

committee deliberations was gathered via meeting notes, recommendation documents, and discussion, and were summarized narratively.

RESULTS:

The amount of literature explicitly discussing ethical issues pertaining to particular technologies varied and was not predicted by the age and maturity of a technology. The axiological approach proved a helpful starting point for ethical reflection, but other methods were used for analysis and presentation. Explicit discussion of ethical issues identified the need for additional information to ensure robust deliberation. Committee members expressed the belief that ethics analysis “brought together” individual sections of the HTA.

CONCLUSIONS:

While many methods exist for ethics analysis, ethics expertise is required to identify and explicitly discuss the complete range of ethical issues relevant to a particular HTA. Ethics analyses create space to challenge assumptions underlying the clinical and economic evidence, raise issues about the value of technologies, and help to integrate the HTA results.

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OP86 Outpatient Initial Management Of New-Onset Diabetes In Children

AUTHORS:

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INTRODUCTION:

Management of new-onset diabetes is important to achieve metabolic stabilization, minimize acute complications, and to provide insulin therapy, diabetes education and psychological support. A health technology assessment (HTA) was conducted to determine if an outpatient setting could be effective and safe for new-onset diabetes in children, and how it can be implemented in our pediatric center.

METHODS:

A systematic search on initial management (outpatient versus in-hospital) of diabetes in children

was performed in multiple databases and grey literature. Practice guidelines (CPGs), systematic reviews (SRs), randomized controlled trials (RCTs) and non-randomized comparative studies (NRCSS) published up to August 2017 were identified. Telephone interviews with key informants from two children’s university teaching hospitals were performed to collect information on outpatient initial management models and issues related to their implementation. An interdisciplinary group of experts from our pediatric center collaborated in this project.

RESULTS:

According to 5 CPGs, hospitalization would not be required for children without acute complications at time of diagnosis or after initial treatment of ketoacidosis if outpatient care facilities, resources, and education are available. Results from one SR and 7 NRCSS suggested that outpatient initial management is associated with good metabolic control (glycated hemoglobin) and is as safe as the inpatient care model, based on rate of hospital admissions, severe hypoglycemia, and ketoacidosis episode. However, few data regarding treatment adherence, knowledge acquisition, and emotional adaptation were identified. Outpatient education programs can be successfully provided on several consecutive or non-consecutive days after diagnosis as reported by two children’s university teaching hospitals.

CONCLUSIONS:

Although data on effectiveness and safety are scarce and of low-quality, outpatient management of newly diagnosed diabetes, uncomplicated or stabilized, is recommended in children. However, data on children and their families should be collected as part of the implementation evaluation in order to enhance its efficacy and the quality of the patients’ and families’ experiences.

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OP87 Nitrous Oxide As Sedation Regimen In Children—How To Assess Safety?

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INTRODUCTION:

Children who undergo short, painful procedures at hospitals are given different kinds of pain relief (analgesics), often in combination with drugs for relaxation (sedatives). Nitrous oxide (NO) is a drug administered for pain relief and relaxation, it is applied by inhalation and its effects are analgesic, anxiolytic and sedative. It is used in several countries, but is not normally used as a sedation method for children in Norwegian hospitals, although widely used in maternity wards during labor. Our aim was to evaluate the effectiveness and safety of this sedation regimen in children. However, we also wanted to assess safety for health personnel after repetitive or long-term exposure.

METHODS:

We performed a systematic review on effectiveness and safety of nitrous oxide for sedation in children. For evidence on efficacy and safety in children, only randomized controlled trials (RCT) were included. For safety of health personnel we also accepted other study designs. For all endpoints, we presented the evidence in summary of finding tables.

RESULTS:

We retrieved twenty-two randomized controlled trials on the effectiveness or safety in children undergoing sedation with nitrous oxide. Outcomes were hospital procedure satisfaction or characteristics, and pain relief. Safety was reported as acute adverse events. None of the RCTs reported evidence on safety for health personnel. We are currently exploring different ways to systematically assess safety for health personnel within the form of an HTA otherwise designed for a different population.

CONCLUSIONS:

Assessing safety of new technologies, methods or procedures through HTAs is a crucial point. However, assessing the long-term safety of the health personnel should also be included, but evidence will often not be retrieved through literature search designed for the patient group, and long-term safety data is in general difficult to retrieve for exposure to a novel technology. We will discuss our approach to this challenge.

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OP88 Reduction Of Biologics In Rheumatoid Arthritis: A Systematic Review

AUTHORS:

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INTRODUCTION:

Reduction of biologics after reaching low disease activity rheumatoid arthritis has been tested in clinical trials. The aim of this systematic review is to assess the effectiveness and safety of the reduction of biologics drugs in patients with rheumatoid arthritis in low disease activity.

METHODS:

The protocol of this review is registered at PROSPERO (CRD42017069080). We searched MEDLINE, Embase, Scopus and The Cochrane Library for randomized controlled trials that reduced or spaced the dose of biologics in patients at low disease activity or remission state compared with maintenance. Two researchers selected studies, extracted the data, and assessed the risk of bias of the studies. Random effects meta-analyses by DerSimonian & Laird method were calculated considering intention to treat analysis to obtain the standardized mean difference (SMD) or relative risk (RR) and 95 percent confidence interval (CI). Quality of evidence will be assessed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE).

RESULTS:

From 725 retrieved records, seven studies were included. Compared to regular doses, reduction of biologics significantly increased the health assessment quality (SMD = 0.20; 95% CI: 0.04 0.37; I² = 3.5%). No difference was observed for low disease activity (RR = 0.83; 95% CI: 0.68, 1.03; I²= 71.3), serious and non-serious adverse events; disease activity scores; patient global assessment and radiographic progression.

CONCLUSIONS:

Preliminary results show no differences in clinically relevant outcomes from reduction of biologics compared to regular doses. As a limited number of studies is available, the certainty of evidence is limited and need to be monitored to better inform patients and clinicians.

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