.madrid.org,
assumpta.mauri@salud.madrid.org
Internet: www.madrid.org/lainentralgo/estudios/
marcevalua/ffevalua.htm

VATAP

Director: Dr Karen Flynn
Contact person: Ms Elizabeth Adams
VA Technology Assessment Program
Office of Patient Care Services (11T)
VA Boston Healthcare System Room 4D-142
150 South Huntington Avenue
Boston, MA 02130 **USA**
Tel: +1 857 364 4469, Fax: +1 857 364 6587
Email: VATAP@med.va.gov
Internet: www.va.gov/vatap

VSMTVA (formerly HSMTA)

Director: Dr Egils Lavendelis
Contact person: Dr Igors Trofimovs
Health Statistics and Medical Technologies State Agency
Duntes 12/22, Riga
LV-1005 **LATVIA**
Tel: +371 7501590, Fax: +371 7501591
Email: igors.trofimovs@vsmtva.gov.lv
Internet: www.vsmtva.gov.lv

ZonMw

Director ZonMw: Mr Henk J Smid
Contact person: Dr Jetty Hoeksema
The Medical and Health Research Council of The Netherlands
PO Box 93245
NL-2509 AE The Hague **THE NETHERLANDS**
Tel: +31 70 349 5260, Fax: +31 70 349 5389
Email: hoeksema@zonmw.nl
Internet: www.zonmw.nl

INAHTA SECRETARIAT

Network Coordinator: Ms Margareta Nordwall
Assistant Coordinator: Ms Elin Kullerstrand
International Network of Agencies for Health Technology Assessment
c/o SBU, PO Box 5650
SE-114 86 Stockholm **SWEDEN**
Tel: +46 8 412 32 00, Fax: +46 8 411 32 60
Email: info@inahta.org
Internet: www.inahta.org

www.inahta.org

INAHTA

c/o SBU
PO Box 5650
Tyrgatan 7
SE-114 86 Stockholm
Sweden

www.inahta.org