Relay Cochrane!

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In the News

A letter to our colleague, Canada's new Minister of Health

Last week, the Canadian Medical Association Journal published a letter to Canada's new Minister of Health, Dr Jane Philpott, congratulating her on her new role and to offer some suggestions on leading the country in a new direction of healthcare. Included in these recommendations, was a request to reinstate funding for Cochrane Canada, saying: "Canada already has, yet risks losing, one of the most authoritative and respected sources of evidence to guide such initiatives. We urge you immediately to restore, through the Canadian Institutes of Health Research or your direct authority, the $2 million annual base funding for Cochrane Canada."
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A new government, a new chance for Cochrane Canada

This past month has brought some stark and refreshing changes to science in Canada. During the federal election campaign—where science became a surprisingly prominent issue—the Liberals made a number of election promises aimed at strengthening science and evidence-based decision-making in Canada. Their commitments included bringing back the mandatory long-form census, letting government scientists speak freely to journalists and the public and making policy decisions based on the best available evidence.
So far, it looks like the Liberals are going to make good on these campaign promises and have already implemented a number of changes in a very short amount of time. One change is how science is represented in cabinet. Under the new cabinet that was sworn in on Nov 4th, science got a bit of a boost with what was formerly the Minister of Industry being renamed to the Minister of Innovation, Science and Economic Development. This minister will work closely with the Minister of Science, making this the first time there are two ministers with science in their title. The Minister of Science, Kirsty Duncan, has said that this division will allow her to focus more on science that isn't business focused, like fundamental and public-interest science, which didn't get much attention from the previous government.

EVENTS

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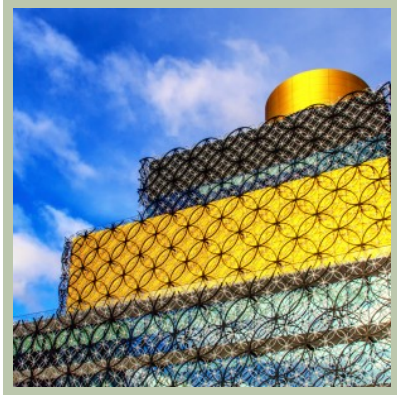

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Cochrane for Practice

Immediate delivery or expectant management of the term baby with suspected fetal compromise for improving pregnancy outcomes

For healthy pregnant women at term, several factors can indicate that the baby's health is at risk. These may be based on either clinical examination or history. Babies not growing appropriately (intrauterine growth restriction) or showing a decrease in their movements may indicate the placenta is not functioning as well as it should, while investigations such as cardiotocography (CTG) and ultrasound can measure amniotic fluid, blood flow or the size of the baby in order to assess the baby's well-being. Results that are clearly abnormal and associated with increased risk for the baby require immediate delivery, but the management for 'suspicious' results remains unclear and varies widely across clinical centres. The balance between allowing the pregnancy to continue for full lung development has to be weighed against removing the baby from an environment that is suspected to be harmful. The best timing of delivery for women presenting with a suspected compromised baby in an otherwise healthy term pregnancy is unclear.

We identified three randomised controlled trials that met our inclusion criteria. They included a total of 546 pregnant women at 37 weeks gestation or more; 269 had a planned early delivery and 277 were managed expectantly. Two of the trials compared outcomes in a total of 492 babies with growth restriction and one involved 54 pregnancies with decreased amniotic fluid (oligohydramnios). Overall, there were no major differences between these two strategies as to whether infants survived, were extremely sick, or had developmental problems as children. There were also no differences as to whether mothers died or were extremely unwell. The risks of breathing difficulty, poor condition at birth, admission to neonatal intensive care unit, infection, and babies with low blood sugars were no different between the two groups. The gestational age at birth was on average 10 days earlier in women randomised to early delivery and more infants in the planned early delivery group were admitted to intermediate care nursery. Although there was no difference in the number of babies with birthweight less than the 10th percentile between the two groups, there were more extremely small babies (< 2.3rd percentile) found in the expectant management group. Women in the early delivery group were more likely to be induced. All three trials were of reasonable quality and at low risk of bias.

In summary, there is insufficient evidence from randomised trials to guide clinical practice regarding earlier delivery versus waiting for term pregnancies where there is a suspicion of fetal compromise. Included trials only addressed growth restriction or oligohydramnios and none of the other potential indications such as decreased fetal movements, ultrasound or CTG abnormalities. Further research is needed to assess the best timing of delivery for these indications.

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Cochrane Library Spotlight: October – December 2015

Alternative Therapies

Different treatment regimens of magnesium sulphate for tocolysis in women in preterm labour

Babies born early - before 37 weeks' estimated gestation - are at an increased risk of dying or being seriously unwell, especially if they are born

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very early. Various drugs have been given to women to try and stop babies being born too soon. Magnesium sulphate has been one of the drugs used when women go into labour too early.
Although it has now been shown that magnesium sulphate does not help prevent babies being born too soon, it is important to know the safest and best way to give magnesium sulphate if it is used for mothers in preterm labour. Particular concerns about high doses of magnesium sulphate for women in preterm labour, including increased risk of deaths of babies, have been raised. (Magnesium sulphate has been shown to help prevent and treat eclampsia in women with high blood pressure during pregnancy, and in mothers at risk of preterm birth, low doses can protect the baby's brain and improve long-term outcomes for the infant. These uses are covered in other Cochrane reviews.)
This review identified three trials (involving 360 women and their infants), but one trial did not provide any relevant data. The trials were small and were assessed as being at a low or unclear risk of bias. The trials did not report many outcomes of relevance to this review. We did find limited evidence to suggest that when magnesium sulphate was given to mothers in preterm labour, differences in the dose (high-dose versus low-dose) did not impact on the number of babies that died (very low quality evidence). There were no data to assess other important outcomes: birth less than 48 hours after entry to the trial, or serious outcomes for mothers or their babies.
The included trials provided very few data for other outcomes relevant to this review (overall, we were only able to examine eight of the 45 outcomes we wanted to examine).
One trial did find that the rate of newborn respiratory distress syndrome (low quality evidence) and the length of stay in the neonatal intensive care unit were reduced with high-dose magnesium sulphate (compared to the babies born to the group of women who were given low-dose magnesium sulphate). However, this result is based on evidence from one small study and should therefore be interpreted with caution.
The rate of caesarean birth did not differ between those women given high-dose and those women given low-dose magnesium sulphate. Nor were there any differences between groups in terms of the number of babies that died before birth or during the subsequent month or the number of babies with low levels of calcium in their blood, low bone density or bone fractures. The frequency of self-reported adverse effects in mothers including flushing, headache (two trials, 248 women), or nausea and vomiting (one trial, 100 women) did not differ between high-dose and low-dose magnesium sulphate groups. Pulmonary oedema was reported in two mothers given high-dose magnesium sulphate, and in none of the mothers given low-dose magnesium sulphate.
No trials have looked at different durations of treatment, timing and other ways of giving magnesium sulphate to mothers going in to labour too early.
Further trials are needed to address the lack of evidence regarding the best dose, duration of therapy, timing of therapy and role for repeat dosing in terms of efficacy and safety for mothers and their children.
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Cancer

Blood CEA levels for detecting recurrent colorectal cancer
After surgery for cancer in the colon or rectum (colorectal cancer), most people are intensively followed up for at least five years to monitor for signs of the cancer returning. When this occurs, it usually causes a rise in a blood protein called CEA (carcino-embryonic antigen). An increased level of CEA can be picked up by a blood test, which is normally done every three to six months after colorectal cancer surgery. Those people with raised CEA levels are further investigated by x-ray imaging (usually a scan of the chest, abdomen and pelvis). We conducted this review to help decide what level of blood CEA should lead to further investigation.

This review shows that setting a low cut-off point will increase the number of genuine cases of colorectal cancer recurrence that are detected (true positives), but a low cut-off will also cause unnecessary alarm by incorrectly classifying too many cases that are not actually recurrences (false positives). In addition, this review shows that a rise in CEA does not occur in up to 20% of patients with a true recurrence (false negatives). The current evidence supports using the highest cut-off point assessed (10 µg/L), but that adding another diagnostic modality (e.g. a single scan of the chest, abdomen and pelvis at 12 to 18 months) is necessary in order to avoid the missed cases.
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Child Health

Methylphenidate for children and adolescents with attention deficit hyperactivity disorder (ADHD)
ADHD is one of the most commonly diagnosed and treated childhood psychiatric disorders. Children diagnosed with ADHD find it hard to concentrate. They are often hyperactive (fidgety, unable to sit still for long periods) and impulsive (doing things without stopping to think). ADHD can make it difficult for children to do well at school, because they find it hard to follow instructions and to concentrate. Their behavioural problems can interfere with their ability to get on well with family and friends, and they often get into more trouble than other children. Methylphenidate is the drug most often prescribed to treat children and adolescents with ADHD.
We found 185 randomised controlled trials (RCTs; studies in which participants are randomly assigned to one of two or more treatment groups), involving 12,245 children or adolescents with a diagnosis of ADHD. Most of the trials compared methylphenidate to a placebo – something designed to look and taste the same as methylphenidate but with no active ingredient. Most trials were small and of low quality. Treatment generally lasted an average of 75 days (range 1 to 425 days), making it impossible to assess the long-term effects of methylphenidate. Seventy-two of the 185 included trials (40%) were funded by industry.
Findings suggest that methylphenidate might improve some of the core symptoms of ADHD – reducing hyperactivity and impulsivity, and helping children to concentrate. Methylphenidate might also help to improve the general behaviour and quality of life of children with ADHD. However, we cannot be confident that the results accurately reflect the size of the benefit of methylphenidate.
The evidence in this review of RCTs suggests that methylphenidate does not increase the risk of serious (life threatening) harms when used for periods of up to six months. However, taking methylphenidate is associated with an increased risk of non-serious harms such as sleeping problems and decreased appetite.
The quality of the evidence was very low for all outcomes. It was possible for people in the trials to know which treatment the children were taking, the reporting of the results was not complete in many trials and for some outcomes the results varied across trials. These considerations limit our confidence in the overall results of the review.
At the moment, the quality of the available evidence means that we cannot say for sure whether taking methylphenidate will improve the lives of children and adolescents with ADHD. Methylphenidiate is associated with a number of non-serious adverse events such as problems with sleeping and decreased appetite. Although we did not find evidence that there is an increased risk of serious adverse events, we need trials with longer follow-up to better assess the risk of serious adverse events in people who take methylphenidate over a long period of time.
Given that methylphenidate is associated with adverse events, designing high quality trials is challenging. It can be easy for clinicians, researchers and participants to work out whether a child is in the experimental group

(receiving methylphenidate) or in the control group (receiving the placebo). This is a serious risk of bias that can make us less confident in the results of a trial. One way to avoid this is to design trials that compare methylphenidate with a placebo that can produce similar adverse events, but which has no other active ingredient. These trials are known as 'nocebo trials'. For ethical reasons, nocebo trials should first be undertaken with adults. Only if the results suggest that methylphenidate is effective for adults, should researchers consider recruiting children to trials with this design.
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Dental

Non-surgical adjunctive interventions for accelerating tooth movement in patients undergoing fixed orthodontic treatment
What effect do non-surgical adjuncts have on the length of time it takes for teeth to move when treated with fixed braces, and the overall time required for orthodontic treatment?
Throughout the world, orthodontic treatment is used to correct the position of teeth in adolescents and adults when they experience problems. Braces are orthodontic appliances made up of brackets glued to the teeth and then connected by wires in order to exert pressure on the teeth to move them and improve their positioning. Depending on the problem, the length of time for treatment may range from several months to several years. However, most treatments take on average, around 24 months. Accelerating the rate of tooth movement may help to reduce the length of time needed for a course of treatment and may reduce the unwanted effects of orthodontic treatment that can sometimes occur, such as tooth decay and the shortening of the tooth root. Several methods, including surgical and non-surgical treatments, have been suggested to accelerate orthodontic tooth movement. The evidence relating to non-surgical procedures to accelerate orthodontic tooth movement is assessed in this review.
Authors for the Cochrane Oral Health Group carried out this review of existing studies. The evidence on which it is based is current up to 26 November 2014.
We included two studies involving a total of 111 participants in this review. A single orthodontic specialist in a private practice in Australia carried out one study, while the other study was conducted on patients treated by orthodontic residents in a university hospital seating in the United States of America. In one study, the age of participants ranged from 11 to 15 years old, and in the second, the average age of participants was 21 years. The studies evaluated the additional use of two devices that use light vibrational forces - Tooth Masseuse in people receiving conventional fixed appliance treatment during the tooth alignment stage and OrthoAccel for those receiving conventional fixed appliance treatment for the space closure stage in orthodontic treatment. Participants receiving additional treatment with the devices were compared to those receiving only the conventional treatment. The trials evaluated different aspects of orthodontic tooth movement and side effects.
The studies evaluated three outcomes: rate of tooth movement; patient perception of pain and discomfort, and unwanted side effects. There were substantial differences between the studies, which meant that we were unable to combine the results.
From the limited evidence available, it is not possible to establish if the use of vibrational forces during treatment with fixed orthodontic appliances has a significant beneficial or harmful effect on either the rate of orthodontic tooth movement or the duration of treatment.
The quality of evidence was very low.
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Mental Health

Zuclopenthixol versus placebo for schizophrenia

People with schizophrenia often hear voices and see things (hallucinations) and have strange beliefs (delusions). The main treatment for these symptoms of schizophrenia is antipsychotic drugs. Zuclopenthixol is an older antipsychotic drug, first introduced in 1962, that has three distinct formulations zuclopenthixol dihydrochloride, zuclopenthixol acetate (or Acuphase), and zuclopenthixol decanoate. Although zuclopenthixol has been in common use for many years, no previous systematic review of its effectiveness compared to placebo ('dummy' treatment) in schizophrenia has been undertaken. Given the widespread use of this drug, it is important to look at the effectiveness of all three formulations of this commonly-used drug so that health professionals, policy makers and people with schizophrenia can make better-informed choices.

We searched for randomised controlled trials comparing zuclopenthixol with placebo in 2013. We found only two studies with 65 participants which could be included in this review. Overall the quality of these studies was low, with small numbers of people and significant bias. The studies were old, from 1968 and 1972, and would be unlikely to pass modern peer review standards. Only short-term information and data could be found, and only about zuclopenthixol dihydrochloride.

The information is very limited but suggests that zuclopenthixol can lead to improvement in global state in comparison with placebo. However, there is also increased risk of side effects such as sedation,and tiredness.

Given the low quality of information and age of the two studies, further research is needed, particularly further research on zuclopenthixol compared to newer and more recent antipsychotic drugs.

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Women's Health

Use of biochemical tests of placental function for improving pregnancy outcome

The placenta (afterbirth) develops in the uterus during pregnancy to provide oxygen and nutrients to the growing baby and to remove waste products from the baby's blood. The placenta attaches to the wall of the uterus and is linked to the baby via the umbilical cord. The placenta plays a critical role in determining the health of the baby and mother. The health of the placenta can be assessed by performing tests on mothers' blood or urine to measure chemicals made by the placenta. Having this information could improve the outcome of pregnancy as professionals could intervene to prevent outcomes such as stillbirth or babies being born too small.

We included three randomised controlled studies. Two trials were at a high risk of bias and one was at a low risk of bias. One study did not contribute any data towards this review. Therefore, this review is based on data from two studies involving 740 mothers. The evidence from these studies was graded as either low or very low quality evidence.

We found insufficient evidence to draw any conclusions about the effectiveness of tests that measure placental health in reducing the number of babies that die before birth (very low quality evidence) or shortly after birth (very low quality evidence), or in reducing the number of babies that are born small for their gestational age (low quality evidence).There was no evidence to suggest that measurement of placental health could cause harm by increasing intervention (planned delivery or caesarean section (low quality evidence) or increasing mothers' anxiety levels. There was no change in the number of babies admitted to the neonatal intensive care unit or the proportion of babies born before 37 weeks gestation (low quality evidence). There were no reports of serious disease for babies (as reported in one study only) or maternal deaths in any of the studies. A number of this review's other outcomes of interest were not reported in the included

studies.
More research is needed to determine the most useful test for placental health as a way of predicting poor pregnancy outcome, and then to investigate whether performing this test on mothers improves pregnancy outcomes.
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Cochrane Canada
The Ottawa Hospital - General Campus
Ottawa Hospital Research Institute (OHRI)
Centre for Practice-Changing Research (CPCR)
501 Smyth Road, Box 711
Ottawa, Ontario, Canada K1H 8L6
ccc.cochrane.org