BMJ Open

Engaging pregnant individuals and healthcare professionals in an international mixed methods study to develop a core outcome set for studies on placenta accreta spectrum disorder (COPAS): a study protocol

Susan E O'Rinn,[1,2] Jon F R Barrett,[3] Janet A Parsons,[4,5] John C Kingdom,[6] Rohan D'Souza [3,6,7]

To cite: O'Rinn SE, Barrett JFR, Parsons JA, *et al*. Engaging pregnant individuals and healthcare professionals in an international mixed methods study to develop a core outcome set for studies on placenta accreta spectrum disorder (COPAS): a study protocol. *BMJ Open* 2023;**13**:e060699. doi:10.1136/bmjopen-2021-060699

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2021-060699).

Received 05 January 2022
Accepted 19 April 2022

For numbered affiliations see end of article.

Correspondence to
Dr Rohan D'Souza;
rohan@mcmaster.ca

ABSTRACT

Introduction Placenta accreta spectrum (PAS) disorder is a life-threatening condition that may result in serious maternal complications, including mortality. The placenta which is pathologically adherent to the uterine wall, places individuals at high risk of major haemorrhage during the third stage of labour. Current research reports on PAS disorder outcomes have highly variable levels of information, which is therefore difficult for investigators to aggregate to inform practice. There is an urgent need to harmonise data collection in prospective studies to identify and implement best practices for management. One approach to standardise outcomes across any health area via the use of core outcome sets (COSs), which are consensus-derived standardised sets of outcomes that all studies for a particular condition should measure and report. This protocol outlines the steps for developing a COS for PAS disorder (COPAS).

Methods and analysis This protocol outlines steps for the creation of COPAS. The first step, a systematic review, will identify all reported outcomes in the scientific literature. The second step will use qualitative one-on-one interviews to identify additional outcomes identified as important by patients and healthcare professionals that are not reported in the published literature. Outcomes from the first two steps will be combined to form an outcome inventory. This outcome inventory will inform the third step which is a Delphi survey that encourages agreement between patients and healthcare professionals on which outcomes are most important for inclusion in the COS. The fourth step, a consensus group meeting of representative participants, will finalise outcomes for inclusion in the PAS disorder COS.

Ethics and dissemination This study has obtained Research Ethics Board approval from Sunnybrook Health Sciences Centre (#2338, #1488). We will aim to publish the study findings in an international peer-reviewed OBGYN journal.

Registration details COMET Core Outcome Set Registration: https://www.comet-initiative.org/Studies/Details/1127.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study adheres to published guidelines on core outcome set (COS) development with adaptations to accommodate challenges arising from the COVID-19 pandemic.
⇒ Through this study we ensure representation of pregnant persons that have experienced placenta accreta spectrum (PAS) disorder as well as a diverse group of healthcare professionals involved directly or indirectly in their care.
⇒ The project has the support and participation of members of international bodies involved in PAS disorder and COS development.
⇒ The study will identify those outcomes that should be included as part of the COS but will not address how these outcomes should be measured; this will be done as part of a separate study.

PROSPERO registration number CRD42020173426.

INTRODUCTION

Placenta accreta spectrum (PAS) disorder describes a continuum of conditions whereby the human placenta is pathologically anchored to the myometrium (placenta accreta), including its invasion of the myometrium (placenta increta) or its penetration invasion through to or beyond the uterine serosa (placenta percreta).[1] The inherent inability of the placenta, in whole or in part, to separate from the uterine wall following childbirth, may result in life-threatening haemorrhage, resulting in severe morbidity or even maternal death. Complications result either directly as a result of massive haemorrhage, or from surgical interventions to arrest blood loss, and include admission to

an intensive care unit, prolonged hospital postoperative stay, increased risks of infection and thrombosis, and a substantially higher risk of maternal death compared with the general obstetric population,[2–6] with some research reporting maternal death rates in up to 7% of instances.[7]

Estimates of the incidence of PAS disorder have risen dramatically in recent decades, from 1 in 4027 pregnancies in the 1970s[8] to 1 in 533 pregnancies in the 2000s.[9] This increase appears to parallel the increase in risk factors, primarily rising global rates of caesarean births,[6 10–12] placenta previa,[6 9–12] advanced maternal age,[13] all types of prior uterine surgeries[13 14] and conception via in-vitro fertilisation.[15]

Though an increasing number of research studies on PAS disorder are now reporting larger numbers of both short-term and long-term maternal and neonatal outcomes, there is little consistency in how these outcomes are defined or reported. For example, five recently published papers on PAS disorder reported over 40 distinct maternal and neonatal outcomes, yet few outcomes were reported in more than one study and the majority of outcomes were reported in a single study.[16–20] Further, the reported outcomes were either defined differently from one study to another, or not defined at all. The lack of standardisation in outcome selection, definitions, and reporting in research, and resulting publications, renders it difficult to compare results across studies, replicate research or use findings to develop clinical practice guideline recommendations with strong recommendations. An international Delphi survey of PAS disorder experts (O'Rinn *et al*, unpublished data, 2015) found that experts did not agree as a group with 70% of the published clinical guideline recommendations at that time for PAS management. Such divergent practice opinions and recommendations contribute to worldwide variations in clinical practice. In addition, the outcomes reported in the literature that inform clinical guideline recommendations have thus far rarely included any preferences and priorities provided by affected patients and their families. Inclusion of preferences of pregnant individuals and families may be vital to guiding effective clinical care[21] and this approach has been shown to increase patient satisfaction and improve overall outcomes.[22]

In recent years, core outcome sets (COSs) have been proposed as a way of standardising outcome reporting for any health condition. This approach formally incorporates the perspectives of multiple stakeholders, including patients and healthcare providers involved in their care. A COS is a consensus-derived, standardised set of outcomes that all studies on a particular health condition should measure and report[23] and when used in all research,[23–27] has the potential to result in: (a) higher-quality trials; (b) results that are easier to compare, contrast and combine for meta-analyses; (c) reduced heterogeneity between trials; (d) research that is more likely to report on relevant outcomes; (e) reduced risk of outcome reporting bias; and (f) all trials contributing usable information.[26] While there is no agreed on gold standard method for the development of COSs,[27] a handbook published by the Core Outcome Measures in Effectiveness Trials (COMET) initiative provides the most comprehensive guidance for COSs development.[26]

This protocol outlines the development of a COS for PAS disorder (COPAS).

METHODS

The development of COPAS involves four distinct, but related, steps: systematic literature review, interviews with relevant stakeholders, Delphi survey and consensus meeting (see figure 1). COPAS has been registered on the COMET website (https://www.comet-initiative.org/Studies/Details/1127) and its development will be guided by a steering committee comprised of this protocol's authors.

Step I: systematic literature review

The primary goal of the first step is to identify existing knowledge and generate a preliminary list of reported outcomes considered important by researchers. All reported outcomes and their definitions in studies on PAS disorder will be identified through a systematic review of the literature. The systematic review will be conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[28] The primary and secondary research questions are 'What maternal and fetal/neonatal outcomes have been reported in studies on PAS disorder?' and 'How have these reported outcomes been defined and measured?'.

The systematic literature review search strategy will be developed with input from a medical information specialist who has prior experience with COS development. A mix of MeSH, Emtree and keyword terms related to PAS disorder will be used to identify articles from several bibliographic databases. All original research articles that report maternal and fetal/neonatal outcomes for pregnant persons with suspected or diagnosed PAS disorder will be included.

All reported outcomes and their definitions or measurement instruments will be extracted verbatim from the source manuscript[29] to ensure transparency in the COS development.[26] Identified outcomes will be grouped under broader domains as per Dodd *et al*'s taxonomy for outcomes in medical research.[30] Study characteristics and data will be extracted and verified for accuracy and completeness. Given that the purpose of this systematic review is to determine what outcomes have been reported in the literature, regardless of the quality of the study, no risk of bias (quality) assessment will be performed. This is consistent with other systematic reviews conducted for the purposes of developing COSs.[31]

Step II: interviews with pregnant individuals and relevant stakeholders

Since outcomes reported in the literature may only represent a fraction of the outcomes considered important to

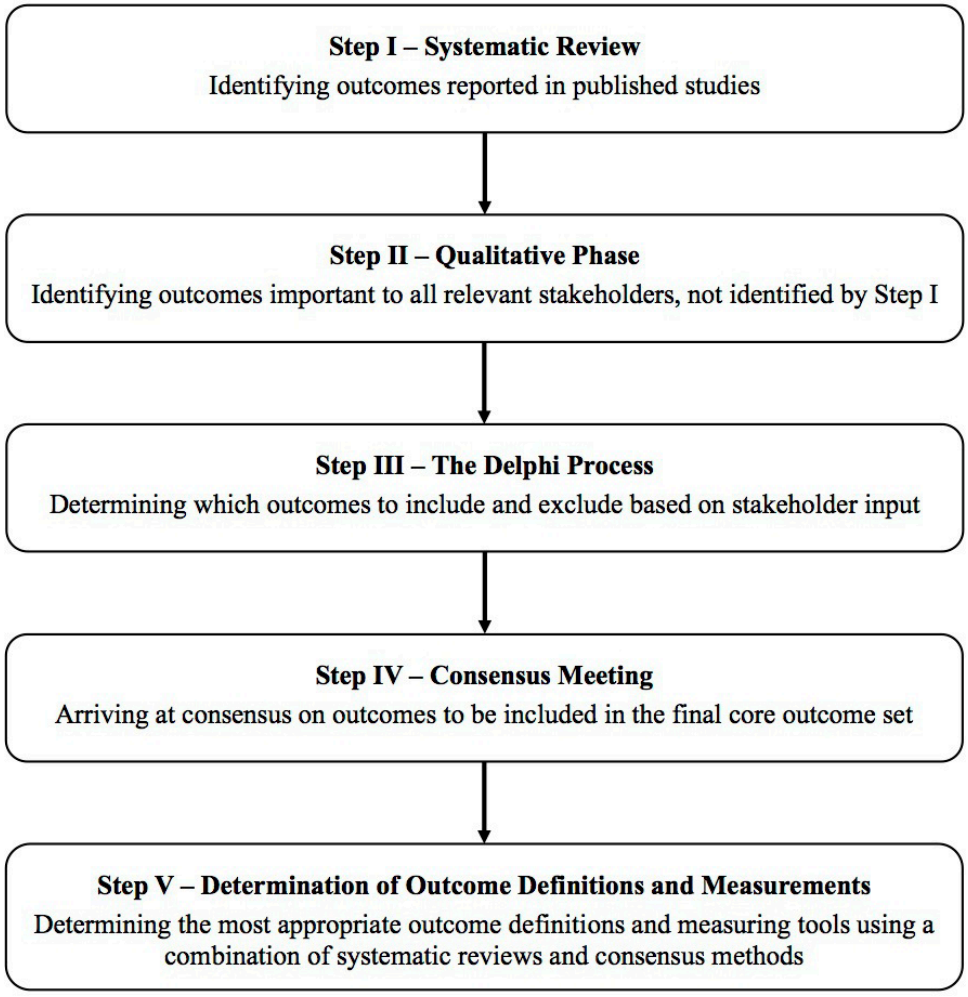

Figure 1 Framework for development of a core outcome set.[31]

measure in clinical trials for pregnancy-related conditions,[32 33] the goal of the second step is to conduct interviews and independently identify outcomes considered important by those that have experienced PAS disorder (patients) and healthcare professionals (eg, maternal fetal medicine specialists, obstetricians, nurses and midwives) who provide care for these individuals.

We will interview participants who have either experienced PAS disorder themselves or who have clinical experience with PAS disorder, in order to identify outcomes important to both groups. A purposive sampling[34] approach will be used to recruit (a) persons who are experiencing or have experienced a pregnancy complicated by PAS disorder; and (b) diverse healthcare professionals involved in the care of individuals with PAS disorder. This approach to sampling aims to elicit a range of perspectives and, given the heterogeneity of potential participants (eg, currently pregnant vs post partum or professional type), it is expected that 15–20 participants from each stakeholder group may be required.[35]

Data collection and analysis

We will conduct interactive, semi-structured interviews with participants to identify outcomes important to them. Separate interview guides will be developed for persons with lived experiences of PAS disorder and for those providing care to persons with PAS disorder. Interviews will be audio recorded, transcribed, and the (deidentified) transcripts analysed qualitatively. Interviews will be conducted until thematic saturation is reached.[36] Data collection and analysis will be an iterative process, with each informing the other.[36] Data will be analysed using the thematic analysis approach outlined by Braun and Clarke.[37] This inductive process includes multiple readings of transcripts, and coding the textual data to identify emerging themes and patterns.[37] Appropriate techniques for ensuring analytic rigour will be employed, including thick description, reflexivity, and comparison within and across groups.[37 38]

Step III: Delphi survey

The primary goal of the third step is to condense the long list of outcomes generated in steps I and II through employing Delphi survey methodology. The Delphi approach is an iterative and sequential process used to achieve consensus[39 40] from relevant stakeholders on which outcomes are most important for inclusion in the COPAS.

Survey development

Prior to the Delphi survey, an outcome inventory, a comprehensive list of outcomes identified in the systematic literature review and the qualitative interviews, will be developed. The outcome inventory will be circulated to the steering committee to review for comprehension, assess the suitability of the domain groupings and ensure that each included statement represents an 'outcome', which for purposes of clinical trials and studies of modifiable exposures, is defined as a measurement or observation used to capture and assess the effect of treatment (such as risk/side-effect or benefit/effectiveness) (COMET handbook), and which therefore, cannot exist before the intervention or exposure. This will eliminate a large number of patient-reported experience measures, which will be presented separately in a thematic analysis, but not used in further steps of COPAS development.

In the context of COSs, the Delphi technique is used to achieve convergence of opinion from experts on the importance of different outcomes in sequential rounds. The Delphi survey will be developed and distributed using DelphiManager,[41] an online survey tool. This will ensure participant anonymity, feasibility, reproducibility and minimise the effects of dominant individuals while being cost-effective and facilitating international participation. The survey will consist of all outcomes identified in the above inventory. Maternal outcomes will be presented under the most relevant domains as described in the taxonomy of outcomes for medical research,[30] and fetal/neonatal outcomes will be presented under a separate domain. The survey will be piloted to identify and resolve issues related to survey structure,[26 42] survey length,[26] lay language summary, and survey logic glitches, prior to the start of the Delphi survey.

Survey panels

The Delphi survey will consist of two panels, one comprised of persons that have experienced PAS disorder and the second of healthcare professionals that have experience caring for those with PAS disorder in various capacities. Experts from both participant groups will be recruited from the following sources: (a) participants from the second step; (b) PAS disorder patients from two University of Toronto-affiliated hospitals in Canada; (c) potential participants identified from patient and professional groups as described in step II; (d) authors identified from studies included in step I; (e) authors and experts involved in generating PAS disorder clinical guidelines; and (f) recommendations from the project's steering committee, in case of a lack of diversity among the recruited participants. This multi-faceted recruitment approach should ensure a heterogeneous sample from both stakeholder groups. Individuals who express interest in participating will be directed to the survey via a link. The survey's landing page will serve as a traditional consent form and will describe the survey, risks and benefits, and expectations. Participants will sign the consent form electronically, identify which stakeholder group they belong to and then complete a brief demographic questionnaire.

Survey group size

While there should be adequate representation from both key stakeholder groups with qualified experts who have a deep understanding of PAS disorder,[42] there is no standard recommendation for a Delphi survey group size with group size expected to be determined based on several factors, including the scope of the COS, existing knowledge and survey feasibility.[26] Based on prior experience with COS development, we will aim to recruit approximately 20 persons with experience of PAS disorder in either a current or a prior pregnancy, with a focus on diverse representation as per other obstetrical COSs.[31] In addition, approximately 40 healthcare professionals that provide care on an ongoing basis for pregnant persons with PAS disorder, representing various disciplines and geographical regions will be recruited.

Survey rounds

The Delphi survey will consist of two rounds.[31 43–45] Each round will remain open for a minimum of 3 weeks, with the option to extend if needed to improve low response rates and minimise the potential for attrition bias. Following the closure of a Delphi round, an additional 2 weeks will be required to analyse the data and prepare for the following round. Participants will score each outcome according to their level of importance on a 9-point Likert scale, wherein a score of 1–3 indicates an outcome is of 'limited importance'; 4–6 an outcome is 'important but not critical'; and 7–9 the outcome is 'critical'. The questionnaire will also include an 'unable to score' category for respondents who feel they lack the expertise or experience to evaluate a specific outcome. During the first Delphi round, participants will be asked to identify any outcomes they feel are missing thus ensuring an exhaustive list of outcomes is included in the Delphi survey. These outcomes will be added to the second round to be scored by all participants, if they fulfil the criteria for outcomes in clinical trials as described above.

Survey feedback between rounds

Survey feedback between the two rounds will assess the extent of agreement (consensus measurement) and increase the likelihood of convergence towards consensus of 'core' outcomes. Feedback for each outcome will be presented graphically and will include the mean score for all participants, the mean score for each stakeholder group,[46] as well as their own score from the previous round. In the second survey round, participants will be encouraged to consider these graphs and their original score before determining whether they would like to change or maintain their score. This feedback provides a mechanism for reconciling different stakeholder opinions and is critical in achieving consensus. Since this Delphi process involves two separate stakeholder groups, feedback will be presented separately for each stakeholder group as

well as together for both groups, as recommended.[47] This approach allows for the preferences of both groups to be considered separately, as well as together.[26] All outcomes from the first round, including newly suggested outcomes from participants, will be carried forward to the second round, regardless of how the outcome was scored in the first round.[48–50] All outcomes that have been scored in both rounds and that achieve consensus, will be included in the next step. Those that were introduced in the second round and therefore were only scored once, will be included in the next step, unless >70% of participants in both groups score the outcome <7.

Survey response rates and attrition

A survey response rate of 80% from each stakeholder group is deemed acceptable based on published recommendations.[26] However, attrition rates for previous Delphi surveys vary from 0%[48] to 17%[51] and 21% to 48% for previous COSs within Obstetrics & Gynaecology and Newborn Medicine, respectively.[39] In order to maximise the response rates and minimise attrition, we will implement strategies such as bi-weekly personalised email reminders and extend the survey window when needed, to make it convenient for participants. In the case of a continued inadequate response, the steering committee will evaluate the nature of attrition (selective groups vs general attrition affecting all groups), cause and likelihood of improving uptake by extending the time period and the general consensus with regard to outcomes, when deciding whether to close data collection for the project.

Defining and assessing the degree of consensus

This survey will follow the consensus classification used by Williamson *et al*:[42] 'consensus in' for inclusion in COPAS will be defined as >70% scoring 7–9 and <15% scoring 1–3; 'consensus out' for exclusion will be defined as >70% scoring 1–3 and <15% scoring 7–9; and 'no consensus' will be defined as those that do not meet either threshold for critical or limited importance outcomes. Outcomes that meet the inclusion for 'consensus in', by all experts or by one group of experts, as well as 'no consensus' outcomes will be considered in the next step of COPAS development.

Step IV: consensus group meeting

At the end of the second round of the Delphi survey, participants will be informed of the virtual consensus group meeting, and will be asked to indicate if they are interested in participating. The primary goal of the fourth step is to bring together key stakeholders to determine which outcomes should comprise COPAS.

A minimum of five Delphi participants from each stakeholder group (pregnant persons with experience of PAS disorder and PAS disorder healthcare professionals) who have expressed interest as well as those that have not participated in prior rounds, will be invited to participate. Participants will be randomly selected while balancing the desire for equal representation among participants. Although some research suggests that face-to-face meetings are critical as they foster interactive debate between participants on key issues[52 53] and allow participants to clarify their position and justify their viewpoint,[54] given the uncertainties of the COVID-19 pandemic and the logistics associated with bringing together international stakeholders, this consensus meeting will be virtual. In order to facilitate global participation and in recognition of differing time zones and participant availabilities, the first stage of the consensus meeting may consist of several smaller meetings with representation from both stakeholder groups where possible while the second stage of the consensus meeting will include all available participants as well as the steering committee.

First stage

Each meeting will start with a presentation of the results from each step of the COPAS development: the systematic review; the qualitative interviews; and the Delphi survey. The moderator will then facilitate a guided discussion starting with the 'no consensus' outcomes from the Delphi survey, followed by an electronic vote for each of these items that will include three options: 'IN', 'OUT' or 'unable to score'. If all participants score an outcome as 'IN' or 'unable to score', the outcome will be included in the next stage and if all participants score an outcome as 'OUT' or 'unable to score', the outcome will be removed from the next stage. All non-consensus outcomes will be debated by the group until a consensus is reached. If consensus cannot be reached for an outcome, the outcome will be included in the next stage.

Second stage

Given the virtual format and the possibility of multiple meetings in the first stage, the second stage of the consensus meeting will consist of the steering committee along with available representatives from each stakeholder group and the final vote for inclusion of outcomes in COPAS will rest with these individuals. This meeting will start with a synthesis of the results from the meetings in the first stage. Obstetrical and gynaecological COSs have included a wide range of outcomes, from 11 to 48,[39] however, this COS will endeavour to keep the number low in an effort to increase uptake by researchers and maintain the focus on the bare minimum number of critical outcomes for inclusion in future research.

Patient and public involvement

PAS disorder is a rare and specific pregnancy-related condition that most members of the public do not have the experience or expertise on. Since prior experience and/or expertise is vital to the development of COPAS, public involvement will not be solicited. The involvement of pregnant individuals (patient involvement) and healthcare professionals involved in their care, is central to the development of COPAS. Since the methodology for COS development has been established,[26] and the systematic review (step I) needs to be conducted by experts,

pregnant persons will be involved in this study from step II onwards. Herein, pregnant persons, independently or as part of online groups, will assist with participant recruitment, study participation, and interpretation of study findings.

ETHICS AND DISSEMINATION

Research Ethics Board (REB) approval for the steps involved in this study have been granted: step two has received REB approval from Sunnybrook Health Sciences Centre (#2338, #1488), The University of Toronto (#38312, #39503) and Sinai Health System (#20-0292-E); and steps III and IV have received REB approval from Sunnybrook Health Sciences Centre (#5087). We will aim to present these findings at appropriate international OBGYN conferences and publish the findings of the various steps in the OBGYN literature. COPAS will be archived in the COMET database and we will aim to publish it in the OBGYN literature.

DISCUSSION

This protocol outlines the COS development comprising the minimum number of outcomes to be included in future studies involving individuals with PAS disorder. The methods described reflect the steering committee's experience with developing COS for pregnancy-related conditions, as part of the Outcome Reporting in Obstetric Studies initiative.[55] In addition, it considers the need for modifications to protocols previously described, such as the need for including smaller numbers, the inclusion of virtual meetings and smaller group sessions, on account of challenges posed by the COVID-19 pandemic. When published, researchers will have an evidence-based rationale to include outcomes that have been prioritised by multiple stakeholders, including persons who have experienced the condition. This COS will contribute to the standardisation of outcome collection and measurement for PAS disorder and will add to the growing literature and methodological approaches to the development of COS.

Author affiliations
[1]Outcomes & Evaluation, Institute of Health, Policy, Management and Evaluation, University of Toronto, Toronto, Ontario, Canada
[2]DAN Women & Babies Program, Evaluative Clinical Sciences, Sunnybrook Research Institute, University of Toronto, Toronto, Ontario, Canada
[3]Department of Obstetrics and Gynecology, McMaster University, Hamilton, Ontario, Canada
[4]Department of Physical Therapy, University of Toronto, Toronto, Ontario, Canada
[5]Applied Health Research Centre, Li Ka Shing Knowledge Institute, Unity Health Toronto, Toronto, Ontario, Canada
[6]Department of Obstetrics & Gynaecology, Mount Sinai Hospital, University of Toronto, Toronto, Ontario, Canada
[7]Health Research Methods, Evidence and Impact, McMaster University, Hamilton, Ontario, Canada

Twitter Rohan D'Souza @singingOB

Acknowledgements We would like to thank Dr Rizwana Ashraf for her help with the preparation and submission of the manuscript.

Contributors SEO and RD conceived the idea. SEO drafted the protocol manuscript based on relevant publications. RD was the content expert for the systematic literature review, the Delphi survey, and the consensus meeting and JAP was the content expert for the qualitative methodology. JCK and JFRB are clinical content experts. All authors have read and edited the manuscript at least once and have approved the final version.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD
Rohan D'Souza http://orcid.org/0000-0002-4049-2017

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