These values were compared with the pooled sensitivities and specificities produced for the systematic review using full-text papers only.

RESULTS:

Preliminary pooled sensitivities of the sixteen full-text Actim Partus studies and sixteen full-texts and two abstracts were 0.77 (95% confidence interval (CI) 0.68, 0.83) and 0.76 (95% CI 0.69, 0.83) respectively whilst pooled specificities were 0.81 (95% CI 0.76, 0.85).and 0.80 (95% CI 0.75, 0.84) respectively. Preliminary, pooled sensitivities of the four full-text PartoSure studies and four full-texts and three abstracts were 0.83 (95% CI 0.61, 0.94) and 0.82 (95% CI 0.65, 0.92), respectively, whilst pooled specificities were 0.95 (95% CI 0.89, 0.98) and 0.96 (95% CI 0.94, 0.97), respectively.

CONCLUSIONS:

Our findings suggest that the test accuracy results would not alter substantially with the inclusion of conference abstracts. However, work is ongoing to investigate how the assessment of heterogeneity and risk of bias across studies would alter given the difficulties associated with limited methodological reporting from conference abstracts.

OP139 Not Using Data From 'Failed' Primary Research Undermines Health Technology Assessment Reporting

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INTRODUCTION:

The reliability of health technology assessment (HTA) is built on accessing evidence systematically to inform conclusions and recommendations; however, the availability of primary evidence is a source of bias which can undermine an HTA. This omission is often because attempts to generate primary evidence have not been completely successful. Where partial evidence exists, ignoring it constitutes avoidable bias. Taking the Hip Op trial as an example (a study of developmental dysplasia of the hip (DDH)) we consider how despite lack of quantitative outcomes data, rich information was obtained that should inform HTA in this area.

METHODS:

The Hip Op trial was an open label trial comparing early against late surgery in the management of DDH. In parallel, a qualitative study attempted to explore the experience of parents of children with DDH.

RESULTS:

The trial protocol called for recruitment of 636 children, but due to changes in clinician equipoise and service configuration only 29 could be recruited. The trial was stopped early. While baseline data for the 29 children was available, no estimate of effect was attempted due to a lack of outcome data; however, the qualitative data was rich, representing the biggest qualitative sample worldwide on this topic. It reflected the patient experience, and shows a clear preference towards early intervention, despite the absence of quantitative evidence.

CONCLUSIONS:

The qualitative work here gives a clear indication that parents have a strong preference. This is data which would not be captured in traditional HTA reports, which tend to focus on quantitative data and meta-analysis. This is, however, information that is important to patients, and should inform clinicians and payers. We discuss how HTA do-ers should make efforts to find this data from 'failed' primary research and incorporate it into their reports, and how HTA do-ers could be alert to this situation.

OP141 A Patient-Reported Outcome Measure For Hemorrhoidal Disease

AUTHORS:

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INTRODUCTION:

Treatment options for hemorrhoidal disease (HD) include conservative treatment (e.g. laxatives), rubber band ligation, and more invasive surgical treatment options. Outcomes reported in clinical trials evaluating treatment effectiveness are heterogeneous, making comparisons difficult. Moreover, clinical outcomes, such as recurrence, complications and symptoms, do not fully represent the relevant benefits and harms of treatment

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to the patient. We therefore developed (i) a core outcome set (COS) for HD treatment, and (ii) a patient-reported outcome measure (PROM) evaluating symptoms and impact on daily life.

METHODS:

Literature review established outcomes most commonly used in studies evaluating HD treatment. A Delphi study with health professionals and patients was conducted to rank and discuss the outcomes in terms of importance and completeness, and reach consensus on a COS. In addition, individual patient interviews (n=15) were held to gain insight into patient experiences with HD and treatment. A panel of experts subsequently developed a PROM that focused on the core outcomes. Face and content validity were assessed (n=10) using a retrospective verbal probing technique.

RESULTS:

Recurrent symptoms, complications and treatment satisfaction were the primary focus for health professionals, while patients were more concerned with overall impact on daily life. Patients ranked blood loss, pain and itching as the most bothersome symptoms. A PROM was developed, consisting of seven items covering three domains: severity of symptoms, impact on daily life, and treatment satisfaction (if applicable). The questions and response options were clear to patients and content validity was good. The questionnaire took approximately three minutes to complete.

CONCLUSIONS:

We developed a COS and a PROM for HD treatment. The PROM can be used in clinical trials as the primary outcome measure evaluating treatment effectiveness from the patient's perspective. It can also support shared decision-making regarding individual treatment pathways in clinical practice. A psychometric validation study is currently underway.

OP143 Conceptualizing Patients' Experience With Atrial Fibrillation

AUTHORS:

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INTRODUCTION:

Conceptual models (CMs) are useful tools for researchers and health technology assessment bodies to understand the interplay among environmental characteristics (e.g., health care system), patient characteristics, health behaviors, and patient outcomes. The objective of this pilot study was to elicit perspectives of patients with atrial fibrillation (AF) and health care providers (HCPs) to develop a patient-centered CM of the AF patient experience in a US-based sample.

METHODS:

We developed two preliminary versions of the Andersen model of healthcare utilization (standard and patient-friendly versions) based on the published literature and the help of a patient advisor. For example, instead of describing "predisposing characteristics," the patient-friendly CM describes, "what is it about me, or other afib patients that could impact disease or outcomes;" "enabling resources" is swapped for "helpful resources," and "perceived need" is changed to "what impacts whether I believe I need to be treated". Five patients from an online patient community and 10 HCPs from the University of Maryland Medical System provided feedback on the preliminary models. Audio recordings of interviews were transcribed verbatim, analyzed, and findings incorporated into a revised CM.

RESULTS:

Interviewee additions under "what impacts whether I believe I need to be treated" included: absence of symptoms and fear of experiencing an AF episode; under "helpful resources" suggested additions include resources for navigating insurer formulary/benefits. Suggested additional outcomes of interest include anxiety, bruising, and shortness-of-breath. While patients found the patient-friendly version easy to understand, HCPs required explanation of standard-version headers, for example 'predisposing characteristics' and 'enabling resources', which had been adapted in the patient-friendly version.

CONCLUSIONS:

Soliciting input from stakeholders ensures CMs are pragmatic, reflect the real-world experiences of patients and HCPs, and incorporate variables or other considerations not currently described in published literature. Researchers can utilize CMs to aid in selection of variables for observational studies.

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