undergoing revascularization, and to assess their psychometric properties and examine suitability for research and clinical use.

METHODS:

Eight electronic databases including MEDLINE and CINAHL were searched from inception to May 2015 and updated in the MEDLINE database to February 2017. A two-stage search approach was used to identify studies reporting the development and/or validation of relevant PROMs in patients with CAD undergoing revascularization. Supplementary citation searching and hand-searching reference lists of included studies were also undertaken. The Consensus-based standards for the selection of health measurement instruments (COSMIN) and Oxford criteria were used to assess the methodological quality of the included studies, and the psychometric properties of the PROMs were evaluated using established assessment criteria.

RESULTS:

Six PROMs, reported in five studies, were identified: 36-Item Short Form Health Survey (SF-36), Euro-QoL-5-Dimension Scale (EQ-5D), Hospital Anxiety and Depression Scale (HADS), Dizziness Handicap Inventory (DHI), Quality of life for CAD scale by Ivanova 2015 and a disease-specific PROM designed by Stolker 2010. The rigour of the psychometric assessment of the PROMs were variable with most only attempting to assess a single psychometric criterion. No study reported evidence on criterion validity and test-retest reliability. The overall psychometric evaluation of all included PROMs was rated as poor.

CONCLUSIONS:

This review highlighted a lack of evidence in validated PROMs used for patients undergoing carotid artery revascularization. As a result, the development and validation of a new PROM for this patient population is warranted in order to provide data which can supplement traditional clinical outcomes (stroke $>$30 days post-procedural, myocardial infarction and death), and capture changes in health status and quality of life in patients to help inform treatment decisions.

OP28 Health Apps: A Proposed Framework To Guide Clinical Risk Assessment

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INTRODUCTION:

Globally, health systems are struggling with reliably appraising the safety and efficacy of rapidly changing digital health interventions whilst allowing useful innovations to be rapidly adopted. Assessment and regulation of the large number of health apps should be proportional to their clinical risk, but there is large uncertainty about suitable criteria to assess risk (1). We aimed to identify criteria for assessing clinical risks associated with different types of health apps.

METHODS:

Our work builds on previous studies that identified some of the risks that health apps can pose and contextual factors that can moderate these risks (2,3). This work is grounded in a review of existing literature; wide consultation of stakeholders; participation in multi-agency policy discussion; and sense-checking successive versions of the framework that evolved over time. We combined different risk domains for apps (technical safety, usability, intervention quality, and engagement) with their functions (learning, behaviour and cognition change, communication, record keeping, and clinical decision support).

RESULTS:

We developed a comprehensive generic risk framework that app users, developers, commissioners, regulators and other stakeholders worldwide can use to guide assessment of the likely risks posed by a specified health app in a specific context. We also propose questions that should help determine whether these risks have been addressed.

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CONCLUSIONS:

Apps are very promising in health care but are very numerous, complex, rapidly evolving and with overlapping functions. A rigorous risk framework should help stakeholders to deal with the large quantity of health apps, classify and manage clinical risks, and improve patient safety by applying generic risk assessment criteria. Further work is needed to test and develop the criteria we propose, especially as apps that integrate different functions are emerging, which will make risk assessment more complex.

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OP30 Health Technology Assessment And The Decision-Making Process Of New Drug Listing In Hong Kong

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INTRODUCTION:

In Hong Kong, the Drug Advisory Committee (DAC) has had the role of evaluating and advising new drugs to be included in the listing of the Hospital Authority Drug Formulary since July 2005. The drug review process was subject to challenge due to a lack of transparency to members of the public and documentation of the scientific basis for decision making. The purpose of this review was to describe the process, evaluation criteria and possible outcomes of decision making for new drugs listed in the Hong Kong Hospital Authority Drug Formulary in comparison to Health Technology Assessment (HTA) policies in overseas countries.

METHODS:

Details of the decision-making processes including new drug listing submissions, the DAC meeting, procedures before and after the meeting, were extracted from the official Hong Kong Hospital Authority drug formulary management website and manual. Publicly available information related to new drug decision making processes for four HTA agencies (National Institute for Health and Clinical Excellence (NICE), Scottish Medicines Consortium (SMC), Australian Pharmaceutical Benefits Advisory Committee (PBAC), and Canadian Agency for Drugs and Technologies in Health (CADTH)) were reviewed and retrieved from official documents on their public domains.

RESULTS:

The DAC is in charge of the systematical and critical appraisal of new drugs for listing on the formulary, reviewing submitted applications, and making decisions of drug listing based on scientific evidence in which safety, efficacy and cost-effectiveness are primary considerations. When compared to other HTA agencies, transparency of decision-making processes of the DAC, relevance of clinical and health economic evidence, and lack of health economic and methodological input to submissions were major challenges of the new drug listing policy in Hong Kong.

CONCLUSIONS:

Despite the challenges identifed, this review provided suggestions for establishing a more transparent, credible, evidence-based decision-making process for the Hong Kong Hospital Authority Drug Formulary. Proposals for improvement in the listing of new drugs in the formulary should be a priority in healthcare reform.

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