used as primary or secondary endpoints in trials and discussed in Food and Drug Administration (FDA) approved product labels between 2003 and 2014.

METHODS:

We examined all 26 PROs included in chapters 1 (Office of Microbial Products) and 2 (Office of Drug Evaluation I) of the FDA's Pilot Clinical Outcome Assessment (COA) Compendium. Three reviewers independently searched PubMed and Google to identify publications or other relevant materials related to method and stage of measure development where patient engagement took place.

RESULTS:

Among 26 evaluated PROMs, we were unable to locate any information on development or validation for 12 (patient diary=9; rating scale=3). Among the remaining 14 PROMs, 5 did not include any evidence of patient engagement (questionnaire=1; patient diary=2; rating scale=2); 3 engaged patients during concept elicitation or psychometric validation only (disease-specific questionnaires=3); and 6 engaged patients during both concept elicitation and cognitive interviewing (disease-specific questionnaires=6). PROMs either previously qualified or submitted for qualification by FDA were more likely to include patient engagement.

CONCLUSIONS:

PROs can provide patient-centered data useful for HTA; however, patient-reported information is not inherently patient-centered. This study found that only a minority of sampled PROMs engaged patients during both concept elicitation and cognitive interviewing. To facilitate patient-centered HTA, manufacturers should ensure that PROMs incorporated into clinical trials measure concepts important to patients. Similarly, HTAs should request data on development and validation of all outcome measures incorporated into trials.

OP96 Standardizing Collection Of Patient-Reported Experience Measures To Drive Service Improvement In Wales

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INTRODUCTION:

Co-production relates to patients and health professionals working in equal partnership with shared decision-making. Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) are increasingly being used to involve patients and measure healthcare quality. We set out to develop a set of universal experience questions for use across Wales. These will be used in various settings, including the national electronic PROMs and PREMs platform, which is already collecting outcome data across Wales and has received over 7,000 responses to date.

METHODS:

Patient experience leads and clinical leads were invited to a workshop to discuss standardized PREMs collection in Wales, with all health boards and trusts represented. It was agreed that quantitative patient experience data collection, while limited, would be a pragmatic way to collect responses from a large cohort. It was agreed that a previously developed set of PREMs questions could be adapted for use in all healthcare settings. Patient focus groups reduced the number of questions to a shortlist of those considered most important by patients. Wording was improved and an additional question was added.

RESULTS:

In partnership with stakeholders we developed and agreed on a set of universal PREMs questions. These have been added to the national electronic platform, with collection commencing imminently. This will allow patients accessing secondary care in Wales to provide PREMs and PROMs responses.

CONCLUSIONS:

Development of a standardized set of PREMs has allowed us to initiate collection on a national basis. Addition of PREMs to the national electronic platform provides a unique means of collecting large volumes of data consistently, allowing us to benchmark across and within organizations. It will also allow experience teams to target improvement initiatives and identify good practice. Together with outcomes responses, the data will be used to measure experience of care in Wales.

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