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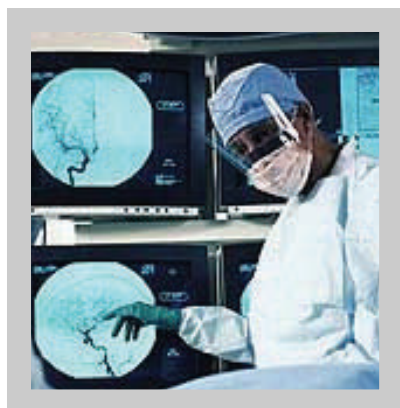
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About the E-Bulletin

The OHTAC E-Bulletin is issued on a regular basis to provide you with the latest updates on the committee's recommendations.

In each E-Bulletin issue you will find brief summaries of technology reviews conducted on behalf of OHTAC by the Medical Advisory Secretariat.

The complete Health Technology and Policy Assessment (HTPA) reports for each technology review, together with the accompanying recommendations, can be downloaded from the OHTAC website located [here](#).



In Vitro Fertilization

Issue

Infertility affects about 8.5-15% of reproductive age couples. It can be caused by a number of factors including: sperm abnormalities, ovulatory failure, tubal obstruction due to infection or damage, and unexplained (idiopathic) infertility. The cause of infertility dictates the choice of therapeutic options. These options from the least invasive to the most invasive treatment are: pharmacological stimulation of ovaries, intra-uterine insemination (IUI), in vitro fertilization (IVF), and IVF with intracytoplasmic sperm injection (ICSI).

In IVF, the most technologically advanced treatment today; eggs (ova) are retrieved from the ovaries, exposed to sperm outside the body and fertilized. The resulting embryo(s) is cultured for 3 to 5 days, and transferred back to the uterus. Unlike other treatment options, IVF allows direct control over the number of embryos transferred in each treatment cycle and thus may help to eliminate or significantly reduce the risk of multiple pregnancy associated with infertility treatment.

Three aspects of IVF treatment were examined: clinical effectiveness of the procedure in patients with infertility other than tubal obstruction; cost-effectiveness of IVF compared to alternative treatments; and the role of IVF in reducing multiple pregnancy rates. The

analysis reviewed post 1993 advances in existing technology and possible impacts on policy.

Findings

- In patients with idiopathic infertility and mild to moderate male factor infertility there were no statistically significant differences between IVF and IUI in terms of pregnancy and live births rates.
- However, when standard IVF was compared to ICSI in patients with moderate male factor infertility, ICSI resulted in almost twice as high fertilization rates when compared to standard IVF. Furthermore, according to expert opinion, ICSI might be the only effective treatment for severe male factor infertility.
- Review of cost-effectiveness studies showed that due to its relatively high cost, IVF should not be recommended as the first line of treatment in the majority of cases. Two important exceptions, however, are bilateral tubal obstruction and severe male factor infertility, where IVF should be offered immediately.

Continued

About OHTAC

OHTAC is envisaged as the first step in creating a single portal for providing advice to the Ontario Ministry of Health and Long-Term Care regarding the uptake, diffusion, and distribution of new health technologies.

Find out more about OHTAC, its application process, and its recommendations [here](#).



Your Input Helps

Website Survey – We are conducting a brief survey to find out more about who is accessing the MAS and/or OHTAC websites. We would greatly appreciate if you would take a moment to complete the [survey](#).

- IVF with single embryo transfer (SET) was shown to result in almost complete elimination of multiple pregnancies. At the same time, SET also leads to lower birth rates compared to IVF cycles when more than one embryo are transferred, resulting in higher cost per birth with SET. This limitation of IVF-SET could be overcome with the use of frozen embryos for cycles following the first attempt, which results in satisfactory cumulative birth rates.
- Based on results of literature review and consultations with experts, four categories of infertile patients who may benefit from additional IVF/ICSI coverage were identified.

They include:

- (1) patients with severe male factor infertility, where IVF should be offered in conjunction with ICSI;
- (2) infertile women with serious medical contraindications to multiple pregnancy, who should be offered IVF-SET;
- (3) infertile patients who want to avoid the risk of multiple pregnancy and therefore opt for IVF-SET and
- (4) patients who failed treatment with IUI and wish to try IVF. However, since in the case of IVF following failed IUI, there has been no significant change in the technology in recent years which would alter existing provincial policy, the latter indication was not considered.

OHTAC Recommendations

Based on the above evidence, OHTAC recommends the following:

There are two indications where OHTAC recommends additional access to IVF:

- [1] IVF/ICSI for patients with severe male factor infertility; and
- [2] IVF-SET in infertile women with serious medical contraindications to multiple pregnancy.

The Society of Obstetricians and Gynecologists of Canada and Canadian Urological Association should be asked to

develop the set of parameters that clearly define the severe male factor infertility as well as a list of maternal medical conditions where multiple pregnancy is absolutely contraindicated.

Couples who wish to avoid the risk of multiple pregnancy could consider IVF SET as an alternative to IUI.

Implications

Improvement in IVF techniques over the last two decades has resulted in higher IVF success rates. ICSI introduced in early 1990 offered an effective way to overcome severe male factor infertility.

The full downloadable version of the OHTAC recommendation for this technology can be found [here](#)

The full downloadable version of this Health Technology Policy Analysis by the Medical Advisory Secretariat can be found [here](#).

About the Medical Advisory Secretariat

The mandate of the Medical Advisory Secretariat is to provide evidence-based policy advice on the coordinated uptake of new health technologies and health services in Ontario to the ministry and other government agencies.

Through systematic reviews of scientific evidence and consultation with experts in the medical community, the Medical Advisory Secretariat provides up-to-date evidence-based assessment and advice to government health care decision-makers about emerging health technologies and health services. The aim is to ensure that residents of Ontario have access to the best available new health technologies that will improve patient outcomes.

The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

Functional Brain Imaging

Issue

Functional brain imaging technologies measure blood flow and/or metabolism. Functional brain imaging includes technologies such as positron emission tomography (PET), functional magnetic resonance imaging (fMRI), magnetic resonance spectroscopy (MRS) and magnetoencephalography (MEG). The results of functional brain imaging are often used in conjunction with structural imaging (i.e. magnetic resonance imaging (MRI) or computed tomography (CT)). PET and MRS identify abnormalities in brain tissues. PET measures abnormalities through uptake of radiotracers in the brain, while MRS measures chemical shifts in metabolite ratios to identify ab-

normalities. The potential role of fMRI is to identify the areas of language, sensory and motor function (sensorimotor cortex), rather than identifying abnormalities in tissues. MEG measures magnetic fields of the electric currents in the brain, identifying aberrant activity. MEG may have the potential to localize seizure foci and to identify the sensorimotor cortex, visual cortex, language and auditory cortex.

There may be a potential role for functional brain imaging in the diagnosis or surgical management of many neurological conditions, including Alzheimer's disease, brain tumours, epilepsy, multiple sclerosis and Parkinson's disease.

Findings

Alzheimer's disease

There is some evidence from observational studies to indicate that PET can accurately diagnose Alzheimer's disease. Yet, at this time there is no evidence to suggest that a diagnosis of Alzheimer's disease with PET alters the clinical outcomes of patients.

Brain tumour

There is evidence from small, observational studies that MRS and FET-PET (O-(2-¹⁸F-Fluoroethyl)-L-Tyrosine) may have higher specificity than magnetic resonance imaging (MRI T1, gadolinium-enhanced) alone in distinguishing between primary malignant and benign tumours. However, the clinical utility of this possible increase in specificity is questionable because biopsy is the gold standard, and patients will likely have a biopsy despite

additional imaging results.

There is also evidence from small, observational studies that MRS, FET-PET and MRI-T2 may have higher specificity than MRI-T1 (gadolinium enhanced) alone in differentiating recurrence from radiation necrosis. There may be clinical utility in the improved specificity of PET, MRS or MRI T2 in the monitoring of patients after treatment of primary tumours with radiation. It is unclear whether there is a significant difference in the specificity of FET-PET, MRS and MRI-T2 in the differentiation of recurrence from radiation necrosis.

Continued

OHTAC Mandate

Examine proposed health technologies in the context of existing clinical practice.

- Provide advice and recommendations to MOHLTC, practitioners and the broader health care system based on a systematic, objective, evidence-based technology assessment and taking into account economic, human resource, regulatory and ethical considerations
- Create a forum to maximize opportunities and prioritize the uptake and diffusion of new / emerging health technologies deemed to significantly improve patient outcomes and/or systems efficiencies relative to other existing or competing interventions.
- Outline implications for implementing OHTAC recommendations including the impact on the public, society, health care sectors and professions
- Provide advice regarding the field evaluation of technologies deemed to be potentially useful but for which there is inadequate existing quality evidence to support multi-million dollar, multi-year investments.
- Provide transparency regarding its recommendations and the analyses upon which these recommendations are made to Ontario's health care system

Epilepsy

The majority of people with epilepsy in Ontario will be effectively treated with drug therapy. Approximately 30% of people will have drug-refractory epilepsy, and will continue to have seizures despite medical management. A possible option for patients with drug-refractory epilepsy is to undergo surgery to resect the area where the seizures are occurring (seizure foci).

The current standard to localize seizure foci in patients with drug-refractory epilepsy includes a series of presurgical evaluations including non-invasive electroencephalography (EEG) with video monitoring. This procedure involves a hospital stay of 5-10 days with patients off their medications. Patients will also undergo MRI, a neuropsychological evaluation and maybe single photon emission computed tomography (SPECT). If the results of these initial tests are inconclusive, patients will be considered for invasive EEG.

Invasive EEG involves placing electrodes directly onto the brain. The electrodes are placed surgically through drilling holes in the skull and inserting the electrodes for placement, or patients may undergo a craniotomy (removing part of the skull) in order to place a subdural grid of electrodes. Patients are monitored in hospital for 5-10 days off their medications with the intent of observing a few seizures. If the seizures are localized, then surgical

resection of the area is considered. If the seizures are multifocal (occurring in many places throughout the brain), surgery is not performed.

Importantly, MEG provides a possible opportunity to replace the invasive EEG because it can potentially localize the seizure foci non-invasively. There is some limited observational data (5 studies, N=190) to suggest that MEG may be as accurate as invasive EEG at localizing the seizure foci. MEG is not only non-invasive, but the investigation is performed during a single examination.

Multiple sclerosis

There is limited clinical utility of functional brain imaging in the management of patients with multiple sclerosis at this time. No studies were identified that met the inclusion criteria for the health technology policy appraisal for patients with multiple sclerosis. Diagnosis of MS is established through clinical history, evoked potentials and MRI. MRI can identify the multifocal white lesions and other structural characteristics of multiple sclerosis.

Parkinson's disease

According to the results of observational studies, PET has high sensitivity and specificity in the diagnosis of PD and the differential diagnosis of parkinsonian syndromes. However, it is unclear at this time if the addition of PET in the diagnosis of these conditions contributes to the treatment and clinical outcomes of patients.

OHTAC Recommendations

Based on the above evidence, OHTAC recommends the following:

Epilepsy

- A field evaluation should be conducted in Ontario to determine the potential substitutive role of MEG vs. invasive EEG.
- A study of the barriers to access to

epilepsy surgery in Ontario should be conducted.

Brain tumour

- The Provincial PET Steering Committee, in collaboration with Cancer Care Ontario's Program in Evidence-based Care, be requested to determine the use of PET-PET versus MRS versus MRI-T2 in distinguishing recurrence from radiation necrosis.

Implications

Based on the literature and administrative data, the potential number of prevalent epilepsy cases eligible for surgery is estimated to be approximately 9,375. However, the rate of patients choosing to undergo surgery worldwide is much lower than the number of patients who are eligible for surgery. There is a lack of awareness regarding epilepsy surgery reported in the literature. It is estimated that approximately 2% of patients eligible for epilepsy surgery in the United States undergo surgery. In Ontario there are ~150 epilepsy surgeries per year (~1.6% of eligible patients).

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Utilization of DXA Bone Mineral Densitometry in Ontario

Health Technologies

Technology encompasses interventions at all stages of health care, from primary prevention and early detection of disease and risk factors, to diagnosis, treatment, rehabilitation and palliative care.

Health technologies may include new and existing diagnostic and treatment-related medical devices and services, equipment and supplies; laboratory tests and clinical procedures used in any health services delivery settings.

Health technologies examined do not include pharmaceuticals or information technology systems.

Issue

Osteoporosis, affects 16% of Canadian women and 6.6% of Canadian men. It is a systemic disease characterized by low bone density, altered bone structure, reduced bone strength, and increased risk of fractures. Dual energy x-ray (DXA) bone mineral density measurement is the current gold standard for detecting and diagnosing osteoporosis for treatment.

Between 1993 and 2005 there was a 10-fold increase in Ontario Health Insurance Plan (OHIP) claims for BMD tests in Ontario. In 2006, the Medical Advisory Secretariat conducted an analysis of administrative data and a systematic review of the research literature in order to evaluate the appropriateness of BMD tests in the province.

Your Input Helps

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Findings

Analysis of Ontario administrative data and review of research evidence showed:

Continued growth in the use of DXA BMD Tests

BMD testing in Ontario is still increasing at a rate of 6% to 7% per year, reaching approximately 500,000 tests in 2005/06. There has been a continued decrease in the rate of hip fractures concomitant with the increase in the rate of BMD tests in the province.

Inappropriate use

The risk of osteoporosis and fragility fracture is low in people age 65 years and younger who do not have other risks factors. However, approximately 20% (98,000) of all 2005/06 DXA BMD tests in Ontario were performed in this low risk population. This is not consistent with current guidelines.

Repeat BMD testing accounted for 40% of all BMD tests in 2005/06, and 21,000 of these tests were repeat tests within a 24 month period performed on low risk individuals.

An analysis showed that:

- For people at a normal rate of bone loss < 1% per year, it will take approximately 3 years for the BMD loss to exceed the least significant change of a 1% precision test.
- For people with normal baseline

BMD (T-score > -1), a rate of bone loss < 1% per year, and at low risk of fractures, serial testing every 2 years may not be necessary, because the BMD is not likely to reach a level requiring treatment in less than 16 years after the baseline test.

- For patients receiving osteoporosis treatment, have a baseline BMD (t-score < -1), have a rate of bone loss greater than 1% per year, or have other major risks for accelerated bone loss, more frequent BMD monitoring may be required.

Under-use after fracture

Less than 20% of Ontario men and women older than 65 years received a BMD test after a fragility fracture despite evidence that a fragility fracture in the hip, spine, wrist, or shoulder increases the risk of future fractures by 2-fold or more, and that current available treatment using bisphosphonates can reduce the risk of fractures in osteoporotic individuals by approximately 40% to 50%.

Under-use in men

Even though Ontario men accounted for 25% of wrist and hip fractures and the mortality rate is higher in men than in women following a fragility fracture, they accounted for only 10% of all BMD tests. Furthermore, the rate of BMD investigation and treatment in Ontario men after a fracture was only half of that in women.

OHTAC Recommendations

Based on the above evidence, OHTAC recommends the following:

- In consultation with the Osteoporosis Program, change the current Ontario reimbursement policy for DXA BMD testing to reflect current guidelines which recommend BMD tests only in people at high risk of accelerated bone loss.

These include:

- People over the age of 65 years regardless of the absence of other risk factors and
- People aged 65 years or younger if they have risk factors that predispose them to low BMD or fractures.

continued

- In consultation with the Ontario Osteoporosis Program, change Ontario reimbursement policy for serial DXA BMD testing for people who have a normal baseline BMD and no major risks for accelerated bone loss other than age over 65 years, so that a repeat BMD may be performed in 3 - 5 years after the baseline test to establish the rate of bone loss. If the rate of bone loss is <1% per year, another BMD is not required for 7 to 10 years.
- BMD should be performed at the discretion of the physician (usually every 1 to 2 years) if one or more of the following risk factors are present:
 - Low baseline BMD (T-score < -1)
 - One or more major risk factors for fractures
 - Rate of bone loss > 1% per year
 - Receiving osteoporosis treatment
- Support the Ontario Osteoporosis Program's initiatives to increase physician and public awareness of appropriate BMD testing and osteoporosis treatment, particularly in all men and women following a fragility fracture after age 40 years.
- Support the Ontario Osteoporosis Program's initiatives to develop and disseminate guidelines for BMD testing in men at high risk of accelerated bone loss and initiatives for ongoing monitoring and evaluation of BMD use in Ontario.
- Ensure that all DXA BMD facilities in the province meet standards for precision and reporting for DXA BMD tests.
- Develop and implement a planning framework to ensure availability of BMD facilities in counties with low BMD claims to ensure equitable access to BMD services in the province.

Implications

To realize the optimal benefits of DXA BMD tests in preventing fractures, the use of the test needs to be shifted from people at low risk of developing osteoporosis to those at high risk of developing osteoporosis and fractures.

An Ontario-based economic analysis showed that shifting BMD testing from the low risk population to high risk populations within Ontario would result in an estimated potential net saving of \$1.2 million to \$5 million (Cdn) when the downstream cost-avoidance due to prevention of future hip fractures was factored into the analysis.

Subscription Information

The OHTAC E-Bulletin is published by the Medical Advisory Secretariat of the Ontario Ministry of Health and Long-Term Care.

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Methadone Compliance Testing

Issue

Methadone is a long-acting synthetic opioid used to treat opioid dependence as well as chronic pain. Persons prescribed methadone for an opioid dependency are monitored by their physician to determine their treatment progress which involves in part determining whether they are taking their methadone as prescribed and if they are successfully being weaned from their dependency. Currently, urinalysis for drugs of abuse is the accepted gold standard method of monitoring.

Urine specimens are often collected under observation because of the possibility of persons tampering with their urine specimen to hide non-compliance with methadone treatment. Observed urine specimen collection can be considered an invasive practice by some patients and by the Methadone Maintenance Treatment (MMT) program staff involved. As well, laboratory tests including measuring urinary pH and creatinine are often done to

help determine the reliability of the urine specimen and the urinalysis results. These tests although relatively inexpensive on an individual specimen level can be costly to the health care system on a program wide basis. Oral fluid testing has been proposed as an alternative to urine drug testing because it can be collected in a non-invasive manner under direct supervision and may reduce concerns of specimen tampering and reliability.

Currently Health Canada has approved only the Intercept Oral Fluid Collection Device® and Enzyme Immunoassay Microplate Assay® for the collection and analysis of oral fluid.

A systematic review of the scientific literature was completed by the Medical Advisory Secretariat to determine the diagnostic utility of oral fluid (saliva) drug testing using the Intercept Oral Fluid Collection Device® for persons enrolled in a methadone maintenance treatment (MMT) program.



From Science to Policy

Information concerning the health benefits; economic and human resources; and ethical, regulatory, social and legal issues relating to the technology assist policy makers to make timely and relevant decisions to maximize patient outcomes.

Findings

The body of evidence consisted of 4 studies that determined the sensitivity (true positive rate) and specificity (true negative rate) of oral fluid testing for opioids, benzodiazepines, cocaine and marijuana detection and 1 study specifically for methadone using urinalysis by enzyme immunoassay (EIA) testing or gas chromatography-mass spectrometry as the gold standard. All studies collected oral fluid using the Intercept Oral Fluid Collection Device ®. The results of the evidence indicated that:

- In general, the parent drug is measured in oral fluids whereas the me-

tabolite(s) of the drug(s) is/are measured in urine.

- The window of detection for urine is up to 3 days but only up to 24 hours for oral fluid.
- The sensitivity for opioids using EIA ranged from 75%-90% and the specificity from 96%-100%. The sensitivity for opioids using gas chromatography-mass spectrometry was 77%. The oral fluid test can miss detecting a person's exposure to opioids up to 25% of the time (false negative).

continued

- The sensitivity for methadone using EIA was 100% and the specificity was 92%. The oral fluid test can miss detecting non-use of prescribed methadone 8% of the time (false positive).
- The sensitivity for benzodiazepines using EIA ranged from 80-100% and the specificity from 99%-100% and the specificity from 94%-99%.
- The sensitivity for cocaine using EIA ranged from 82%-100% and the specificity from 94%-99%.

- The sensitivity for marijuana using EIA ranged from 5%-39% and the specificity from 93%-100%.

There is no point of care test kit (other than that for alcohol) available for oral fluid testing for drugs of abuse. Oral fluid testing must be completed in a laboratory setting whereas urinalysis may be completed onsite in the physicians office or clinic (point of care testing) or in a laboratory. The physician will get reimbursed for a point of care urinalysis whereas the laboratory will get reimbursed if the urinalysis is sent for laboratory analysis.

OHTAC Recommendations

Based on the above evidence, OHTAC recommends the following:

- Because of the narrower window of detection, high opioid false negative rate, and lack of point of care testing methodology, oral fluid testing should not replace urinalysis for methadone treatment compliance monitoring.
- However, because oral fluid can be collected under direct observation in a non invasive manner it may be useful in an MMT program under a limited number of circumstances including:
 - When an observed urine specimen is difficult to ob-

tain;

- When the health of the patient would interfere with obtaining a reliable urine specimen;
- If tampering practices are thought to be compromising the reliability of the urinalysis.
- The decision to use either oral fluid testing or urinalysis should be left to the discretion of the attending physician.
- Because of the 25% risk of opiate (other than methadone) false negative rate, it is recommended that opiate negative results be followed up with urinalysis.

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Implications

These findings have been brought to the attention of the Physician Payment

Schedule Unit, the Addiction Programs Community Health Division, the Health Systems Accountability and Performances Division Laboratories Branch, and the Methadone Task Force of the Ontario Ministry of Health and Long-Term Care.

The College of Physicians and Surgeons of Ontario estimates that currently 15,500 persons in Ontario are being treated for opioid addiction through an MMT program. There are 3 approaches to methadone treatment:

1. Fully funded multidisciplinary methadone clinics where a physician, nurse, social worker are on site (i.e.

Breakaway Clinic in Toronto) and can be located within a multi-service organization (e.g., community health centre).

2. Physicians in solo or group practices who bill the Ontario Health Insurance Plan (OHIP) for the services they provide (i.e., Ontario Addiction Treatment Centres)
3. Community based health organizations who offer methadone programs through existing funding (i.e., needle exchanges), and the physicians bill OHIP for their services.

There are about 150 provincially funded substance abuse programs across the province. There were 158,000 admissions to substance abuse services in 2005-06 and of those an estimated 3,000 clients are receiving MMT.

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June	Intra-Articular Viscosupplementation With Hylan G-F 20 for Treatment of Osteoarthritis Knee Pain
June	Physiotherapy Rehabilitation after Total Knee or Hip Replacement
May	Intrathecal Pumps for Baclofen Infusion for Spasticity
May	Interim Report on Endovascular Repair of Abdominal Aortic Aneurysms (EVAR)
April	Osteogenic Protein-1 for Long Bone Nonunion
April	Multi-Detector Computed Tomography Angiography for Coronary Artery Disease
March	Spinal Cord Stimulation for the Management of Neuropathic Pain
March	Sacral Nerve Stimulation for the Management of Urge Incontinence, Urgency-Frequency, Urinary Retention and Fecal Incontinence
March	Deep Brain Stimulation in Parkinson's Disease and Other Movement Disorders
January	Bariatric Surgery

2004

December	Balloon Kyphoplasty
December	Vacuum-assisted closure (V.A.C. therapy) for chronic wounds (Updated : please see July 2006 Recommendation)
October	Thermal Balloon Endometrial Ablation for Dysfunctional Uterine Bleeding (TBEA)
September	Primary Angioplasty
August	Bispectral Index Monitor
June	Repetitive Transcranial Magnetic Stimulation (rTMS) for the Treatment of Major Depressive Disorder
June	Radiofrequency Ablation for hepatocellular carcinoma or primary liver cancer
May	Indication for Positron Emission Tomography Imaging of a Single Pulmonary Nodule
March	Pyrocarbon Finger Joint Implants
March	Endovascular Coil Embolization for the Treatment of Intracranial Aneurysm (Updated : please see January 2006 Recommendation)
March	Computer assisted Surgery using Telemanipulators
March	Computer assisted Hip and Knee Arthroplasty : Navigation and Robotic Systems
March	Video-assisted Laryngoscopy for Tracheal Intubation
February	Bone Morphogenetic Proteins and Artificial Disc use in spinal surgery for degenerative disc disease
February	Patient Monitoring System for Magnetic Resonance Imaging (MRI)
February	Tension-free Vaginal Tape for Stress Urinary Incontinence in Women (Updated : please see February 2006 Recommendation)