



< Volume 30 - March 2015>

### SYMPOSIUM NEWS

In the News

# New Partner: The Canadian Association of Paediatric Surgeons Evidence-Based Resource (CAPS-EBR)

The goal of the Canadian Association of Paediatric Surgeons Evidence-Based Resource (CAPS-EBR) is to promote evidence-based practice among pediatric surgeons in order to ensure that children and youth within Canada and around the world receive the best surgical care. The CAPS-EBR responds directly to the information needs of paediatric surgeons by providing them with easy access to up-to-date research evidence on key topics of concern, with the addition of clear assessments of the quality of the evidence. By doing so, they facilitate the rapid update of good evidence into practice. They also promote the advancement of high-quality research in the field by highlighting topics where additional research is required.

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# Press Release: Effect of natural sweetener Xylitol in preventing tooth decay still unproven

New research out today concludes that there is limited evidence to show that xylitol is effective in preventing dental cavities in children and adults. Xylitol is a natural sweetener that is widely promoted globally, and can be found in wide range of everyday products including sugarfree chewing gum, toothpaste, gels, lozenges and sweets. Read more

# Press Release: Hormone replacement therapy for postmenopausal women

HRT, now more commonly known as hormone therapy, is widely used for controlling menopausal symptoms. It has also been used for the prevention of cardiovascular disease in post-menopausal women. This latest evidence looked at the effects of using hormone therapy for at least six months and involved more than 40,000 women across the world. Cochrane Canada Annual Symposium 2015



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#### Press Release: Chlorhexidine skin care

A low-cost antiseptic used to cleanse the cord after birth could help reduce infant death rates in developing countries by 12%, a systematic review published in The Cochrane Library suggests. Authors of the review found that when chlorhexidine was used on babies born outside of a hospital, it reduces the number of newborn babies who died or suffer from infections.

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### **Cochrane for Policy**

# Case management approaches to home support for people with dementia

Many people are affected by dementia and the numbers are expected to rise as populations age. Most types of dementia are characterised by loss of memory and impairment in other cognitive functions, accompanied by functional impairment and difficulties in performing activities of daily living. The increasing number of people with dementia means more demand for both informal and formal sources of care. The extent of support provided depends on factors such as living situation, patient's and carer's characteristics, service provision, and availability of social networks. There are also wider financial costs of care, for example carers missing work for appointments or crises, becoming part-time workers, or leaving work altogether. Developing interventions such as case management, which enhances the co-ordination between different agencies involved in community care, might offer the support necessary to cover some of the needs of people with dementia and their carers. How case management is organised and implemented varies widely, and access to this type of care is influenced by long-term care funding policies and cultural variations in different countries. Case management has been tested in people with dementia and in carers in a number of countries and healthcare systems, but it is not clear whether current evidence supports its effectiveness.

We found 13 randomised controlled trials (RCTs), including 9615 participants with dementia worldwide. Eleven RCTs also included carers. Studies were conducted in different countries, varied in size and healthcare systems and compared various types of case management interventions with usual care or augmented usual care.

Some studies examined the benefit of case management in reducing admissions to residential or nursing homes (institutionalisation). We found benefits at six months and 18 months but not at 12 and 24 months. However, when only studies which were clearly focused upon delaying institutionalisation or prolonging the period of community care were included we found a reduction in institutionalisation at 12 months. Some studies examined the benefits of case management in terms of reduced hospital length of stay, and there was evidence to suggest that it might increase at six months. Some studies indicated that case management was more effective at reducing behaviour disturbance at 18 months, reducing carer burden and depression and improving carer well-being at six months and social support at 12 months. Case management increases the use of community services but there was some indication that overall healthcare costs may be reduced in the first year. Some studies reported that case management was no more effective than usual care in improving patient depression, functional abilities or cognition. There was not enough evidence to clearly assess whether case management could reduce the length of time until people with dementia were admitted to care homes. Read more



### Cochrane Library Spotlight: January – March 2015

### **Alternative Therapy**

#### Morita therapy for anxiety disorders in adults

Anxiety disorders are some of the most prevalent mental disorders. Morita therapy, a systematic psychological therapy based on eastern philosophy, has been used to treat anxiety disorders for decades. It encourages people with anxiety disorders to accept anxiety as a natural feeling, while at the same time it engages them in constructive behaviours via four phases, which sequentially are bed rest in isolation, light work, heavy work and preparation for normal daily living. Acceptance is merely redirecting attention towards purposeful behaviour. People get better when they stop trying to eliminate anxiety and fulfil their desires with study and work in their actual personal and social lives.

The efficacy of Morita therapy for the treatment of anxiety disorders has been a much-contested issue, often dividing opinion. To date, a systematic review (a review addressing a clearly worded question that uses systematic and explicit methods to identify, select and critically appraise relevant research) investigating the strength of evidence for Morita therapy in the treatment of anxiety disorders has not been conducted.

We found seven small Chinese studies with 449 participants to include in the review. Six of the seven studies provided useable data for us to analyse; they assessed Morita therapy for generalised anxiety disorder (a long-term illness that causes people to feel anxious about a wide range of situations and issues; one study), social phobia (a persistent fear about social situations and being around people; two studies) and obsessive-compulsive disorder (where a person has obsessive thoughts and repetitive behaviours; three studies). However, these studies were small, imprecise and contained considerable risks of bias, so we were unable to draw conclusions on the effectiveness of Morita therapy in the treatment of anxiety disorders. The review highlighted the need for high-quality studies to assess the efficacy of Morita therapy on anxiety disorders.

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#### Cancer

# Effect of testing for cancer (on cancer and blood clot-related death and illness) in patients with unprovoked blood clots in the legs and lungs

Venous thromboembolism (VTE) refers to blood clots in leg veins (known as deep venous thrombosis (DVT)), which can travel to the lungs (causing pulmonary embolism (PE)). PE can often be fatal. Signs of DVT include pain and swelling of the leg while signs of PE include breathlessness and chest pain. Risk factors for VTE include surgery, prolonged bed rest, trauma, a family history, pregnancy and blood deficiencies. However, sometimes a VTE happens for no apparent reason (it is unprovoked). In such patients an undetected cancer may be the cause of the VTE. This has raised the question of whether patients with an unprovoked VTE should be investigated for underlying cancer. This is potentially important as the management of VTE in patients with and without cancer differs. A cancer diagnosis would ensure that patients received the optimal treatment to reduce the risk of another VTE. A diagnosis could also lead to the cancer being treated earlier, at a more curable stage.

This review assessed whether testing for undiagnosed cancer in

patients with a first unprovoked VTE (DVT or PE) was effective in reducing cancer and VTE-related illness and death. We found two studies with a combined total of 396 patients. Both studies compared cancer tests with no tests. One study used a complete range of tests while the second study performed fewer tests. The quality of the evidence was moderate because although the studies were judged to be at a low risk of bias, the studies were small. Combining the results of the two studies showed that testing had no effect on the number of cancer-related deaths. Additionally, testing did not identify more people with cancer. However, testing did identify cancers at an earlier stage (approximately 10 months earlier). Neither study looked at the number of deaths due to any cause, deaths and illness associated with VTE, side effects of cancer tests, side effects of VTE treatment nor patient satisfaction. This review found that there are too few trials to determine whether testing for undiagnosed cancer in patients with a first unprovoked VTE (DVT or PE) is effective in reducing cancer and VTErelated deaths and illness. Further good-quality and large-scale studies are required.

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### Chemotherapy after surgery for early stage non-small cell lung cancer

Non-small cell lung cancer is the most common type of lung cancer. If the tumour is early stage, not too big and has not spread to other parts of the body, doctors usually operate to remove it. At the same time, they will also remove a bit of the lung, or the entire lung that has the tumour. They may also give radiotherapy (treatment with x-rays) after the operation, aiming to kill any remaining cancer cells. They may also give chemotherapy (drug treatment) after surgery to lower the risk of the cancer coming back. This treatment is called adjuvant chemotherapy.

In 1995, we did a systematic review and meta-analysis of individual participant data looking at adjuvant chemotherapy and surgery (with or without radiotherapy). It brought together information from all patients who took part in similar trials. These trials compared what happened to people with non-small cell lung cancer who were given chemotherapy after surgery (with or without radiotherapy) with those who had surgery without chemotherapy (with or without radiotherapy). We found that it was not clear whether chemotherapy helped patients with non-small cell lung cancer live longer.

Since this study was completed, many new trials have been done. Therefore, we carried out a new systematic review and meta-analysis of individual participant data that included all trials, old and new. This study aimed to find out if giving chemotherapy after surgery (with or without radiotherapy) can a) help patients live longer, b) stop the cancer coming back (recurrence), and c) stop the cancer spreading to other parts of the body (metastases).

We carried out two studies called meta-analyses that included patients with non-small cell lung cancer that took part in randomised controlled trials comparing:

- a) surgery versus surgery plus adjuvant chemotherapy; and
- b) surgery plus radiotherapy versus surgery plus radiotherapy plus adjuvant chemotherapy.

Results were first published in the Lancet in 2010.

Results found that people with non-small cell lung cancer that had surgery followed by chemotherapy (with or without radiotherapy), lived longer than those who had surgery without chemotherapy (with or without radiotherapy).

After five years, 64 out of every 100 patients who were given chemotherapy after surgery were alive compared to 60 patients out of every 100 who just had surgery. For those who also received radiotherapy, after five years, 33 out of every 100 patients who received chemotherapy, surgery and radiotherapy were alive compared to 29 out of every 100 patients who received surgery and radiotherapy.

Quality of life information was not routinely collected during the trials, but where toxicity was assessed and mentioned in the publications, it was thought to be manageable. In both studies, there was little variation in the effect of chemotherapy according to the type of chemotherapy given, other trial characteristics, or by the type of patient included in the trial. Read more

# Diagnostic accuracy of endoscopic ultrasonography (EUS) for the preoperative locoregional staging of primary gastric cancer

EUS is a diagnostic test that can be used to determine how far (stage) cancer of the stomach reaches prior to surgery. It consists of an endoscope coupled with an ultrasound device capable of scanning the stomach wall, which shows the different layers of the stomach. Changes from the normal ultrasonographic patterns due to the tumor growth can be used to determine the extent of cancer in the stomach wall (T-stage) and the lymph nodes related to the stomach (N-stage). Since the correct staging of the tumor enables physicians to personalize cancer treatment, it is important to understand the reliability of staging devices.

We conducted a meta-analysis according to the most recent methods for diagnostic tests. The last literature search was performed in January 2015. We included 66 studies (of 7747 patients) in the review. We found that EUS can distinguish between superficial (T1 - T2) and advanced (T3 - T4) primary tumors with a sensitivity and a specificity greater than 85%. This performance is maintained for the discrimination between T1 and T2 superficial tumors. However, EUS diagnostic accuracy is lower when it comes to distinguishing between the different types of early tumors (T1a versus T1b) and between tumors with versus those without lymph node disease. Read more

#### Oxycodone for cancer-related pain

Many patients with cancer experience moderate to severe pain that requires treatment with strong painkillers that are classified as opioids. Oxycodone and morphine are examples of such strong painkillers that are used for the relief of cancer pain. Strong painkillers are, however, not effective for pain in all patients nor are they well-tolerated by all patients. The aim of this review is to assess whether oxycodone is associated with better pain relief and tolerability than other strong painkillers for patients with cancer pain. We found 17 relevant studies that compared different types of oxycodone to each other or to other strong painkillers. Generally, the studies showed that oxycodone is an equally effective strong painkiller whether taken every 6 or every 12 hours. All the strong painkillers examined in the studies are also associated with a number of unwanted effects, such as vomiting, constipation and drowsiness. Overall, we found that the current evidence base is comprised of studies that contain small numbers of patients of which there is a significant (20%) dropout rate. However, given the absence of important differences within this analysis, it seems unlikely that larger head to head studies of oxycodone versus morphine are justified.

Read more

#### Conservative interventions for preventing clinically detectable upper-limb lymphoedema in patients who are at risk of developing lymphoedema after breast cancer therapy

About one in five people treated for breast cancer develop lymphoedema later on. We reviewed the available evidence to determine whether some methods, such as manual lymph drainage (a massage therapy), compression, exercise or only education could help prevent lymphoedema.

No firm conclusion can be drawn about the effect of manual lymph drainage in addition to exercise and education on preventing the incidence of lymphoedema. This is because the two included studies found contradicting results. In addition, no firm conclusion can be drawn about manual lymph drainage in combination with other interventions, because only two studies were found that each tested different combinations. One of these studies found that manual lymph drainage combined with exercise lowered the risk of lymphoedema. The other study combined manual lymph drainage with compression, but this study was too small to draw conclusions.

Arm mobility (i.e. reaching upwards over the head) was better after manual lymph drainage than without it, but this improvement lasted only for the first few weeks after breast cancer surgery.

When assessing whether early or late shoulder exercises reduced the likelihood of developing lymphoedema, the studies did not provide a clear result. The likely incidence of lymphoedema ranged from 5% to 27% (early start) compared to 4% to 20% (for delayed start) during the first 6 to 12 months after surgery. Starting shoulder exercises immediately after surgery may improve shoulder mobility in the first month, compared to starting after the first week but no firm conclusions can be drawn and mobility is comparable later on.

Progressive resistance training did not increase the risk of developing lymphoedema compared to restricted activity, on the basis that symptoms were monitored and treated immediately if they occurred. For all investigated interventions, no firm conclusion can be drawn about their effectiveness in reducing pain or improving quality of life. Read more

### **Child Health**

# Pharmacological interventions for pain in children and adolescents with life-limiting conditions

Pain is commonly experienced in children and young people with diseases that are not curable and which may shorten their lives. These may be cancers or other diseases. Sometimes the pain is undertreated, particularly for those nearing the end of their lives. There are many different types of drugs that have been developed to treat pain. There are also drugs that were not developed primarily to treat pain but which have an action that may provide pain relief. However, clinical guidelines to support doctors in their choice of treatment for pain are limited. This is because there are few trials specifically in children and young people that have tested the benefits and safety of such drugs.

In this review we sought to find out precisely what the evidence is on drug treatments for pain in children and young people with diseases that are not curable and that may shorten their lives.

We searched five large databases of published research projects. We found nine relevant randomised controlled trials. Five were for children and young people with cerebral palsy and four for those with a degenerative bone disease called osteogenesis imperfecta.

Overall, these trials did not find clear evidence of a benefit of the drugs tested in the treatment of pain. This was apart from the two on cerebral palsy where pain relief occurred with the use of baclofen delivered via a catheter into the spinal cord. However the procedure to deliver this medication resulted in most side effect reported in these trials; this was swelling at the site of the catheter, and in one study it reported that this occurred in around half of the children (8/17). Five children also leaked spinal fluid from the catheter resulting in headache and nausea and, for two children, a prolonged hospital stay.

The trials were limited by the quality of their methods and most did not set out to measure the benefit of the drug in reducing pain as a main focus. In conclusion, the evidence on pain treatment in children and young people with life-limiting health conditions is very limited, and only evaluated in participants with certain diseases and not for drug treatments primarily used to treat pain. The trials that were identified evaluated the drugs in small samples of children. There remains a need for more research to help guide doctors in their decisions on how to treat pain in these children and young people.

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## Influenza vaccines for preventing acute otitis media in infants and children

AOM is one of the most common infectious diseases in infants and preschool children. Symptoms include ear pain and fever, but it may cause hearing loss due to ear drum perforation or fluid accumulation in the middle ear. AOM is usually bacterial in origin and antibiotics are often used to treat it, but they carry their own side effects and the risk of antibiotic resistance. Even so, AOM is often preceded by viral infection such as influenza. Preventing viral infections might prevent AOM. Therefore, we investigated whether influenza vaccines might reduce the occurrence of AOM in infants and children.

The evidence is current to July 2014. We selected randomised controlled trials (RCTs) comparing influenza vaccine with placebo or no treatment in infants and children younger than six years old of either sex and any ethnicity, with or without a history of previous episodes of AOM. Nine out of 10 studies (and all five studies that contributed to the primary outcome) were funded by the vaccine manufacturers. The review found a 4% (this could be between 2% and 7%) reduction in AOM. It also found about a 15% (this could be between 0% to 30%) reduction in the number of antibiotic prescriptions. There was no difference in the number of doses, courses, settings, seasons or types of vaccine administered between those vaccinated and unvaccinated. Influenza vaccine side effects included an increase in fever and runny nose. It remains uncertain whether it reduced visits to healthcare facilities or hospital admissions. Data were also insufficient to show that this benefit might be traded off against more serious or rarer side effects from the vaccine.

The review has included subgroup analyses for AOM episodes by season, which we did not include in our protocol (plan for the review). The 'respiratory season' is when viruses that cause the common cold and other respiratory conditions occur more frequently and AOM generally occurs in the respiratory season. In temperate climates, the respiratory season occurs in the autumn and winter and in tropical climates, during the rainy season. In the equatorial belt, the respiratory season may occur throughout the year. The respiratory season may not coincide with the influenza season, which may occur in the winter and spring. However, it can vary depending on the presence of influenza virus epidemics.

Although we observed a reduction in antibiotic usage, this impact is uncertain because the current practice is to avoid overuse of antibiotics. Coupled with other vaccine safety concerns, the use of influenza vaccine to reduce AOM is not yet justified and additional research is needed.

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#### **Mental Health**

### Therapist-supported Internet cognitive behavioural therapy for anxiety disorders in adults

Many adults suffer from anxiety disorders, which have a significant impact on their everyday lives. Anxiety disorders often result in high healthcare costs and high costs to society due to absence from work and reduced quality of life. Research has shown that cognitive behavioural therapy (CBT) is an effective treatment which helps to reduce anxiety. However, many people are not able to access face-toface CBT due to long waiting lists, lack of available time for appointments, transportation problems, and limited numbers of qualified therapists.

Internet-based CBT (ICBT) provides a possible solution to overcome many of the barriers to accessing face-to-face therapy. Therapists can provide support to patients who are accessing Internet-based therapy by telephone or e-mail. It is hoped that this will provide a way of increasing access to CBT, particularly for people who live in rural areas. It is not yet known whether ICBT with therapist support is effective in reducing symptoms of anxiety.

This review aims to summarise current research to find out whether ICBT with therapist support is an effective treatment for anxiety. The review aims to answer the following questions:

- is ICBT with therapist support more effective than no treatment (waiting list)?
- how effective is ICBT with therapist support compared with face-to-face CBT?
- how effective is ICBT with therapist support compared with unguided CBT (self-help with no therapist input)?
- what is the quality of current research on ICBT with therapist support for anxiety?

Databases were searched to find all high quality studies of ICBT with therapist support for anxiety published until May 2013. To be included in the review, studies had to be randomised controlled trials involving adults over 18 years with a main diagnosis of an anxiety disorder; 30 studies with a total of 2181 participants were included in the review.

ICBT with therapist support was significantly more effective than no treatment (waiting list) at improving anxiety and reducing symptoms. The quality of the evidence was low to moderate.

There was no significant difference in the effectiveness of ICBT with therapist support and unguided CBT, though the quality of the evidence was low to very low. Patient satisfaction was generally reported to be higher with therapist-supported ICBT, however patient satisfaction was not formally assessed.

ICBT with therapist support may not differ in effectiveness as compared to face-to-face CBT. The quality of the evidence was low to moderate.

There was a low risk of bias in the included studies, except for blinding of participants, personnel, and outcome assessment. Adverse events were rarely reported in the studies.

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#### Dance movement therapy for depression

Depression affects 350 million people worldwide, impacting on quality of life, work, relationships and physical health. Medication and talking therapies are not always suitable or available. Dance movement therapy (DMT) uses bodily movements to explore and express emotions with groups or individuals. This is the first review of the effectiveness of DMT for depression and will add to the evidence base regarding depression treatments. Databases were searched for all published and unpublished randomised controlled studies of DMT for depression up to October 2014, with participants of any age, gender or ethnicity. Three studies (147 participants) met inclusion criteria: two of adults (men and women); and one of adolescents (females only).

Due to the low number of studies and low quality of evidence, it was not possible to draw firm conclusions about the effectiveness of DMT for depression. It was not possible to compare DMT with medication, talking therapies, physical treatments or to compare types of DMT due to lack of available evidence. Key findings were:

Overall, there is no evidence for or against DMT as a treatment for depression. There is some evidence to suggest DMT is more effective than standard care for adults, but this was not clinically significant. DMT is no more effective than standard care for young people.

Evidence from just one study of low methodological quality suggested that drop-out rates from the DMT group were not significant, and there is no reliable effect in either direction for quality of life or self-esteem. A large positive effect was observed for social functioning, but since this was from one study of low methodological quality the result is imprecise.

Future studies should be of high methodological quality, comparing DMT with other treatments for depression, and include economic analyses.

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### **Smoking Cessation**

### Interventions to increase adherence to medications for tobacco dependence

Medications that help people to stop smoking such as nicotine replacement therapy (NRT) are safe and effective treatments for smoking cessation. However, people often do not take the medication they are prescribed as they should. In the current review, we examined whether there are effective approaches to increasing adherence to these treatments, which should improve smokers' chances of quitting. These approaches, or interventions, typically involve providing additional information about the medication and helping people to overcome any problems they have in taking it as prescribed.

A systematic search located eight studies of interventions to improve adherence, involving 3336 participants. Five studies assessed whether or not participants achieved a specified satisfactory level of medication taking, with statistical combination of the results suggesting that the interventions led to modest improvements. Four studies assessed how much medication was taken, finding a small effect that may be due to chance. There was also some evidence that interventions to increase adherence to medication led to modest improvements in quitting smoking. The evidence that was included in the review was considered to be of low-to-moderate quality, suggesting that further research is necessary if we want to increase our confidence in these results.

In summary, there is some evidence that interventions that devote special attention to improving adherence to smoking cessation medication can increase this, though the evidence is not strong and is limited in both quality and quantity. There is also some evidence that these approaches improve the chances of quitting smoking but again this is relatively weak.

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#### Women's Health

#### Timed intercourse for couples trying to conceive

Many couples find it difficult to achieve a pregnancy and have

concerns about their fertility. Each cycle, a woman is fertile from approximately five days before ovulation until several hours after ovulation, due to limited survival times of the sperm and egg. Therefore, prospectively identifying this fertile period of a woman's menstrual cycle, to guide timing of intercourse, may improve conception rates. This may reduce unnecessary medical treatment and costs of advanced infertility treatment, but could also cause adverse events such as stress. The fertile period can be identified by different methods including urinary fertility monitoring, calendar charting, observing changes in cervical mucous and basal body temperatures or follicular maturation on ultrasound. The aim of this review was to assess the benefits and risks of timed intercourse on pregnancy outcomes in couples trying to conceive.

We found five randomised controlled trials comparing timed intercourse versus intercourse without ovulation prediction, in a total of 2840 women or couples trying to conceive. The evidence was current to August 2014.

One large included study (1453 women) has not published usable results and could therefore not be analysed. One study reported live birth rates and found no evidence of a difference; however, the study was too small to have any clinical value. Only one study reported levels of stress and showed no evidence of a difference between timed intercourse with urinary fertility monitoring and intercourse without urinary fertility monitoring. No other adverse events were reported. Only two studies reported clinical pregnancy rates, and showed no evidence of a difference in pregnancy rates in couples with subfertility. The evidence suggested that if the chance of a clinical pregnancy following intercourse without ovulation prediction was assumed to be 16%, the chance of a clinical pregnancy following timed intercourse would be between 9% and 33%. However, if including self-reported pregnancies (not confirmed by ultrasound), pregnancy rates were higher after timed intercourse. The evidence suggested that if the chance of a pregnancy following intercourse without ovulation prediction was 13%, the chance following timed intercourse would be between 14% and 23%.

No difference in effect was found between couples trying to conceive for less than 12 months versus 12 months or more. One trial reported time to conception data and showed no evidence of a difference in time to conception.

### What's Ahead

### **Cochrane Canada Symposium 2015 Registration**

The 12th Annual Cochrane Canada Symposium is taking place at the University of Calgary from 21-22 May 2015. The theme of this year's Symposium is "Reaching New Heights, Measuring Success".

Early bird registration closes 1 April 2015! Please visit our <u>website</u> for more information. The Symposium is open to policy-makers, health practitioners, researchers, students, patients/consumers, caregivers, and anyone who has an interest in evidence-based health care.

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