



INAHTA Briefs

INAHTA

International Network of
Agencies for Health
Technology Assessment

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INAHTA Briefs

The series, *INAHTA Briefs*, is published quarterly as a forum for member agencies to present brief overviews of published reports. *INAHTA Briefs* are distributed regularly along with the INAHTA Newsletter, and are also available free-of-charge at www.inahta.org

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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.

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c/o SBU

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Introduction

The International Network of Agencies for Health Technology Assessment (INAHTA) is a global network linking 35 non-profit, governmental institutions from 18 countries (2001).

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: Ultrasonic Coronary Thrombolysis

Agency: CEDIT, Comité d'Evaluation et de Diffusion des Innovations Technologiques

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Reference: CEDIT Report 99.11 (in French)

Aim

To provide aid in technology implementation and utilization at AP-HP hospitals.

Methods

The first step is to synthesize existing data on technical, medical, economic, organizational, and ethical issues related to ultrasonic coronary thrombolysis in the treatment of myocardial infarction. In the meantime, expert advice is sought.

Acceptable study designs included randomized trials, controlled clinical trials, case series, and case reports. Fourteen papers met the inclusion criteria. They were tabulated and critically appraised in terms of methodology, design, outcomes, and the possible influence of bias.

Results

Ultrasonic coronary thrombolysis (UCT) is a new type of endovascular treatment, the principal indication for which is acute-phase myocardial infarction. The method is also being studied for the treatment of stenoses and chronic occlusions of aorta-coronary bypasses. Studies published to date have addressed only the feasibility of the technique. Very few studies have been carried out, including only small numbers of patients, but all have drawn the same definitive conclusions: this technique is rapid and effective. Its medical value lies in its greater ability to remove obstructions and in the higher quality of myocardial reperfusion resulting from the lower frequency of distal embolism. This technique may prove useful in patients at high risk for hemorrhage and in those at risk for thromboembolism. However, no long-term results are available, particularly with respect to the frequency of restenosis. To date, no study has compared ultrasonic coronary thrombolysis with other mechanical and chemical techniques. Comparative studies are currently under way. In particular, a prospective European study has been initiated by an industrial company, but the results will not be available for 2 to 3 years. The public price is about 16 035 USD for the equipment and about 959 USD for the Acolysis^R specific, single-use catheter. UCT is a method suitable for managing myocardial infarction in a hospital environment. In financial terms, for patients at high risk for hemorrhage the replacement of new-generation antithrombotic treatment (Reopro^R) by UCT results in a surcharge of 260 USD per patient. For patients who have had a thrombus for several hours, UCT combined with PTCA could replace PTCA combined with the administration of Reopro^R and the possible insertion of an endoprosthesis. This substitution would result in a surcharge estimated at 260 USD per patient without stent insertion, and a saving of 287 USD per patient with stent insertion.

Conclusion

The surcharge for UCT in the overall management of the patient is not currently justified by the clinical benefits obtained. The medical results of the trials already under way and of future multicenter studies will more precisely determine the clinical efficacy of this new technique. CEDIT, taking into account the stakes involved in the management of myocardial infarction, considers that ultrasonic coronary thrombolysis may be of value as an alternative treatment, but that the benefits of this technique have not been definitively demonstrated.

Written by Djamel Tiah, Sandrine Baffert, Anne-Florence Fay, Elisabeth Fery-Lemonnier, CEDIT, France



Title: Heart laser treatment (transmyocardial laser revascularization)

Agency: SMM, The Norwegian Center for Health Technology Assessment

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www.oslo.sintef.no/smm/

Reference: SMM Report No. 6/2000. ISBN 82-1402178-2

Aim:

The Norwegian Centre for Health Technology Assessment (SMM) was asked by the Norwegian Health Ministry to perform a systematic review of the evidence concerning the effect of heart laser treatment (often referred to as transmyocardial laser revascularization).

Conclusions and results:

- A search revealed that 267 articles had been published on the subject. All articles except those in Chinese and Japanese and one review article were retrieved and read by the project group. The conclusions from this systematic review are based mainly on findings presented in 5 randomized controlled clinical trials (Schofield 1999, March 1999/Frazer 1999, Burkhoff 1999/Jones 1999, Allen 1999 and Aaberge 2000)
- Treatment with a heart laser does not save lives. On the contrary, mortality related directly to heart laser treatment is not insignificant (3% to 20%). Mortality appears to be particularly high among patients with unstable angina or cardiac failure.
- Treatment with a heart laser does not lead to an improvement in cardiac function.
- Treatment with a heart laser does result in pain reduction for many (~70%) of the patients treated.
- The report summarizes the findings from experimental studies and discusses possible mechanisms behind the pain reduction reported by patients. Clearly, a placebo effect is at work – but this may not be the entire explanation.

Methods:

Embase and MEDLINE were searched in the beginning of 2000. In addition, abstract collections from recent cardiological congresses and relevant journals from 1999 were hand searched. Unpublished material from Norwegian research groups was also available.

Further research/reviews required:

The expert group recommends further research to clarify the mechanics of heart laser treatment, the effects of heart laser treatment given by methods other than thoracotomy, and the long-term effects of such treatment. The expert group acknowledges the need for large, blind, randomized controlled trials in this field of medicine.



Title: Patient diabetes education in managing adult type 2 diabetes

Agency: AHFMR, Alberta Heritage Foundation for Medical Research, HTA Unit

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Reference: ISBN 1-896956, full text downloadable www.ahfmr.ab.ca

Aim:

To identify published evidence on the efficacy/effectiveness of formal/formalized patient diabetes education (PDE) programs in terms of long-term patient outcomes. The aim is to provide evidence to guide recommendations on program formats which may be most effective in helping patients with type 2 diabetes achieve long-term diabetes control.

Conclusions and Results:

The past decade witnessed a shift from traditional approaches in formal PDE to a focus on patient-centered perspectives, self-efficacy, and empowerment. However, the evidence reported by the reviewed quantitative research was inconclusive on whether formal PDE is effective in promoting self-management in adult patients with type 2 diabetes in the long-term to prevent/delay associated morbidity and mortality and improve patients' quality of life. Important issues associated with the use of formal PDE have yet to be clarified, eg, how comprehensive the programs should be to produce and maintain long-term beneficial effects, which approaches and components are more effective in what category of patients with type 2 diabetes. The quantitative studies reviewed did not meet the desirable criteria for methodological quality, and several methodological problems limited the interpretation of the reported results. None of the quantitative studies were conducted in Canada. Findings from the qualitative research were useful in better understanding the context in which formal PDE should be applied to be successful in promoting self-management behaviors and lead to good long-term diabetes control.

This assessment revealed a lack of consensus on the value and impact of formal PDE on long-term diabetes control needed to prevent/delay diabetes-associated morbidity and mortality and improve patients' quality of life. The long-term diabetes control outcomes of formal PDE when used to promote self-management in adults with type 2 diabetes, which types of programs or what components are most effective, and the category of patients who might benefit most have yet to be established. Future quantitative research should attempt to overcome the limitations of the reviewed studies. Recently published qualitative research identified factors that may potentially influence the impact of diabetes care and education regimens on diabetes control outcomes in the long-term.

Recommendations:

Administrators of PDE programs should be aware that trends in the delivery of PDE suggest a need for an ongoing patient-centered PDE approach, described as a step-by-step process which involves diabetes care and education providers, the patients, and their caregivers.

Methods:

Systematic review of the literature published from 1990 onward and a critical appraisal of 3 meta-analyses, 7 systematic reviews, 7 primary quantitative (3 RCTs, 4 controlled studies) and 8 qualitative research studies were performed. Data sources included MEDLINE, CINHALL, HealthSTAR, EMBASE, ERIC database, PsycINFO, The Cochrane Library, ISTAHC database and Dissertation Abstracts database.

Written by Christa Harstall, AHFMR, Canada



Title: Laparoscopic-Assisted Resection of Colorectal Malignancies

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

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Reference: ASERNIP-S Report number 8

Aims:

1. To systematically review the literature to compare the safety and efficacy of laparoscopically-assisted resection of colorectal malignancies with open colectomy.
2. To assess the laparoscopic treatment of colorectal malignancies in relation to long-term survival rates and the risk of tumor implantation in the laparoscopic port sites.

Methods:

Search Strategy – Two search strategies were devised to retrieve literature from the MEDLINE, Current Contents, Embase and Cochrane Library databases up until July 1999.

Study Selection – Papers were included using a predetermined protocol, independent assessments by two reviewers, and a final consensus decision. Human studies of laparoscopic colectomies (but excluding abdominoperineal resections and transverse colectomies), and animal studies of tumor spread were included. English language papers were selected. Acceptable study designs included randomized controlled trials, controlled clinical trials, case series, or case reports.

Data Collection and Analysis – Eighty papers met the inclusion criteria. They were tabulated and critically appraised in terms of methodology and design, outcomes, and the possible influence of bias, confounding, and chance.

Results:

Little high-level evidence was available, with few randomized controlled trials. Laparoscopic resection of colorectal malignancy was more expensive and time consuming. Some evidence suggested that patients may be at higher risk for short-term immune suppression, but little evidence suggested high rates of port site recurrence. The new procedure's advantages revolve around early operative recovery and reduced pain.

Safety and Efficacy Classification:

The ASERNIP-S review group recommended a classification of 2: "The safety and/or efficacy of the procedure cannot be determined at present due to an evidence base of incomplete and/or poor quality. Further research should be conducted to establish safety and/or efficacy." (the classification list is available at www.racs.edu.au/open/asernip-s/asernipsreviewprocess.htm) Specifically, a controlled clinical trial (ideally with random allocation to intervention and control groups) should be conducted to help remedy the lack of evidence detailing circumferential marginal clearance of tumors in the rectum, ascending and descending colon, and the necessity of determining a precise incidence of cardiac and other major morbidity, along with wound and port site recurrence. Long-term survival rates also need to be clearly assessed. The proposed multicenter Australian trial of Laparoscopic-Assisted Resection of Colorectal Malignancies would be a suitable vehicle to evaluate all of these variables. Since its protocol is similar to the large American NIH study now underway, a meta-analysis of the combined data will be possible as will a definitive picture of the relative risks of laparoscopically-assisted resection and traditional open resec-



Title: Laparoscopic Adjustable Gastric Banding

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

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Reference: ASERNIP-S Report number 9

The aim of the report is to systematically review the literature on assessing the safety and efficacy of laparoscopic adjustable gastric banding in treating obesity.

Methods:

Search Strategy – Two search strategies were devised to retrieve literature from the MEDLINE, Current Contents, Embase, and Cochrane Library databases up until February 2000.

Study Selection – Inclusion of papers was based on a predetermined protocol that specified suitable studies by type of participants, comparators, outcomes, and type of study. English language papers were selected. Acceptable study designs included randomized controlled trials, controlled clinical trials, case series, or case reports.

Data Collection and Analysis – Thirty-seven papers met the inclusion criteria. They were tabulated and critically appraised in terms of methodology and design, outcomes, and the possible influence of bias, confounding, and chance.

Results:

There was little high-level evidence available and few comparative studies.

Safety: Mortality rates were below 1 in 1000, which is less than the rates quoted in many reviews of other surgical procedures for treating obesity. Likewise, morbidity rates did not appear to exceed those quoted for other procedures.

Efficacy: Most operations appear to be completed in under 2 hours. Most studies reported rates of conversion to open procedures of under 4%. Patients appear to be discharged earlier than those undergoing vertical banded gastroplasty, and also appear to become more mobile and independent after surgery, although initially positive responses to the surgery tend to diminish with time. The laparoscopic adjustable gastric band appears capable of producing substantial weight loss up to 4 years, although longer-term data has not been published. The consistency of weight loss across the patient population is also unclear due to poor reporting of variance in most studies.

Safety and Efficacy Classification:

The ASERNIP-S review group recommended a classification of 2: “The safety and/or efficacy of the procedure cannot be determined at present due to an evidence base of incomplete and/or poor quality. It is recommended that further research be conducted to establish safety and/or efficacy.” (the classification list is available at www.racs.edu.au/open/asernip-s/asernipsreviewprocess.htm) Specifically, a register of adjustable bands and a record of serious complications should be established, possibly with anonymous reporting. Manufacturers of the adjustable bands should be encouraged to participate.

Written by Mr. Andrew Chapman, ASERNIP-S, Australia



Title: Clinical practice guideline: Eradicating therapy for *Helicobacter pylori* infections associated with duodenal ulcers in primary care

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Reference: Brief Reports No. BR98001 September 1998

The recommendations in this guideline are based on a systematic review of current scientific evidence. The general objective of this analysis is to evaluate the efficacy and safety of eradication therapy, by means of triple therapy, for Helicobacter pylori infections associated with peptic ulcers.

Aim:

The aim of this clinical practice guideline is to formulate recommendations to assist professionals in determining and selecting the most appropriate diagnostic and/or therapeutic options in the clinical management of *Helicobacter pylori* infections associated with duodenal peptic ulcer.

Main points of interest:

- Infection by *Helicobacter pylori* (*H. pylori*) is the most important pathogenetic factor associated with the presence of gastric or duodenal ulcers, unrelated to the use of nonsteroidal antiinflammatory drugs (NSAIDs).
- Results from the meta-analysis of randomized controlled trials showed a higher efficacy for triple therapy in eradicating *H. pylori* and in healing newly diagnosed gastric or duodenal ulcers.
- Results from the clinical decision analysis model showed the highest cost-effectiveness ratio for the empiric administration of triple therapy in cases of noncomplicated, previously-diagnosed duodenal ulcers without diagnostic confirmation.
- Results from this study made it possible to present a clinical practice guideline that recommends 7-day treatment with triple therapy, ie, **Proton pump inhibitor (standard dose) + Clarithromycin 500mg/12h + (Amoxicillin 1,000mg/12h or Metronidazole 500mg/12h)** as first choice eradicating therapy.
- The choice of antibiotics should be based on the local and national profile of bacterial resistances



Title: Functional food

Agency: Center for Technology Assessment at the Swiss Science and Technology Council

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www.ta-swiss.ch

Reference: Full report: TA 37/ 2000 "Functional Food", 363 pages, in German. ISBN 3-908194-12-1

Short version TA 37A / 2000 "Between the Pantry and the Pharmacy: Functional Food – A Grey Area", 10 pages in English (also available in German and French), ISBN 3-908194-13-X

Aim: The present level of knowledge concerning functional food is comprehensively investigated. The study addresses the basic scientific and technical aspects of functional food, the functionality and market potential of corresponding products, and the international and Swiss position with regard to legislation. The status of the current discussion related to functional food is systematically summarized. Recommendations for handling questions related to functional food products in Switzerland are proposed. The report should feed the public discussion concerning this new form of food with information which is as comprehensive and as balanced as possible.

Conclusions and results:

- In general, functional food is perceived as processed food which not only feeds consumers, but promises additional benefits related to the preservation and improvement of physical well-being and a reduction in the risk of falling ill from nutrition-related diseases.
- At present, functional food products are mainly developed to prevent cardiovascular diseases and osteoporosis and to influence gastrointestinal health.
- Currently, the most important functional ingredients are pro-, pre- and synbiotics, antioxidants, secondary plant metabolites, structured lipids, polyunsaturated fatty acids, fat replacers and substitutes, bioactive peptides, fibers, vitamins, and minerals.
- It is assumed that functional food represents a long-term trend which offers interesting growth opportunities for multinational food-processing companies, small and medium-sized companies in the food industry, and ingredient suppliers.
- Although functional food can potentially contribute positively toward the health of individuals, the influence of functional food on public healthcare costs in the short and medium term is considered to be limited. Reasons for this assessment are the small market share of functional food and the current product range which only partly focuses on the most important nutrition-related diseases and population groups with nutritional deficiencies and malnutrition.

Recommendations:

- Functional food should be embedded in a sensible way in a comprehensive plan for well-balanced nutrition.
- The public should be comprehensively informed about functional food and health-related nutrition.
- To remove the current uncertainty concerning regulation and practices for market approval and control of functional food, it is recommended that effective procedures be established to clarify definitional problems among the authorities responsible for controlling food and pharmaceuticals.
- The allowed health claims (which go beyond nutritional claims and refer to health-supporting effects) should be defined and should be indicated in a general way for defined groups of functional food.

Methods:

The international (scientific) literature was extensively studied, and 40 experts have been interviewed in Switzerland. The individuals and institutions taken into consideration mainly include the foodstuffs industry, nutritional sciences, preventive medicine, administration, trade, representatives of consumer interests, and nutritional consultants. Furthermore, a questionnaire has been sent to 307 persons and institutions in Switzerland.

Further research/reviews required:

It is recommended to support research activities aimed at improving the scientific basis for assessing the function, efficacy, and safety of functional food.

Written by Walter Grossenbacher-Mansuy, SWISS-TA, Switzerland



Title: Dyspepsia

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Reference: SBU Report 150, 2000 ISBN 91-87890-66-6

Aim:

To systematically review the evidence on the:

- effectiveness of *Helicobacter pylori* (*H. pylori*) eradication
- effectiveness of proton pump inhibitors (ppi) in treating different forms of dyspepsia
- effectiveness of screening for *H. pylori* in identifying stomach cancer
- cost-effectiveness of testing for and treating dyspepsia

Conclusions and results:

- eradication of *H. pylori* in case of ulcers only (two antibiotics + ppi the most effective)
- ppi for GERD and NSAID-related ulcers only, not for functional dyspepsia
- screening of *H. pylori* is not motivated for stomach cancer prevention
- test-and-scope more cost-effective than test-and-treat

Recommendations:

Not addressed

Methods:

A comprehensive search strategy for published studies in English (for functional dyspepsia also German, Spanish, Swedish, Norwegian, and Italian) included various electronic (mainly MEDLINE and EmBase) and bibliographic sources, originally for the period 1966 through 1998, but later extended through February 1999.

Further research/reviews required:

Additional research is needed to determine:

- the importance of genetic, life-style, and environmental factors, since not everyone infected with *H. pylori* develops ulcers (prospective epidemiological studies needed)
- the mechanisms in the mucosa of the stomach that protect from, or increase the risk for, development of ulcers
- if certain forms of *H. pylori* are more virulent than others, and if can they be diagnosed by simple methods.



Title: Vaccination for Influenza in Elderly

Agency: DIHTA, Danish Institute for Health Technology Assessment, Denmark

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Reference: Medicinsk Technologivurdering 2000; 2(1)

This report is based on a structured literature review and estimates of Danish conditions and policies on influenza vaccination in people older than 65 years.

Four different organizational regimes are compared:

- A. Non-structured activities.
- B. Personal invitations from the GP to the elderly. Patient fee charged for vaccination.
- C. Personal invitation from a public agency. Vaccination by a nurse free of charge.
- D. Personal invitation for vaccination administered by family doctor, free of charge.

The analysis is based on the assumption that 17 vaccinations are needed to prevent one case of influenza, and that the life expectancy of those who died is equal to the life expectancy of the remaining population.

The clinical effect of a vaccination offer ensuring that 70% of the elderly over 65 are vaccinated is compared with the hypothetical situation that no elderly people are vaccinated. In Denmark (total population approx 5 million), this would prevent 33 000 reported cases of influenza, reduce the number of in-bed days by 4300, reduce the number of deaths by 196, and save 1540 life years. Surveys, however uncertain, indicate that regimen A results in 40% vaccinated, regimen B in 50%, regimen C in 66%, and regimen D in 70% vaccinated.

Based on these figures, and on the actual costs for the regimens, regimen D would save the most life years and regimen A would save the least. Regimen C would be the least expensive, and regimen D would be the most expensive in socioeconomic costs. Regimen C would be the most cost-effective and regimen A would be the least cost-effective. Thus, in this study, the structured regimes were superior to the non-structured ones.

Cost-effectiveness analysis (CEA) for each of the four regimens, assuming that no one is vaccinated

Organizational regimen	Years of life gained	Socio-economic costs (DKK million)	CEA ratio (DKK 1000/year of life)
A – Non-structured activities	881	68.4	78
B – General-practice vaccination; user free	1 101	73.6	67
C – The Copenhagen regimen	1 453	34.7	24
D1 – General-practice vaccination; free of charge	1 541	92.0	60
D2 – General-practice vaccination; free of charge	1 541	69.3	45

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Written by Assoc. Prof. Jan Adolfsson, SBU, Sweden



Title: Preoperative Hair Removal

Agency: SMM, The Norwegian Center for Health Technology Assessment

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Reference: SMM Report No.2/2000

The prevention of postoperative surgical site infection through preoperative skin preparation has a long history. One of the measures has been hair removal in the operation field, traditionally using a razor (shaving). Since the questions of when and how to remove hair preoperatively have not been subjected to a systematic literature review, we decided to perform an assessment on the topic.

This report is a part of a wider project - Assessment of hygienic measures in operating theatres used to prevent surgical site infections.

A literature search was performed in MEDLINE, Cochrane Trial Register, Embase, CINAHL, Database of Abstracts of Reviews of Effectiveness (DARE), National Health Service Economic Evaluation Database, and Health Technology Assessment Database. The keywords used were “surgical site infection/s OR surgical wound infection/s” AND “depilation OR hair OR shaving”. Reference lists of relevant articles published during the 1990s were searched manually. Ten experts having expertise in surgery, epidemiology, preventive medicine, nursing, microbiology, or statistics assessed all relevant articles and authored the report.

SMM Conclusions:

- There is no strong evidence to dissuade preoperative hair removal with respect to surgical site infections.
- Several randomized studies and observational studies with controls show that dry or wet shaving the day before surgery yields a significantly higher incidence of surgical site infections compared to depilation, electrical clipping, or no hair removal.
- Among depilation, electric clippers, or no hair removal there are no convincing differences in effects as regards surgical site infections.
- Hair removal should be done as close to the time of surgery as possible.
- Considerations of cost-efficiency suggest that the hair removal method giving the lowest prevalence of surgical site infections should be preferred.
- These conclusions differ somewhat from those presented in a recent guideline published by the Centers of Disease Control and Prevention (CDC), USA.

The report is available in Norwegian at: www.sintef.no/smm.



Title: Economic evaluation of zanamivir for the treatment of influenza

Agency: CCOHTA, Canadian Coordinating Office for Health Technology Assessment
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www.ccohta.ca

Reference: CCOHTA Technology Report, Issue 13, January 2001.
ISBN 1-895561-96-5 (print); 1-895561-93-0 (online); www.ccohta.ca

Aim:

To assess the cost-effectiveness of zanamivir for treating patients with influenza, specifically:

- the general population (aged 12 years and older; presenting to a physician with an influenza-like illness within the recommended 48 hours of symptom onset), and;
- those at-risk of developing complications related to influenza.

Results:

From the perspective of a government healthcare payer base case results show an incremental cost per quality-adjusted life-year (QALY) gained of \$195 000 to \$235 000 (\$194 to \$234 per symptom day avoided) when the diagnostic rate is low (ie, 14%). When the diagnostic rate is higher (ie, 35%), the results are \$77 000 to \$95 000 per QALY (\$77 to \$93 per symptom day avoided). These results fall below \$50 000 if hospitalization is significantly reduced due to treatment with zanamivir combined with a high rate of diagnostic accuracy. Most of the societal costs associated with influenza fall outside the healthcare system, ie, on those who are ill and their caregivers.

Conclusions:

There is evidence that timely treatment with zanamivir can have a modest impact on health outcomes. However, the analysis suggests that it is not a cost-effective strategy for publicly funded drug plans to prescribe zanamivir for the treatment of influenza in those who are not at risk of influenza-related complications. Zanamivir could be cost-effective in high-risk groups if the accuracy of diagnosing influenza was relatively high and if significant hospitalizations could be prevented. However, the evidence for this is inconclusive. Major concerns include the impact on primary care of the demand for zanamivir and the potential for widespread unnecessary prescribing of the drug.

Methods:

This economic evaluation uses a decision analytic model to derive the results on cost-effectiveness. Evidence on the efficacy and safety of zanamivir is reviewed and health outcomes, resource use, and costs associated with treating influenza using zanamivir are compared with using over-the-counter medications for symptom relief. Results of the model are presented in terms of incremental cost per symptom day avoided and quality-adjusted life-years gained. A number of sensitivities were performed. Data on the efficacy and safety of zanamivir are taken from a meta-analysis of clinical trial results that were provided by the National Institute of Clinical Excellence (NICE). Data for disease epidemiology, unit costs, and resource use are derived from published studies and databases and are based on estimates for Canada, where available.

Further research/reviews required:

Further analysis may be warranted when additional data on the efficacy and effectiveness of the drug, particularly in high-risk groups, becomes available. Analysis using other antiviral agents as a comparator would also be useful.

Written by Brady B, McAuley L, Shukla VK, CCOHTA, Canada



Title: Mammography screening: mortality rate reduction and screening interval

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Reference: HTA 21; June 2000; ISBN 1-896956-29-7

The ultimate aim of mammography screening of asymptomatic women is early detection to prevent or delay mortality from breast cancer. Breast cancer is the most frequently diagnosed cancer in Canadian women, accounting for about 30% of all new cancer cases each year. In year 2000, an estimated 1650 new cases of breast cancer will be diagnosed in Alberta, and 430 women will die of the disease.

The Alberta Clinical Practice Guidelines Program, in updating its clinical practice guidelines (CPG) on breast cancer screening, requested a review to assess the current scientific evidence on:

- the effective time interval for mammography screening in asymptomatic women aged 50 to 69 years;
- the effective screening interval in asymptomatic women aged 40 to 49 years; and
- the mortality rate reduction of mammography screening in asymptomatic women aged 40 to 49 years.

Evidence from eight randomized controlled trials (RCTs) launched between 1963 and 1983 consistently showed a reduction in breast cancer mortality in screened women aged 40 to 74 years (screening intervals of 12 to 33 months). The trials were designed to determine the efficacy of mammography screening alone or in combination with clinical breast examination, but not the appropriate screening intervals for different age groups. Only one of the trials, the Canadian National Breast Screening Study, specifically studied the efficacy of mammography screening in younger women (aged 40 to 49 years), but failed to show any reduction in mortality.

Two uncontrolled, retrospective studies attempted to determine the appropriate screening intervals for the different age groups. These study designs were weak and would fail to exclude chance or bias as alternative explanations for their findings. Methodologically sound studies have not assessed the appropriate screening intervals for asymptomatic women aged 50 to 69 years or for women aged 40 to 49 years.

Generally, mortality reduction is lower in younger women than in older women, and the interval between initiating screening and observing reduced mortality is longer for younger women. A 10-year multicenter RCT started in the UK in 1991 and aims to address the efficacy of commencing annual mammography screening in asymptomatic women at the age of 40 and 41 years. However, it will not answer the question about appropriate screening intervals in this age group.

The report concludes that the Alberta CPG, *Guidelines for the Early Detection of Breast Cancer* (April 1999) is consistent with the scientific evidence published to date. The screening intervals recommended by the Alberta CPG reflect those recommended by other international guidelines and national screening programs. However, the guidelines vary in relation to the age at which screening should begin or the frequency of screens in the different age groups. They appear to mirror different ways of interpreting the evidence and the perspectives of the agencies or organizations that produce the guidelines.



Title: Erythropoietin in Tumor Anemia

Agency: ITA, Institute of Technology Assessment at the Austrian Academy of Sciences

Strohgasse 45, 1030 – Vienna, Austria; www.oeaw.ac.at

Reference: ITA-Reports June 1/2000

The excellent results achieved with the use of Epoetin (recombinant human erythropoietin, EPO) in the chronic anemia of renal insufficiency raised the expectation that it might also be suited to treat chronic anemia in cancer. While EPO is most effective in treating anemia of (some) hematological malignancies, the results in anemia of solid tumors are less conclusive: 40% to 50% of tumor patients do not respond to EPO. The treatment of anemia with EPO is an expensive intervention.

The report is based on a systematic review of the clinical literature and clinical guidelines. The assessment was discussed with experts (hemato-oncologists) in an expert hearing and approved by them before publication.

- Assessment of the available clinical information focuses on overall efficacy and effectiveness of EPO in tumor anemia: response rates and response criteria, doses-regimes, response of different types of tumors to EPO, and models for early recognition of responders and nonresponders.
- The economic assessment focuses on quality of life (QoL), therapy options, and transfusion-reduction.

The project aims to provide relevant information to health insurers on the appropriate treatment with EPO in tumor anemia.

Results:

- Patients achieving an Hb-increase >2 g/dl are considered as responders. Only 50% to 60% of tumor patients respond to EPO.
- Of the responders, 20% to 30% still require transfusions.
- The effect of EPO treatment is measured by increased QoL and prevention/reduction of transfusion needs. There is little evidence on QoL for the responders who still need transfusion.

There is insufficient evidence to show an association between response rates and types of tumors.

Conclusion:

- Early recognition of responders and nonresponders is the key to appropriate and cost-effective treatment with EPO. Different prediction parameters, combined with transfusion requirements and life expectancy/ stability of tumor status, predict the chances of patients benefiting from EPO treatment.

The assessment is available in German only. Full report available at: www.oeaw.ac.at/ita/hta/



Title: Effectiveness and cost-effectiveness of automated and semi-automated cervical screening devices: A systematic review

Agency: NZHTA, New Zealand Health Technology Assessment

Christchurch School of Medicine, PO Box 4345, Christchurch, New Zealand; tel/fax:+64 3 364 1152,

<http://nzhta.chmeds.ac.nz>

Reference: NZHTA Report, Issue 3(1) 2000. ISBN 1-877235-13-X

<http://nzhta.chmeds.ac.nz/nzhtainfo/csv3nl.pdf>

Aim:

To systematically review the evidence for effectiveness and cost-effectiveness of introducing “new” devices in place of conventional Pap testing in New Zealand’s population-based screening program. Devices considered included automated liquid-based slide preparation systems (Thinprep and AutoCyte Prep) and a semi-automated, computerized image processor for ranking slides according to their likelihood of being abnormal (AutoPap System).

Conclusions and results:

- Estimates of test sensitivity and specificity could not be reliably determined. There was no reliable evidence for improved detection of high-grade abnormalities by the devices.
- To date, there is minimal evidence relating to new devices’ test specificity. Therefore, the possibility that new devices may increase false positive diagnoses has not been comprehensively evaluated in the literature.
- In cost-effectiveness models, additional abnormalities assumed to be detected by new devices were found to have little impact on cancer mortality.

Recommendations:

- The vast majority of missed abnormalities will be detected at subsequent screens for women who are routinely screened appropriately, assuming acceptable levels of smear taking and laboratory performance. The Pap test should therefore remain the standard of care in New Zealand’s three-yearly, population-based cervical screening program (this recommendation has been accepted by the New Zealand government’s health purchasing body).
- Industry-produced promotional material should be balanced by independent, evidence-based material (this recommendation is being acted upon by the New Zealand government).
- Resources required to introduce new devices into the National Cervical Screening Programme may lead to better outcomes if dedicated to other strategies.

Methods:

The comprehensive search strategy conducted by Susan Bidwell included various electronic and bibliographic sources, Internet websites, New Zealand government publications, and citations of retrieved papers. Searches were limited to English language material published from January 1997 through May 2000 to update the search dates of a 1998 review produced by the Australian Health Technology Advisory Committee (AHTAC). The search strategy identified 26 papers eligible for full appraisal from over 700 identified. The report includes a comprehensive chapter discussing methodological issues in cytological research. Six expert consultants provided advice and peer review.

Further research/reviews required:

Higher quality research is required to generate valid estimates of test sensitivity and specificity for new cervical screening devices. Methodological limitations to address include the application of appropriate reference standards for verification of cytological diagnoses, including test negatives. Economic modeling studies would be more meaningful with more valid estimates of test characteristics, and a comprehensive measurement of screening costs from a societal perspective, including careful investigation of the impact of screening and clinical management on quality of life. It is recommended that the conclusions of this report be revisited in October 2001.



Title: The effects of extending the use of mammography screening
A report on the cost-effectiveness of breast cancer screening
in 60 to 69 year-old women

Agency: FinOHTA, Finnish Office for Healthcare Technology Assessment

STAKES, POB 220, FIN-00531, Helsinki, Finland; tel:+358 9 3967 2297, fax:+358 9 3967 2278;

finohta@stakes.fi, www.stakes.fi/finohta/

Reference: FinOHTA Report 16, ISSN 1239-6273, ISBN 951-33-0530-9
www.stakes.fi/finohta/raportit/016/

Aim:

The Ministry of Social Welfare and Health asked FinOHTA to estimate the costs and effects of extending breast cancer screening past the age group presently targeted in Finland (women aged between 50 and 59 years), up to 69 years of age. This report is based on literature searches, expert information, and surveys by a working group in May 2000.

Conclusions and results:

Estimates of the effects of breast cancer screening vary considerably in the literature. Although several large studies have been completed, the relatively small number of women dying from breast cancer makes it difficult to show the exact changes in mortality. Another difficulty is separating the independent effect of screening from the mortality decrease caused by recent improvements in treatment. The screening-induced increase in life expectancy is also technically demanding to separate from increases due to other factors, such as changes in general health in successive cohorts of women.

In the model used for this study, the cost per life-year saved by mammography screening was estimated to be 36 600 Finnish marks (6100 Euro). This did not include treatment costs. When items in the basic estimate were varied, the expected changes in mortality had the largest effect. The second most important factor in the cost calculations was the increase in life expectancy. When all factors were varied within reasonable limits, the cost estimate ranged from 11 600 FIM (2000 Euro) at best to 223 000 FIM (38 000 Euro).

Finland has a sufficient number of screening devices and professionals experienced in screening to potentially expand mammography screening. However, their geographic distribution is uneven. Some municipalities will need notable extra resources to extend screening to new age groups, while others can manage with their existing arrangements.

Recommendations:

Not addressed

Methods:

Systematic review (MEDLINE, Cochrane, DARE, INAHTA)

Further research/reviews required:

Not addressed



Title: Effectiveness of early interventions for preventing mental illness in young people

Agency: NZHTA, New Zealand Health Technology Assessment

Department of Public Health and General Practice, Christchurch School of Medicine, PO Box 4345,

Christchurch New Zealand; tel/fax:+64 3 364 1152, nzhta@chmeds.ac.nz

Reference: NZHTA Report 1999; 2(3); ISBN 1-877235-10-5

This is a critical review of the literature regarding prevention of mental health conditions in youth relating to substance abuse, conduct disorder, mood, eating disorders and/or anxiety, and intervention in the early stages of a mental health condition to alter its development or pathway.

An extensive list of databases and many other electronic and bibliographic sources were searched. Searches were limited to English language material from 1995 onward and were run between mid-May and mid-June 1999.

Studies were selected and appraised if they quantitatively evaluated the effectiveness of early interventions to affect the mental health outcomes for people aged 14 to 24 years.

After applying inclusion and exclusion criteria, 35 papers of 171 identified articles were eligible for selection.

Data were extracted, reviewed by two reviewers, and synthesized according to the relevant mental disorder.

Sixteen of the 35 studies related to early interventions for substance abuse, eight to conduct disorders/violence prevention, three to mood disorder prevention, four to eating disorder prevention and four to general mental health interventions are presented in a systematic way. Also reviewed were two studies conducted in New Zealand that did not meet the criteria defined.

The report, written by B Nicholas and M Broadstock, contains a thorough discussion of the problem and concludes that, in line with mental health prevention generally, good quality research on program effectiveness is lacking. This lack of research may reflect a focus by programs to intervene in mid-childhood rather than in adolescence.

The report ends with *a summary leading to eight recommendations (abbreviated here), that*

1. early intervention program providers look to the work of others internationally and consider which program development strategies would best meet their needs,
2. early intervention program providers consider transferring programs already implemented elsewhere,
3. early intervention programs are pilot-tested on a small scale,
4. early intervention programs involve outcome evaluation strategies which are well planned, realistically resourced, and appropriately extended over time,
5. early intervention programs include process evaluations,
6. evaluations of early interventions include the cost-effectiveness of conducting the programs,
7. workforce development and training initiatives are instituted in the areas of early intervention program development, implementation, and evaluation,
8. advice and expertise on planning and conducting evaluation program is available from the early stages of developing the program.



Title: Surgical Treatment of Parkinson's disease

Agency: AETSA, Agencia de Evaluación de Tecnologías Sanitarias de Andalucía

Luis Montoto 89, 4ª Planta 41071, Sevilla, Spain; tel: +34 95 500 6841, fax: +34 95 500 6845, aetsa@cica.es

Reference: AETSA report for the Ministry of Health of Spain, 1999

This is a systematic review of the literature on the safety and effectiveness of three surgical treatments for Parkinson's disease: pallidotomy, deep brain stimulation (DBS), and transplantation.

The MEDLINE, EMBASE, INAHTA, and Cochrane databases were searched using a specific strategy for each surgical procedure (English, Spanish, French, and German languages, from 1990 to 1999). Three HTA reports on pallidotomy were found (Wessex, Alberta, and VATAP), and 23 articles were selected from 147 identified after applying inclusion criteria. Six articles were related to pallidotomy, eight to DBS (4 thalamus, 2 globus pallidum, 2 subthalamic nuclei), eight to transplantation, and one was a comparative study.

The report includes a synthesis of efficacy and safety studies, current physiopathologic knowledge, and descriptions of each procedure. Diffusion in Spain and other countries and social and ethical issues are also considered. Most studies are case series, with only one well-designed trial recently published, but followup is too short. Although most researchers draw similar conclusions, the quality of evidence is poor, and many methodological problems remain unsolved, particularly outcome assessment.

Surgical procedures are mainly applied to advanced Parkinson's disease stages after failure of medical treatment. Pallidotomy shows some reduction in symptoms, mainly in tremor, bradykinesia, and drug-related dyskinesias, generally maintained for at least 2 years. DBS of the globus pallidus shows similar results and better antiparkinsonian effects. DBS of the subthalamic nucleus involves a wider range of benefits on parkinsonian symptoms, including postural stability and gait, but its beneficial effect on dyskinesias is due, in part, to the reduction in medication.

Pallidotomy is followed by adverse effects that must be taken into account when the indication is considered (visual field defects, intracerebral hematomas) and some authors recommend exclusion of the bilateral procedure. Adverse effects of DBS are usually well tolerated and only occasionally are they serious and permanent. The high cost of the devices and the difficulty in setting the stimulation parameters may counterbalance the indication in some instances.

Fetal mesencephalon transplantation to the striatum is usually followed by amelioration of parkinsonian symptoms in the case series that have been published. The transplant is usually well tolerated, but adverse effects including confusion and small hemorrhages, and more often problems derived from immunosuppression can occur. Ethical issues and the difficulty in obtaining 4 to 8 human fetuses per patient are additional limitations associated with this technique. Coimplants of adrenal medulla and peripheral nerves are reported to have benefits similar to fetal mesencephalon transplantation, but the method seems to have been abandoned due to high mortality and morbidity rates. Recent experiences in animal models with autotransplants of carotid body cells showed promising results. The procedure could be safer and more available, and the first study in humans is currently underway in Andalusia.

Recommendations:

The procedures listed above should be performed only in carefully selected patients by neurosurgeons with a high level of expertise in stereotactic methods. A national registry for outcome evaluation should be established. Well-designed randomized controlled trials are needed to provide better evidence, particularly concerning long-term outcomes, functional ability, and quality of life measures.



Title: Guidance on the use of donepezil, rivastigmine, and Galantamine for the treatment of Alzheimer's disease

Agency: NICE, National Institute for Clinical Excellence

11 Strand, London WC2 N 5HR, United Kingdom; tel :+44 20 7766 9191, fax:+44 20 7766 9123;

nice@nice.nhs.uk, www.nice.org.uk

Reference: Technology Appraisal Guidance No19, ISBN 1-84275-061-7 Issue Date: January 2001, Review Date: December 2003

Aim:

To review and consider the available evidence on the clinical and cost-effectiveness of donepezil, rivastigmine, and galantamine for the treatment of Alzheimer's disease, and to issue guidance on their use to the National Health Service in England and Wales.

Conclusions and results:

- A systematic review identified 5 randomized controlled trials for donepezil, 5 for rivastigmine, and 3 for galantamine. It also identified 3 systematic reviews for donepezil, 3 for rivastigmine, and one for galantamine.
- RCT evidence demonstrates that all 3 drugs to have some effect on global outcome measures. All 3 drugs also show statistically significant improvement in cognitive function with average improvements of 1-2 points (out of 30) in mini-mental state examination (MMSE) over 6 months compared to placebo (N.B. there is an average decline of 4-5 points over the same period in placebo-treated patients).
- Not all patients benefit from using these drugs. It is also difficult to predict before treatment commences who will benefit the most.
- Evidence that quality of life has been improved by treatment with these drugs is mixed.
- A systematic review of health economic evidence identified nine published studies, 5 for donepezil and 4 for galantamine.
- The main economic benefit of these drugs is the cost saving from delayed progression to the requirements for nursing home care. This cannot be estimated reliably from existing trial evidence.
- Many of the published economic studies were conducted in settings outside the United Kingdom. About half of the studies suggested that the drugs are cost saving. Other studies show a cost per QALY gained ranging from zero to approximately £30,000.
- The three manufacturer submissions present a cost per QALY gained ranging from cost saving up to approximately £10,000.
- Mini-mental state examination scores of above 12 are necessary to demonstrate cost effective use of these drugs.

Recommendations:

The 3 drugs should be made available in the National Health Service for England and Wales as one component in the management of people with mild and moderate Alzheimer's disease whose mini-mental state examination score is above 12 points. This is subject to a number of conditions including specialist assessment before therapy is initiated, and a further assessment, which will usually be 2 to 4 months after the patient has reached the maintenance dose. Patients should be reviewed using the MMSE score every 6 months and therapy maintained only while their score remains above 12 points.

(continued next page)

Written by Dr. Carole Longson, NICE, United Kingdom



Title: Guidance on the use of donepezil, rivastigmine, and galantamine for the treatment of Alzheimer's disease

Agency: NICE, National Institute for Clinical Excellence

11 Strand, London WC2 N 5HR, United Kingdom; tel :+44 20 7766 9191, fax:+44 20 7766 9123;

nice@nice.nhs.uk, www.nice.org.uk

Reference: Technology Appraisal Guidance No19, ISBN 1-84275-061-7 Issue Date: January 2001, Review Date: December 2003

Methods:

A comprehensive systematic literature review was undertaken by the Wessex Institute for Health Research and Development at the University of Southampton and submitted to the Institute as an Assessment report (the full Assessment Report is available on our website. The Appraisal Committee of the Institute considered the Assessment Report together with submissions from manufacturers, and patient and professional organizations. Expert clinicians and patient advocates provided personal representation at the Appraisal Committee meeting.

Further research/reviews required:

Research should identify whether these drugs are of similar effectiveness, their place in the treatment of severe dementia, and whether they are of benefit in the treatment of other forms of dementia. The effect of these drugs on the delay in progressing to institutionalised care is not well established. Health economic studies should be carried out which allow more precise estimates of the magnitude of this effect to be made.



Title: Back and Neck Pain

Agency: SBU, The Swedish Council on Technology Assessment in Health Care, Sweden

PO Box 5650, 114 86, Stockholm, Sweden; tel:+46 8 412 3200, fax:+46 8 4113260, www.sbu.se

Reference: SBU report No.145, ISBN 91-87890-60-7, 91-87890-65-8 (in Swedish)

This is an 800-page report on the epidemiology, diagnosis, and treatment of back and neck pain. Also covered in the report are the economic, social, and psychosocial aspects of back pain. An international working group of 13 researchers in the fields of medicine, epidemiology, psychology, and economics did a systematic review of the findings from clinical research of different options to treat back pain. Report took 4 years to complete. English summary of the report is available at www.sbu.se

Altogether 25 000 studies were identified of which 2000 were finally referenced in this report. The evidence was graded as strong (A), moderate (B), limited (C), or no evidence (D).

The scientific basis for more than 30 different treatments was systematically reviewed.

For the majority of these there are either no evidence or limited evidence in favor of treatment. For some modalities there is strong or moderate evidence against their effectiveness, eg, by traction, aerobics, stretching, and bed rest. For a minority of treatments there is strong evidence of effectiveness, eg, for antiinflammatory and muscle relaxant drugs, manual treatment, manipulation, exercise, multidisciplinary treatment, spa treatment, and continuation of normal activities.

For diagnosing: Systematic anamnesis and physical examination are good foundations for correct diagnosis (B). Radiographic studies are of limited value.

For acute low back pain: Normal activities result in faster recovery and fewer chronic functional disorders (A), anti-inflammatory and muscle relaxant drugs offer effective pain relief (A), while bed-rest is not effective (A).

For chronic back pain: Manual treatment/manipulation, back training, and multidisciplinary treatment effectively relieve pain (A). Intensive treatment at a health resort reduces pain in the short term for elderly patients (>60 years of age) with chronic low back problems (A).

Surgery: For herniated discs, effective (A). For surgical fusion, no evidence (D).

For neck pain, the evidence is sparse. The only firm evidence is that acupuncture is not effective (A). Psychological and social factors may have a strong influence on back and neck pain.

SBU conclusions include:

- Back and neck pain is common. Healing is promoted by staying active, returning to work, and exercising at an appropriate intensity.
- A thorough anamnesis and physical examination is important for relieving anxiety about the consequences of pain and sufficient for identifying those who should be referred to a specialist.
- For most patients with back pain, the interventions that can be offered in primary care are the only ones needed.
- Back pain and its consequences are not isolated physical problems but are associated with other conditions such as social, psychological, and workplace-related factors.
- Knowledge on how to prevent back pain has been applied and assessed to a surprisingly minor degree.
- There is little scientific evidence on the effectiveness of most treatments.

Written by Assoc. Prof. Jan Adolfsson, SBU, Sweden



Title: Whiplash – diagnosis and evaluation

Agency: SMM, The Norwegian Center for Health Technology Assessment

SINTEF Unimed, Postboks 124 Blindern, 0314 Oslo, Norway; tel:+47 22 06 7808, fax:+47 22 06 7979,

www.oslo.sintef.no/smm/

Reference: SMM Report No. 5/2000 ISBN 82-1402169-3

Annually, there are approximately 2000 new cases of whiplash injury due to motor vehicle collisions in Norway. The increasing incidence of whiplash injuries from motor vehicle accidents in Norway and a general lack of certainty and agreement regarding how such injuries should be managed has been the background for this health technology assessment. Uncertainty exists both in the diagnosis and treatment of patients and in the handling of possible insurance and compensation claims.

This report is a systematic review. An English summary is available at www.sintef.no/smm.

SMM Conclusions:

- Three to five percent of all persons exposed to a whiplash injury mechanism following a motor vehicle collision develop acute whiplash injury symptoms within 0 to 3 days.
- The most common symptoms of acute whiplash are neck pain and stiffness (80% of the 3% to 5% who develop symptoms) and headache.
- There is no documented evidence to support a causal relationship between type or grade of injury and specific symptoms or symptom constellations.
- A minority of patients (10% of the 3% to 5% who develop symptoms) develop chronic complaints that have a considerable impact on their level of functioning.
- The clinical characteristics related to the development of chronic symptoms are unclear. Objective signs are far from specific and are not robust enough to lead one to common pathophysiological mechanisms for “chronic whiplash syndrome”.
- Evidence-based documentation has not been found to support the contention that chronic complaints following a whiplash injury mechanism are specific or are directly related to the actual injury mechanism.
- We are thus left with an incomplete ‘diagnostic explanation’ for this condition, and thus stress the need for further research in this area. Also needed is greater knowledge of the normal physiology of the neck and the general development of chronic pain.

The report is available in Norwegian at: www.sintef.no/smm.



Title: Treatment of lumbar disc herniation

Agency: SMM, The Norwegian Center for Health Technology Assessment

SINTEF Unimed, Postboks 124 Blindern, 0314 Oslo, Norway; tel:+47 22 06 7808, fax:+47 22 06 7979,
www.oslo.sintef.no/smm/

Reference: MM Report No. 1/2001

Aim:

The aim of the present report is to summarise the documentation on treatment of patients with lumbar disc herniation and nerve root affection.

Conclusions and Results:

Conservative treatment:

Traction of patients with lumbar disc herniation has no effect. Furthermore, no positive effect was found for non-steroidal anti-inflammatory drugs (NSAIDs). Documentation is limited and somewhat weak as regards behavioral interventions, physical training, and electrotherapy (eg, electro-acupuncture and ultrasound), and further clinical research is warranted. No studies of manipulation of acute disc herniation were found. Moderate evidence was found in the literature that would encourage patients with lumbar disc herniation to return to light daily activities instead of bed rest. However, some patients initially have severe pain and have no other option than to stay in bed until the most severe pain has tapered off. Clinical controlled trials show that postoperative guided training can be valuable and lead to reduced pain and increased physical function, but the long-term effects are less impressive.

Invasive treatments:

Some patients need emergency treatment, eg, surgery for cauda equina syndrome. Also patients that need sustained opioide-like drugs for long-lasting strong pain are candidates for surgery. Chemonucleolysis and percutaneous discectomies are chemical and mechanical degradation, respectively, of the lumbar disc. Studies of good methodological quality show that chemonucleolysis (chymopapain) is significantly better than placebo. Only limited and contradictory evidence indicates that percutaneous discectomies yield inferior results compared to surgery, and more studies are needed. Discectomy is indirectly documented: Chemonucleolysis is more effective than placebo, and discectomy again shows a somewhat better effect than chymopapain. Discectomy has good effect in selected patients who have not responded to conservative treatment. No difference between microdiscectomy and standard discectomy was found. One randomized study compared video-assisted arthroscopic microdiscectomy with discectomy. The technique led to less postoperative pain and shorter rehabilitation compared to discectomy, but the study showed no differences in the patients' ability to return to work and perform normal activity or physical function.

Methods:

A literature search was performed in MEDLINE, Embase and Cochrane Trial Register. SBU Report 145/1-2 was also used in the assessment.

Written by Dr. Inge Kjønnesen, SMM, Norway



Title: Treatment of urinary incontinence

Agency: SBU, The Swedish Council on Technology Assessment in Health Care

PO Box 5650, 114 86, Stockholm, Sweden; tel:+46 8 412 3200, fax:+46 8 4113260, info@sbu.se

Reference: SBU report No.143, February 2000; ISBN 91-87890-56-9

This exhaustive HTA report covers treatments, epidemiology, diagnostics, health economics, and care organization related to incontinence.

The report was authored by a project group of 10 persons representing general practice, urology, gynecology, and nursing. Five external experts reviewed the final report.

The report is based on a critical appraisal of the literature available in MEDLINE and other sources. The scientific basis for current diagnostic procedures and treatments are evaluated. Due to the nature of the condition, both quantitative and qualitative outcome parameters were used. The conclusions of the working group were ranked from A (based on several studies of good quality) to C (based on single studies of acceptable quality). The report is structured in sections on epidemiology, work-up and diagnosis, conservative treatment, pharmacological treatment, surgical treatment, quality of life, incontinence in primary care, incontinence in elderly, incontinence aids, and health economics.

A summary in English is available at: www.sbu.se

SBU Conclusions:

Urinary incontinence is a public health problem. In Sweden, 500 000 people (total population – 9 million) are estimated to be incontinent, but only half of them seek treatment. The level of information to the public about available treatment needs to be assessed. Ways of informing the public about incontinence and its treatment need to be developed.

Urinary incontinence is treated by a variety of methods, conservative, pharmacological, and surgical but a large number of patients are treated only with adult diapers. Many of these methods show good results, but comparative evaluations are needed. The efficacy of prophylaxis, eg, during and after pregnancy, needs to be further evaluated.

An improvement in urinary incontinence is of importance for the patient's quality of life. However, perceptions on life quality are individual, and this issue needs to be addressed and investigated in future studies.

Urinary incontinence is a common and often hidden problem across the entire population. The true prevalence needs to be investigated. Preferably, urinary incontinence should be registered as a separate entity in public health statistics so that prevalence and changes in prevalence can be monitored.



Title: Recombinant-FSH as adjuvant in assisted reproduction. Some data on the efficacy and efficiency of recombinant-FSH related to FSH of urinary origin.

Agency: CAHTA, Catalan Agency for Health Technology Assessment and Research
Travesera de les Corts, 131-159, 08028 Barcelona, Spain; tel: +34 93 227 2900, fax:+34 93 227 2998,
diraatm@olimpia.scs.es, www.aatm.es

Reference: Brief Reports No. BR02/2000. February 2000

Since the birth of the first girl conceived by in vitro fertilization in 1978, assisted human reproduction technologies have opened new, interesting procreation possibilities for many people with fertility problems. In the two decades that have elapsed since the first successful case, the development and acceptance of these techniques has increased considerably.

This report assesses the relative efficacy of recombinant FSH (r-FSH) and the cost-effectiveness of drug consumption compared to FSH of urinary origin for the two main therapeutical indications for this hormone: controlled ovaric hyperstimulation in assisted human reproduction and ovulation induction in the hypothalamic-hypophyseal portal system.

Based on the results of a systematic review of the scientific literature, the following **conclusions and recommendations** were drawn:

- Recombinant FSH seems to be slightly more effective in terms of consumption, and generated between 3% and 4% more pregnancies than urinary forms, although in no cases do pregnancy rates surpass 30%.
- However, the supposed extra efficacy of the recombinant drug does not seem to offset the price difference. Taking this variable into account, recombinant FSH is about 40% less cost-effective than urinary FSH.
- At the prices used, recombinant FSH is not cost-effective in relatively young women (aged below 35 years) with well-defined sterility problems and without other additional risk factors.
- It is likely that in other groups of women, such as women with low ovarian response, the greater efficacy of recombinant FSH will be particularly cost-effective.
- One cannot draw conclusions on effectiveness and cost-effectiveness of the recombinant formula in other situations. Therefore, we need to set up mechanisms to learn more about these aspects and establish criteria based on knowledge about the convenience of both drugs.
- Nevertheless, social trends, scientific progress, and industry interests do not favor the consumption of urinary substances in the long term.

Written by Mr. Antoni Parada, CAHTA, Spain



Title: A systematic review of tension-free urethropexy for stress urinary incontinence: intravaginal slingplasty and the tension-free vaginal tape procedures

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

Box 688, North Adelaide, SA 5006, Australia; tel +61 8 82391144, fax +61 8 82391244; College.asernip@surgeons.org

Reference: ASERNIP-S Report No. 11, ISBN 0 909844 40 2;
www.surgeons.org/open/asernip-s/publications.htm

Aim:

To assess the safety and efficacy of tension-free urethropexy for treating stress urinary incontinence in women in comparison to the two “gold standard” procedures - the Burch colposuspension and the pubovaginal sling.

Conclusions and Results:

Low-level evidence suggested that tension-free urethropexy may have possible benefits with respect to post-operative voiding dysfunction, operating time, post-operative catheterization, resumption of voiding, and convalescence when compared to the traditional procedures. Short and medium term objective cure rates for stress incontinence were similar for the new and traditional procedures. There were no available contrasting data on long term objective cure rates.

Recommendations:

It was recommended that a randomized controlled trial should be conducted to assess the safety and efficacy of the two-stage intravaginal slingplasty (IVS). Ideally, the two-stage IVS should be compared to the tension-free vaginal tape (TVT) procedure, along with the Burch colposuspension as the “gold standard”.

For the TVT procedure, it was recommended that a randomized controlled trial be conducted, with the Burch colposuspension as the control arm. Such a trial is currently underway in the United Kingdom and full publication of its short and long-term results are awaited with interest.

Methods:

A systematic review was conducted, with qualitative synthesis of information. Medline, Current Contents, Embase, and the Cochrane Library were searched for all studies on tension-free urethropexy up until August 2000. Recent grey literature was also canvassed. Independent assessment by two reviewers identified 17 peer-reviewed studies that met the specified inclusion criteria - all were pre-test/post-test case series and thus the lowest level of evidence. Data were extracted from these studies on specified safety and efficacy outcomes using tables developed *a priori*, and descriptive statistics were calculated. Critical appraisal was undertaken using a predetermined checklist. Data from 11 foreign language and grey literature abstracts were extracted, but could not be used to inform the safety and efficacy assessment. Due to the lack of comparative studies, high level evidence on the safety and efficacy of the “gold standard” procedures was identified to provide benchmark information.

Further research/reviews required:

This review will be reappraised by ASERNIP-S in 12 months. Further research is suggested in the Recommendations presented above. Specifics regarding further research are also provided in the review.

Written by Tracy Merlin et al, ASERNIP-S, Australia



Title: Transurethral microwave thermotherapy (TUMT) for benign prostatic hyperplasia

Agency: CEDIT, Comité d'Evaluation et de Diffusion des Innovations Technologiques

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Reference: CEDIT Report 00.03 (in French)

Aim: This report, based on a literature review, aims to estimate the value of transurethral microwave thermotherapy (TUMT) for benign prostatic hyperplasia (BPH) in terms of efficacy, safety, and economic considerations.

Microwave thermotherapy systems are intended to heat the prostate, resulting in the necrosis of periurethral prostatic tissue, providing relief from urinary symptoms in patients with obstructive BPH. These devices heat the prostate to therapeutic levels ($>45^{\circ}\text{C}$) using microwave energy delivered by an antenna contained within a specially designed urethral catheter. To prevent overheating, the systems circulate cooling fluid through the urethral catheter and automatically vary microwave energy output during treatment based on information supplied by temperature sensors placed behind the prostate, within the rectum. Several treatment protocols are currently available: low-energy TUMT (60 min of treatment), high-energy TUMT (60 min) and 30-minute high-energy TUMT (30 min). The literature review indicates TUMT is a virtually bloodless operation that could be performed on an outpatient basis under local anesthesia or intravenous sedation. Studies have shown that there is a placebo effect after sham treatment which, although minimal and certainly less than the effect of TUMT treatment, is essentially significant for subjective parameters. A significant improvement is observed after low-energy TUMT, essentially in the subjective parameters. After high-energy TUMT, a significant improvement is observed in both objective and subjective parameters, but the improvement is generally smaller than that observed after transurethral resection of the prostate (TURP). Thirty-minute high-energy TUMT cannot be adequately assessed from the data currently available. Morbidity levels are significantly lower after TUMT than after TURP, particularly in terms of a lack of major complications and preservation of sexual function. However, adverse effects increase with high-energy devices; lengthy postoperative catheterization period and higher rates of urinary tract infections (UTI) and urinary retention were observed compared to TURP. Moreover, no significant change in prostate volume was achieved by TUMT, and the mean reoperation frequency was considerably higher than for TURP. It has to be noted that an FDA Public Health Notification was published in October 2000 about the potential for serious thermal injury and related complications associated with the use of microwave energy to treat BPH.

The economic evaluation shows that the cost of TUMT (2410 to 2670 €) per patient calculated on the basis of 5 years) would be intermediate between that of the medical management (2060 €) and TURP (2900 to 4270 €), taking into account re-treatments after treatment failure.

Recommendations: In light of the literature review, there are uncertainties concerning the indications for TUMT, especially about the clinical baseline parameters capable of predicting a good response to treatment. However, TUMT appears to be attractive for patients with a medical treatment failure or with contraindications for TURP. In this context, results are required from clinical studies with the new 30-minute high-energy TUMT protocol to provide evidence for the safety and efficacy of the procedure, particularly in terms of long-term outcome and identification of predictive baseline clinical parameters.

Sources of information: Reports by other agencies and government organizations, contacts with manufacturers and experts, systematic literature analysis (clinical trial, controlled clinical trial, meta-analysis, multicenter study, randomized controlled trial, cost analysis) in English or French (Medline, Embase, Health STAR, Cochrane database, NHS Center for Reviews and Dissemination, Current Contents).

Written by Emmanuelle Simon, CEDIT, France



Title: Guidelines for the introduction and acquisition of new health technologies in Andalucía (GANT).

Agency: AETSA, Agencia de Evaluación de Tecnologías Sanitarias de Andalucía

Luis Montoto 89, 4ª Planta 41071, Sevilla, Spain; tel: +34 95 500 6841, fax: +34 95 500 6845, aetsa@cica.es

Reference: AETSA report, 1999

The aim of this guideline is to provide a useful tool for decision-making in the process of selecting and acquiring new technologies in the Andalusian healthcare system.

Methods: The literature was reviewed to identify studies on: factors influencing the introduction of new technologies; decision-making processes on funding and coverage; and similar previous experiences. Main references on HTA methodology and reports from other INAHTA agencies were also included. A multidisciplinary working group was formed to identify key elements for the guideline and to analyze the current situation and processes followed in the region. Ethical and legal issues were also considered. The format selected for the guideline was an application designed as a questionnaire, followed by evaluation criteria and recommendation categories.

A pilot study on nine technologies was carried out in four hospitals to assess the feasibility of the process and the internal validity of the questionnaire. The results were positive.

The final version includes the following:

- Recommendations for identifying and selecting technologies for which GANT is applicable, and organizational issues.
- Recommendations to assist applicants in completing the questionnaires and finding relevant information and resources.
- General criteria for initial assessment of applications.
- Specific criteria on how to assess the evidence provided and to classify it into different categories.
- When and how to apply to AETSA for a complete assessment report.
- GANT questionnaire, including the following sections:
 - A. Description of the technology or service proposed, including regulation issues.
 - B. Clinical characteristics: need assessment, indications, and proposed benefits.
 - C. Evidence of efficacy, effectiveness, and safety.
 - D. Impact of the technology on service management and organization
 - E. Implications for patients, and legal and ethical issues.
 - F. Economic evaluation.

Appendix: Worksheet for calculating annual costs (fixed costs provided by Andalusian health service when available).

An implementation strategy has being designed. It includes a strategy for the wide distribution of the guideline (paper and electronic versions, also available on AETSA's website: <http://www.csalud.junta-andalucia.es/orgdep/AETSA/GANT.htm>) the involvement of health service executives and managers, and AETSA support for applicants. A planned feature is the annual evaluation of impact.

Written by Dr. Eduardo Briones, AETSA, Spain



Title: (Near-patient) CRP testing by physicians in private practice to reduce antibiotic prescriptions

Agency: ITA, Institute of Technology Assessment at the Austrian Academy of Sciences

Strohgasse 45, 1030 – Vienna, Austria; www.oew.ac.at

Reference: ITA-Reports June 2/2000

CRP (C-reactive protein) testing is an established method to diagnose and monitor infectious diseases. While the (quantitative) CRP tests carried out in hospitals or ambulant laboratories are not under question, the semiquantitative tests that can be carried out within minutes in a physician's practice are not yet reimbursed by most Austrian health insurers. General practitioners and pediatricians argue in favor of reimbursement on the grounds that the CRP test might be a powerful tool to reduce the amount of antibiotics prescribed.

The aim of this project is to provide information on the potential of the CRP test to reduce antibiotic prescriptions. The report is based on a structured literature review.

- The assessment focuses on the validity of near-patient CRP test systems and established alternatives, and their relevance for diagnosing viral or bacterial diseases typical in ambulant patients.
- A second section of the report focuses on the general prescription behavior of physicians in private practice and the impact of the near-patient CRP tests on antibiotic prescriptions.

Results:

- The (semiquantitative) near-patient CRP test is exact enough to diagnose infectious diseases and to help differentiate between viral and bacterial infections.
- In most cases, the near-patient CRP test is superior to alternative near-patient systems because of its specificity in diagnosing the acute phase reaction, and its practicability (faster, less blood required).
- Because many factors influence antibiotic prescription behavior, a decline in antibiotic prescriptions cannot be expected.
- A reduction in transfers to external laboratories and related costs (additional tests) can be expected.

Conclusion:

- The (semiquantitative) near-patient CRP test should be reimbursed: To exclude the possibility for added applications of CRP *and* an alternative test, optional reimbursement should leave an either-or decision to the physician.

The assessment is available in German only. Full report available at: www.oew.ac.at/ita/hta/



Title: Effectiveness of self-management programs for obstructive respiratory problems

Agency: AÉTMIS (formerly CETS), Agence d'évaluation des technologies et des modes d'intervention en santé

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Reference: ISBN 2-550-36432-5 (French), ISBN 2-550-37289-1(English)

Aim:

To assess the current knowledge on the efficacy of self-management programs for obstructive respiratory problems and the expected effectiveness of this technology in the Quebec healthcare system.

Conclusions and Results:

- For the adult population, the efficacy of asthma self-management programs as a means to improve asthma control has been proven by a meta-analysis carried out by the Cochrane Collaboration. According to experts, patients with insufficient control of their asthma should be the target group at highest priority during the systematic implementation of self-management programs.
- Asthma self-management programs are complex interventions which base effectiveness on changes in patient and physician behavior. According to the logic model of plausible links between the components of self-management programs, intermediary effects, and the impact on asthma control, the intermediary effects comprise patient compliance, adherence to guidelines by physicians, and organizational changes in healthcare services. Based on this model, the effectiveness of a systematic implementation of this technology in the Quebec healthcare system is expected to be high.
- For the pediatric population, current evidence on the efficacy of asthma self-management programs is conflicting.
- For patients with COPD, preliminary results from a high-quality RCT suggest that they might benefit from the self-management approach. However, these results on efficacy remain to be confirmed by further research.

Recommendations:

- Asthma self-management programs for the adult population should be implemented systematically in the Quebec healthcare system.
- Current resources for asthma self-management programs in the pediatric population should be maintained and re-examined in light of the results from a meta-analysis by the Cochrane Collaboration, currently under preparation
- Research on the effectiveness of self-management programs for patients with COPD could lead to gradual and coordinated implementation of self-management programs for this disease.

Methods:

Systematic review of published scientific literature and information obtained from external reviewers. Development of a logic model based on concepts from the field of program evaluation.

Further research/reviews required:

- Meta-analysis on the efficacy of self-management programs for asthma in children.
- Further RCTs on the efficacy of self-management programs for patients with COPD.
- Evaluative research concerning effectiveness of self-management programs in terms of quality of life and reduction in health services utilization for asthma in adults and for patients with COPD.

Written by Dr. Reiner Banken, AETMIS, Canada



Title: The Annual Report of the NHS Health Technology Assessment Programme 1999

Agency: NCCHTA, National Coordinating Office for Health Technology Assessment
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Reference: NHS, Department of Health, Catalogue No. 16545

The 6th report of the NHS Health Technology Assessment Programme was just released and contains a useful summary of its activities under the former directorship of Sir Miles Irving, who recently retired. The new Chair of the Standing Group on Health Technology is Professor Kent Woods, Professor of Therapeutics at the University of Leicester, who will continue the development of the Programme.

Over 7 600 potential research topics have been submitted to the Programme for consideration. Tables 1 and 2 summarize the actions taken on these proposals. The report also summarizes the present situation regarding the 389 topics that have advanced to a competitive tender. The report lists all work commissioned thus far and presents executive summaries of the reports published during the current year (Health Technology Assessment 1998; 2: 10 - 20, 1999; 3: 1 - 16).

The range of technologies examined is broad: for example, molecular genetic diagnosis of Down’s syndrome, stents for abdominal aortic aneurysms, screening for prostate cancer, telemedicine, and the use of laxatives in the elderly.

All parties interested in health technology assessment should read and contemplate the content of this extensive report, and also visit the NCCHTA website at: www.hta.nhsweb.nhs.uk

Table 1 NHS HTA Program since 1993

	1993	1994	1995	1996	1997	1998
Number of topics identified	1300	400	400	400	1800	1350
Shortlisted by panels	91	64	60	66	60	65
Prioritized	56	49	42	54	44	42
Number of funded projects	76	51	33	47	22	4
Draft reports	21	10	7	2	1	1
Monographs published	32	13	1	-	1	-

Table 2 Commissioning workload of the HTA Program 1993 - 1998 (Systematic reviews only)

	1993	1994	1995	1996	1997	1998
Topics-Areas advertized	39	20	17	23	17	21
Suggested outlines	428	189	105	112	79	115
Full proposals	125	30	31	49	28	42
HTA Board approved	50	27	17	22	16	3



Title: Gene therapy - current status and possibilities in clinical medicine

Agency: SMM, The Norwegian Center for Health Technology Assessment

SINTEF Unimed, Postboks 124 Blindern, 0314 Oslo, Norway; tel:+47 22 06 7808, fax:+47 22 06 7979

Reference: SMM Early Warning Report No.1/2000

In this early warning, an expert group has identified 401 gene therapy protocols focusing mainly on their current status in clinical medicine and the promising results from preclinical research. The expert group assessed the possibilities for gene therapy in the future, in particular, diseases that may be relevant for this type of intervention.

Between three and four thousand patients worldwide have been treated with different gene therapy strategies in more than 400 clinical studies. Gene therapy today is dominated by preclinical and clinical research. Of several thousand published articles on gene therapy, only approximately 80 articles describe results from clinical trials. Most of these studies are phase I or II with few patients in each study. Only three of the protocols represent phase III studies. None of the existing international databases of gene therapy protocols are complete. SMM has constructed a database of the identified protocols. Apart from the use of soluble antisense oligonucleotides against cytomegalovirus (CMV), which has been approved in the United States for use in eye infections among AIDS patients, gene therapy is currently not an established treatment modality for any disease. Gene therapy has been tested in particular for different genetic diseases, including both inherited diseases, resulting from mutations in a single gene and diseases where mutations in several genes can contribute to disease development, such as cancer. In addition, gene therapy can also be implemented in certain diseases to add a drug or an active component. While most gene therapy studies have been performed in the treatment of cancer, some have targeted viral infections (HIV in particular, but also others) and monogenic diseases where the gene is characterized and cloned. Recently, several studies concerning cardiovascular diseases have been initiated, and trials have also commenced in autoimmune diseases and certain neurological diseases such as amyotrophic lateral sclerosis (ALS). The report will be available in English in April/May. For more information: www.sintef.nolsmm

SMM Conclusions:

- Promising results have already been observed in early cancer clinical trials and most recently in certain forms of cardiovascular diseases.
- Gene therapy has developed to a point where it is now important to build up national competence in the field.
- Somatic gene therapy is ethically sound. This does not represent a new ethical principle. Gene therapy must be reserved for treatment of serious diseases.
- Both children and adults should be evaluated for gene therapy research.
- Gene therapy in utero should not be performed until more knowledge is available.
- Germline gene therapy or gene manipulation of embryos or germ cells should be forbidden in accordance with international consensus and Norwegian law.
- Genetic enhancement should not be allowed under any circumstances.
- Research on the ethical issues related to gene therapy should be supported.

More translational research – between basic and clinical research will prevent establishment of new and exciting methods before their clinical effect has been demonstrated.

Written by Dr.Anita Lyngstadaas, SMM



Title: Telemedicine: Report on evaluation and applications in Andalusia

Agency: AETSA, Agencia de Evaluación de Tecnologías Sanitarias de Andalucía

Luis Montoto 89, 4ª Planta 41071, Sevilla, Spain; tel: +34 95 500 6841, fax: +34 95 500 6845, aetsa@cica.es

Reference: AETSA Report, May 2000; ISBN 84-923802-5-X

Aims:

- 1) To know the state of the art in telemedicine, with syntheses of evidence on security, efficacy, effectiveness, efficiency, acceptability, and satisfaction regarding different applications of telemedicine.
- 2) To describe the various applications and services of telemedicine.
- 3) To identify the progress of projects that have been initiated and are underway in the Andalusian public health system.

The decline in the cost of electronic devices, the development of communication networks in Spain, and the subsequent changes in customs over the past 15 years have promoted a growing interest in these technologies on the part of health systems. Telemedicine technologies are expected to increase accessibility to medical services in villages that may lie in remote areas. Furthermore, they are expected to lead toward centralizing specialized services and facilitate the flow of clinical information in urban areas. We used a systematic review as the methodology for this report, although we were aware of the fact that, given the nature of the studies' results, a quantitative synthesis would not be possible.

Sources of information: reports by other agencies and government organizations, study of reviews, personal contacts, books, specialized written media, MEDLINE, EMBASE, COCHRANE LIBRARY and the Índice Médico Español (Spanish Medical Index).

The results suggest that telematic systems of data and image transmission constitute an important element in health care and administration. A result, the patient-staff relationship and the interrelationships among health professionals are changing. Consequently, in the short term, these technologies should be taken into account when designing healthcare programs and systems. Despite these facts, scientific production as regards telemedicine is not of high quality, and includes an abundance of mere system demonstration, a stage which we consider to be somewhat outdated. The implications of the necessary organizational changes have therefore taken on decisive importance.

Conclusions:

1. In general, evidence in telemedicine is poor. Most reports agree on which aspects should be evaluated and how this should be done.
2. It is a safe technology which can improve the management of some types of patients and reduce unnecessary transfers while being suitable for both patients and health professionals.
3. The benefits of data transmission from ambulances to hospitals (or emergency coordinating centers) speed the treatment of patients with acute heart pathology, improving their prognosis.
4. Transmission speed and particularly image quality depend on the communications infrastructure.

(continued next page)



Title: Telemedicine: Report on evaluation and applications in Andalucia

Agency: AETSA, Agencia de Evaluación de Tecnologías Sanitarias de Andalucía

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Reference: AETSA Report, May 2000; ISBN 84-923802-5-X

5. Some studies have shown that telemedicine is cost-effective beyond a certain number of consultations or studies. It will take considerable time before the initial investment can be paid off.
6. The various applications show a high degree of accuracy and concordance in diagnosis, with some controversy in the case of teleradiology.
7. In casualties and emergencies, the benefits of early attention and the impact on prognosis improvement are more important, especially in health systems that provide paramedical outpatient care.
8. Although norms exist to safeguard patients' confidentiality and protect their computerized data, some misgivings exist regarding the security of information circulating on the Internet.
9. Despite the fact that few telemedicine systems are currently used in Andalucia, the situation is favorable, owing to the introduction of the Junta de Andalucía's Corporate Network, the computerization of Health Centers and medical records, and the extensive telecommunication coverage that exists at a regional level.



Title: Chemotherapy for Cancer

Agency: SBU, Swedish Council on Technology Assessment in Health Care

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Reference: ISBN 91-91-87890-71-2

Aim:

To systematically review the literature on cancer chemotherapy in certain major tumor groups, to describe the practice of chemotherapy in Sweden, to compare practice with scientific knowledge, and to analyze the costs and cost-effectiveness of chemotherapy.

Conclusions and Results:

- Chemotherapy plays a well-documented role in the curative and palliative treatment of patients with certain types of cancer.
- Side effects from chemotherapy are common. This creates a difficult balance between the benefits and risks of treatment and is of particular concern in palliative treatment.
- Chemotherapy in Sweden is practiced generally in accordance with the evidence presented in the scientific literature. Overutilization and underutilization appear to be marginal.
- Since cancer treatment is far from achieving total success, there is a major need for further research.
- Well-documented studies have shown relatively minor palliative effects of treatment with newer drugs or with older drugs in new therapeutic situations. A survey of current practice in Sweden shows that, in these cases, chemotherapy was delivered to a small percentage of the patients. If such treatment would be offered to all patients, it would require either investing more resources in health care or redistributing resources within the healthcare sector. It is essential to openly discuss the consequences of such options.
- The cost of chemotherapy in relation to its benefits may be perceived as high, but is not notably different than the cost of treating many other diseases.

Methods:

The extensive body of scientific literature was reviewed according to strict criteria that reflected the scientific weight of the literature. Studies published through 1998 were searched through Medline, Cancerlit, and the Cochrane Library. The data search for controlled clinical trials covered at least the past 20 years. Literature reviews were also studied. References cited in the reviewed literature were used to identify and review older, yet important reports. The systematic review is based on results from 1496 studies involving 558 743 patients.

Further research/reviews required:

A major need exists for controlled clinical trials. When appropriate, such trials should include an assessment of the impact on patients' quality of life (QoL) and economic consequences in conjunction with cancer treatment. Assessment of QoL is clearly in need of further methodological development to be able to report reliable data. Since cancer treatment is far from successful in all cases, there is a need for further research. The survey showed that only about 10% of the treatments were given within clinical trial protocols aimed at further clarifying treatment effects. The figure should be considerably higher.



Title: PubliForum on transplantation medicine

Agency: Center for Technology Assessment at the Swiss Science and Technology Council
(in collaboration with Federal Office for Public Health and Swiss National Science Foundation)

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Reference: Citizen Panel Report, TA-P 2/2000, available in English, French, German, and Italian
www.publiforum2000.ch

Aim:

Developments in the transplantation of organs, tissues and cells raise many hopes. However, many uncertainties and problems are also emerging. This PubliForum would like to help initiate a broad debate on the possibilities and limitations of transplantation medicine, and promote the exchange of ideas between specialists and the man/woman on the street. Such a dialogue is especially important as the Swiss authorities are currently drafting legislation on transplantation.

Conclusions and Results:

The PubliForum gave a group of 30 laypeople the opportunity to discuss various aspects of transplantation medicine with professionals from a broad array of specialized branches. The laypeople then wrote a report giving their perceptions of the situation and their recommendations to decision-makers in the fields of politics, the economy, medicine, and scientific research.

Recommendations:

The recommendations of the laypanel included the following:

- We are seriously concerned in seeing that the general population is better informed on transplantation medicine so as to enhance transparency and increase the willingness to donate.
- Although the explicit prior patient consent solution respects the dignity of the donor to the highest degree, we would recommend that Parliament incorporate the extended solution into the law on transplantation in view of increasing the availability of organs.
- It appears that medical personnel exert significant influence on the willingness to donate organs. For this reason, we would recommend that stronger emphasis be placed on training them in the area of communication and in dealing with family members.
- The advantages of xenotransplantations mentioned by the experts are hardly capable of offsetting the extensive risks. Therefore, we place enormous emphasis on alternatives (eg, artificial organs, stem cells).

Methods:

The PubliForum has been developed on the basis of the “Consensus Conference” method.

The following steps were involved in this PubliForum:

- About 10 000 persons living in Switzerland were randomly contacted.
- From the 100 persons who registered, 30 were selected taking into consideration age, sex, profession, and linguistic region.
- The Citizen Panel met for 2 preparatory weekends to determine which questions were to be discussed in the course of the PubliForum and which experts were to be asked to provide information on these questions.
- The Citizen Panel met these experts for 2 days and wrote a report.

A professional mediator assisted the Citizen Panel throughout the process.

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