CROWN
CORE OUTCOMES IN WOMEN'S HEALTH

Khalid Khan

Professor of Women's Health and Clinical Epidemiology

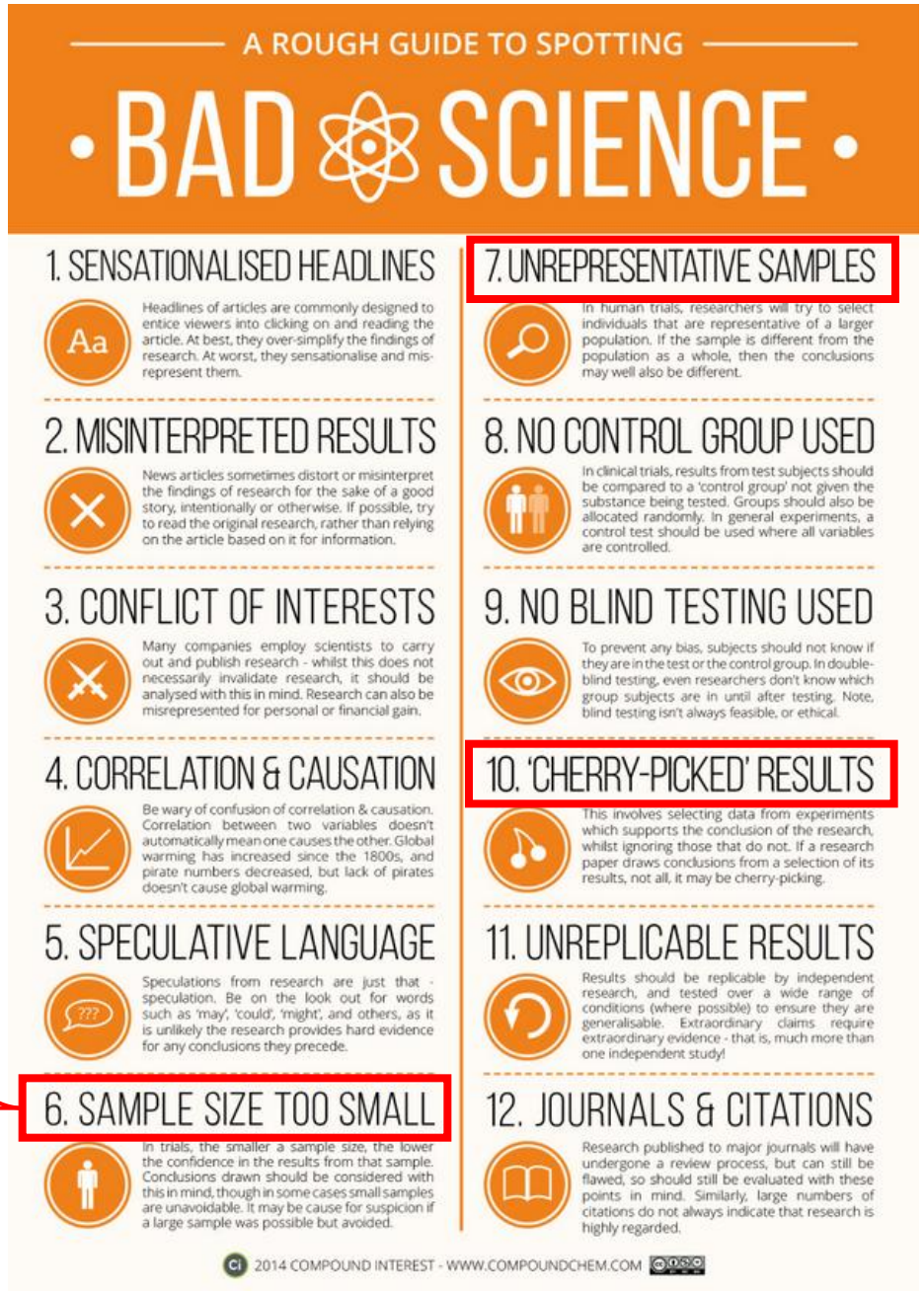
Editor in Chief, *BJOG*

@Profkkhan

figo
vancouver
Oct 2015

EXTREME RESULTS

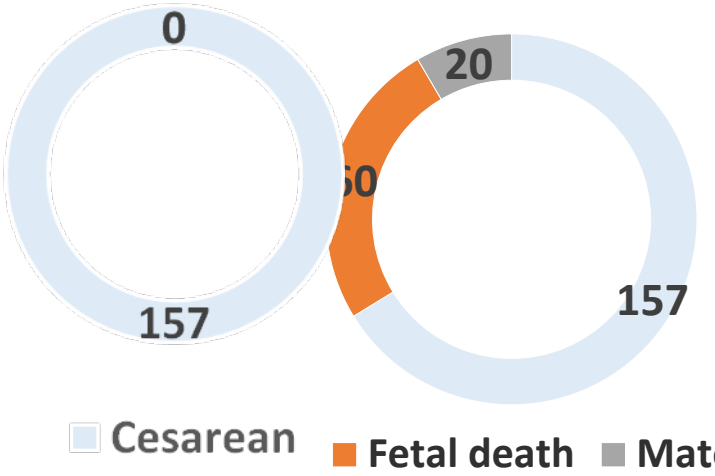
TYPE II ERROR

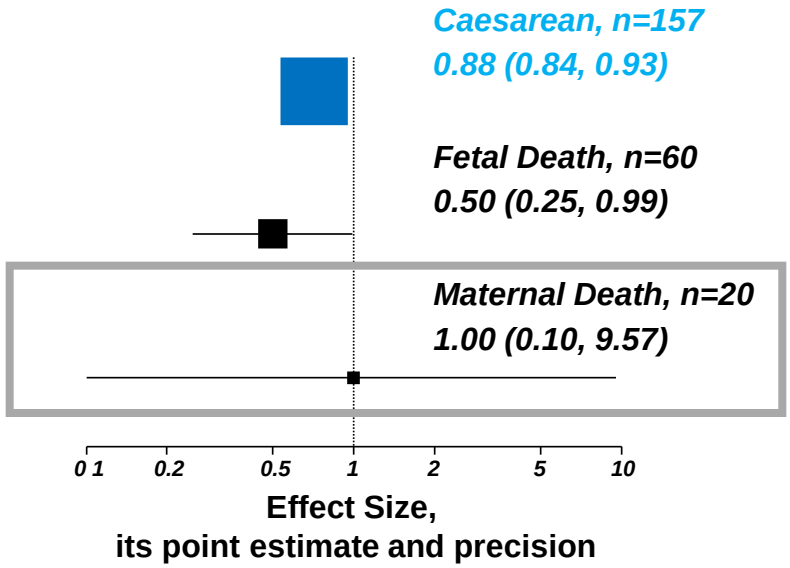


CMAJ RESEARCH

Use of labour induction and risk of cesarean delivery: a systematic review and meta-analysis

Ekaterina Mishanina MBBS, Ewelina Rogozinska MSc, Tej Thatthi, Rehan Uddin-Khan MBBS, Khalid S. Khan MBBS MSc, Catherine Meads MBChB PhD





As the outcomes reported reduce in number the results become unreliable and unusable for guidance: It is not possible to be certain about the effect on maternal mortality as it is reported in only 20 of 157 studies

DOI: 10.1111/1471-0528.12593
www.bjog.org

Systematic review

Choice of primary outcomes in randomised trials and systematic reviews evaluating interventions for preterm birth prevention: a systematic review

S Meher,[a,b] Z Alfirevic[a]

Most common primary outcomes in Cochrane Reviews and protocols	Cochrane Reviews reporting primary outcome* (*n* = 33)	Randomised trials reporting primary outcome (*n* = 103)
at follow up (variously defined)		
Preterm birth <34 weeks of gestation	8 (24%)	3 (3%)
of gestation		
NICU admission for baby	3 (9%)	0
Maternal death	3 (9%)	0
Maternal hospital stay	3 (9%)	1 (1%)

*More than one primary outcome in 27/33 reviews.

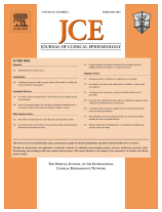
It's time to agree on standard and clinically important primary outcomes

J Scott

Core outcome sets will improve the quality of obstetrics research

P Williamson

COMET Initiative



ELSEVIER

Journal of Clinical Epidemiology 64 (2011) 293–300

Journal of Clinical Epidemiology

Systematic review highlights difficulty interpreting diverse clinical outcomes in abnormal uterine bleeding trials

David D. Rahn[a,*], Husam Abed[b], Vivian W. Sung[c], Kristen A. Matteson[c], Rebecca G. Rogers[d], Michelle Y. Morrill[e], Matthew D. Barber[f], Joseph I. Schaffer[a], Thomas L. Wheeler II[g], Ethan M. Balk[h], Katrin Uhlig[b], for the Society of Gynecologic Surgeons—Systematic Review Group

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[b]Henry Ford Health System, Detroit, MI, USA
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European Journal of Obstetrics & Gynecology and Reproductive Biology 180 (2014) 61–67

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/ejogrb

ELSEVIER

Review

Variations in the reporting of outcomes used in systematic reviews of treatment effectiveness research in bladder pain syndrome

Seema A. Tirlapur[a,*], Richeal Ni Riordain[b], Khalid S. Khan[a,c] on behalf of the EBM-CONNECT Collaboration

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Systematic review

Choice of primary outcomes in randomised trials and systematic reviews evaluating interventions for preterm birth prevention: a systematic review

S Meher,[a,b] Z Alfirevic[a]

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Correspondence: Dr S Meher, Department of Women and Children's Health, Institute of Translational Medicine, University of Liverpool, Liverpool L8 7SS, UK. Email smeher@liv.ac.uk

Accepted 12 November 2013. Published Online 27 February 2014.

Background The inappropriate and inconsistent selection of primary outcomes (POs) in randomised controlled trials (RCTs) and systematic reviews (SRs) can make evidence difficult to interpret, limiting its usefulness to inform clinical practice.

Objectives To systematically review the choice and consistency of POs in RCTs and SRs of preventative interventions for preterm birth.

Search strategy Cochrane Pregnancy and Childbirth Group's

with preterm birth before 37 weeks of gestation being the most common (18/103, 18%). Few RCTs chose perinatal morbidity (4/103) or mortality (1/103), or their composites (5/103), as POs. In 33 Cochrane Reviews, 29 different POs were reported. The three most common POs were based on death or morbidity in the baby, with death of the baby being the most common (22/33, 67%). POs were variably defined.

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Systematic Reviews ajog.org

GYNECOLOGY

Variation in outcome reporting in endometriosis trials: a systematic review

WORKING TOWARDS ENDORSEMENT FROM CROWN CORE OUTCOMES IN WOMEN'S HEALTH

Martin Hirsch, BM; James M. N. Duffy, MBChB; Jennie O. Kusznir, BMedSci; Colin J. Davis, FRCOG; Maria N. Plana, MD; Khalid S. Khan, MRCOG; on behalf of the International Collaboration to Harmonize Outcomes and Measures for Endometriosis

OBJECTIVE: We reviewed the outcomes and outcome measures reported in randomized controlled trials and their relationship with methodological quality, year of publication, commercial funding, and journal impact factor.
DATA SOURCES: We searched the following sources: (1) Cochrane Central Register of Controlled Trials, (2) Embase, and (3) MEDLINE from inception to November 2014.
STUDY ELIGIBILITY: We included all randomized controlled trials evaluating a surgical intervention with or without a medical adjuvant therapy for the treatment of endometriosis

Endometriosis affects 1 in 10 women and impairs health related quality of life in the domains of fertility, pain, psychological, and social functioning. Endometriosis is poorly understood and is currently managed with holistic, medical, and surgical interventions. There is no consensus among patients,

European Journal of Obstetrics & Gynecology and Reproductive Biology 195 (2015) 193–199

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journal homepage: www.elsevier.com/locate/ejogrb

ELSEVIER

Review

Variation in the reporting of outcomes among pregnant women with epilepsy: a systematic review

Bassel H. Al Wattar[a], Anna Placzek[a], Joy Troko[b], Alexander M. Pirie[b,c], Khalid S. Khan[a,d,*], Dougall McCorry[c], Javier Zamora[a], Shakila Thangaratinam[a,d] for the EMPIRE Collaborative Network

[a]Women's Health Research Unit, Barts and the London School of Medicine, Queen Mary University London, London, UK
[b]Birmingham Women's Hospital, Mindelsohn Way, Birmingham, UK
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ABSTRACT

Studies on pregnant women with epilepsy should evaluate both neurological and pregnancy outcomes. We undertook a systematic review of the literature of studies on pregnant women with epilepsy to collate the outcomes reported, and the quality of outcomes report in these studies.

We searched major electronic databases (from 1999 until January 2015). Two independent reviewers selected studies and extracted data on study design, the risk of bias of the studies, journal impact factor and the quality of reported outcomes. We assessed the quality outcomes report using a six items standardised tool (score range 0–6).

There were 70 different outcomes reported in 232 studies (maternal neurological (13/70, 19%), fetal and neonatal (28/70, 40%), and obstetric outcomes (29/70, 41%)). Most studies reported on major congenital fetal abnormalities (103/232, 44%), followed by live birth (60/232, 26%). Quality of the reported outcomes was poor (mean 1.54, SD 1.36). It was associated with journal impact factor ($p = 0.007$), but not with study design ($p = 0.60$), or risk of bias ($p = 0.17$).

The outcomes reported in studies on pregnant women with epilepsy varied widely, and the quality of the outcomes report was poor. There is a need to identify a set of core outcome to harmonise reporting in future clinical studies.

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1 Inconsistent reporting of outcomes across studies

Pharmacologic Intervention for Retained Placenta

A Systematic Review and Meta-analysis

James M.N. Duffy, MBChB, MRes, Sophie Mylan, MBChB, MSc, Marian Showell, MILS, MPH, Matthew J.A. Wilson, FRCA, MD, and Khalid S. Khan, MBBS, FRCOG

There was limited reporting of secondary outcomes…

2 Variation in outcomes and outcome measures

Laparoscopic surgery for endometriosis

James MN Duffy[1], Kirana Arambage[2], Frederico JS Correa[3], David Olive[4], Cindy Farquhar[5], Ray Garry[6], David H Barlow[7], Tal Z Jacobson[8]

Pain was measured using seven different outcome measures which limited our ability to combine data from different trial studies together.

3 Limited reporting of clinically relevant outcomes

Growth hormone for in vitro fertilization

James MN Duffy[1], Gaity Ahmad[2], Lamiya Mohiyiddeen[3], Luciano G Nardo[4], Andrew Watson[5]

We were unable to draw any conclusions regarding live birth rate.

4 Limited reporting of patient preferred outcomes

Postoperative procedures for improving fertility following pelvic reproductive surgery

James M N Duffy[1], Neil Johnson[2], Gaity Ahmad[3], Andrew Watson[4]

No trials reported adverse events.

TABLE 2

Outcome reporting in endometriosis trials: outcome and outcome measures reported

Domain	RCTs	Outcomes	Outcome measure
Pain	37	32	24
Subfertility	32	28	11
Quality of life	9	10	10
Surgical adverse events	14	34	5
Medical adverse events	8	22	0

RCT, randomized controlled trial.

Hirsch. Outcome reporting in endometriosis trials. Am J Obstet Gynecol 2016.

GYNECOLOGY

Variation in outcome reporting in endometriosis trials: a systematic review

Martin Hirsch, BM; James M. N. Duffy, MBChB; Jennie O. Kusznir, BMedSci; Colin J. Davis, FRCOG; Maria N. Plana, MD; Khalid S. Khan, MRCOG; on behalf of the International Collaboration to Harmonize Outcomes and Measures for Endometriosis

WORKING TOWARDS ENDORSEMENT FROM CROWN CORE OUTCOMES IN WOMEN'S HEALTH

TABLE 3

Outcome reporting in endometriosis trials: reported pain and fertility outcomes *(continued)*

Outcome domain	Outcome	Trials, n
Pain outcomes	Dysmenorrhea	23
	Dyspareunia	21
	Pelvic pain	15
	Nonmenstrual pelvic pain	6
	Dyschezia	6
	Overall pain	5
	Postoperative pain	3
	Abdominal pain	2
	Back pain	2
	Aggregate pain	1
	Analgesia use	3
	Analgesic requirement	2
	Chest discomfort	1
	General discomfort	1
	General pain	1
	Global intensity of pain	1
	Lateral menstrual pain	1
	Painless first stage of labor	1
	Postoperative opioid analgesia	1
	Rectal pain	1
	Shoulder pain	1
	Thigh pain	1
	Voiding pain	1

Hirsch. Outcome reporting in endometriosis trials. Am J Obstet Gynecol 2016.

Study \ Outcome	Study size (n)	Pain									Fertility									
		Triad			Other						Pregnancy outcome							ART**		
		Dyschezia	Dysmenorrhoea	Dyspareunia	Overall pain	Abdominal pain	Shoulder pain	Pelvic pain*	Thigh pain	Postoperative pain	Pregnancy	Ectopic preganancy	Miscarriage	Twin pregnancy	Term delivery	Live birth	Still birth	Gonadotrophin use	Number of follicles	Embryos per cycle
Alkatout 2013	450		X	X		X					X	X	X		X					
Marcoux 1997	348										X	X								
Zhao 2013	320										X									
Vercellini 1999	269				X											X				
Vercellini 2003A	180		X	X				X			X									
Healey 2010	178	X	X	X	X	X		X	X											
Zhao 2013B	176																			
Matorras 2002	172																			
Zhu 2014	156		X	X	X					X		X	X				X			
Moini 2012	146										X									
Alborzi 2010	144		X	X				X			X									
Cosson 2002	142				X						X									
Zullo 2003	141		X	X				X												
Abu Hashim 2012	136										X		X	X		X		X	X	
Nowroozi 1987	123						X				X									
Creus 2008	104										X		X							
Parazzini 1999	101										X		X		X					
Alborzi 2004	100				X						X									
Vercellini 2002	90		X	X				X												
Seiler 1986	90										X									
Busacca 2001	89		X	X				X			X									
Alborzi 2007	88										X								X	
Soysal 2004	80																			
Bianchi 1999	77		X					X			X									
Parazzini 1994	75							X			X									
Other studies (29)	1452	5	14	14	0	0	0	13	0	2	9	1	2	0	0	3	0	0	1	1

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TABLE 4

Outcome reporting in endometriosis trials: outcome measures for commonly reported outcomes

Outcome	Outcome measure	n
Dysmenorrhea	Visual analog scale (0–10)	8
	Visual analog scale (0–100)	7
	Visual analog scale (0–10 with description)	3
	Visual analog scale (no description)	1
	Ranked ordinal scale (1–5)	1
	Likert scale (0–10)	3
	Questionnaire (with description)	2
	Questionnaire (ranked symptoms)	1
	Questionnaire (no description)	1
	Number of episodes	1
	Not specified	2
Pregnancy	Serum βHCG	4
	Ultrasound (visualizing fetal heart)	4
	Ultrasound (growth scan)	2
	Not specified	20

Research: increasing value, reducing waste 5

Reducing waste from incomplete or unusable reports of biomedical research

Paul Glasziou, Douglas G Altman, Patrick Bossuyt, Isabelle Boutron, Mike Clarke, Steven Julious, Susan Michie, David Moher, Elizabeth Wager

Research publication can both communicate and miscommunicate. Unless research is adequately reported, the time and resources invested in the conduct of research is wasted. Reporting guidelines such as CONSORT, STARD, PRISMA, and ARRIVE aim to improve the quality of research reports, but all are much less adopted and adhered to than they should be. Adequate reports of research should clearly describe which questions were addressed and why, what was done, what was shown, and what the findings mean. However, substantial failures occur in each of these elements. For example, studies of published trial reports showed that the poor description of interventions meant that 40–89% were non-replicable; comparisons of protocols with publications showed that most studies had at least one primary outcome changed, introduced, or omitted; and investigators of new trials rarely set their findings in the context of a systematic review, and cited a very small and biased selection of previous relevant trials. Although best documented in reports of controlled trials, inadequate reporting occurs in all types of studies—animal and other preclinical studies, diagnostic studies, epidemiological studies, clinical prediction research, surveys, and qualitative studies. In this report, and in the Series more generally, we point to a waste at all stages in medical research. Although a more nuanced understanding of the complex systems involved in the conduct, writing, and publication of research

Lancet 2014; 383: 267–76

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http://dx.doi.org/10.1016/S0140-6736(13)62228-X

See Perspectives page 209

This is the fifth in a Series of five papers about research

Centre for Research in Evidence Based Practice, Bond University, Robina, QLD, Australia (Prof P Glasziou FRACGP); Centre for Statistics in Medicine, University of Oxford, Oxford,

What is the problem?

The CONSORT Statement

The main product of CONSORT is the CONSORT Statement, which is an evidence-based, minimum set of recommendations for reporting randomized trials. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.

Table 2 | Items to include when reporting a randomised trial in a journal abstract

Item	Description
Authors	Contact details for the corresponding author
Trial design	Description of the trial design (such as parallel, cluster, non-inferiority)
Methods:	
Participants	Eligibility criteria for participants and the settings where the data were collected
Interventions	Interventions intended for each group
Objective	Specific objective or hypothesis
Outcome	Clearly defined primary outcome for this report
Randomisation	How participants were allocated to interventions
Blinding (masking)	Whether participants, care givers, and those assessing the outcomes were blinded to group assignment
Results:	
Numbers randomised	Number of participants randomised to each group
Recruitment	Trial status
Numbers analysed	Number of participants analysed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision
Harms	Important adverse events or side effects
Conclusions	General interpretation of the results
Trial registration	Registration number and name of trial register
Funding	Source of funding

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CORE OUTCOMES IN WOMEN'S AND NEWBORN HEALTH

Trials

BioMed Central

Commentary

Open Access

Standardising outcomes for clinical trials and systematic reviews

Mike Clarke

The impact of outcome reporting bias in randomised controlled trials on a cohort of systematic reviews

Jamie J Kirkham,[1] Kerry M Dwan,[1] Douglas G Altman,[2] Carrol Gamble,[1] Susanna Dodd,[1] Rebecca Smyth,[3] Paula R Williamson[1]

Research: increasing value, reducing waste 5

Reducing waste from incomplete or unusable reports of biomedical research

Paul Glasziou, Douglas G Altman, Patrick Bossuyt, Isabelle Boutron, Mike Clarke, Steven Julious, Susan Michie, David Moher, Elizabeth Wager

ANALYSIS

What is missing from descriptions of treatment in trials and reviews?

Replicating non-pharmacological treatments in practice depends on how well they have been describ

Clarke and Williamson *Systematic Reviews* (2016) 5:11
DOI 10.1186/s13643-016-0188-6

Systematic Reviews

COMMENTARY

Open Access

Core outcome sets and systematic reviews

Mike Clarke[1*] and Paula R. Williamson[2]

Abstract

Systematic reviews seek to bring together research evidence to answer the question for the review. The reviewers usually wish to compare, contrast and, if appropriate, combine the findings of the existing research studies. However, these intentions are often thwarted by inconsistencies in the outcomes that were measured and reported in the individual studies. This, in turn, makes it difficult for readers of the review to use it to make informed decisions and choices about health and social care. One solution is for trials in a particular topic area to measure and report a standardised set of outcomes, which would then be used in the review. Core outcome sets are a means of doing this,

Core Outcomes for Clinical Trials: Moving Ahead

Timothy Rowe, MB BS, FRCSC
Editor-in-Chief

At the recent World Congress of the Royal College of Obstetricians and Gynaecologists in Liverpool, I met Professor Khalid Khan, the Editor-in-Chief of the British Journal of Obstetrics and Gynaecology. We had an amicable discussion about the present and fut of publishing in our specialty (he's a big fa by the way), but one subject of discussion re continues to do so. It was the subject of clini for studies submitted to journals of obstetrics, and reproductive medicine, and how the h of the outcomes of RCTs makes comparis and combination of results across studies sometimes impossible.

BJOG An International Journal of Obstetrics and Gynaecology

Explore this journal >

Editorial

The CROWN Initiative: journal editors invite researchers to develop core outcomes in women's health

Khalid Khan

First published: 3 June 2014 Full publication history
DOI: 10.1111/1471-0528.12929 View/save citation
Cited by: 5 articles Citation tools
22

On behalf of Chief Editors of Journals participating in The CROWN Initiative (Appendix 1).
For further information please visit the CROWN Initiative webpage under Special Features.

View issue TOC
Volume 121, Issue 10
September 2014
Pages 1181–1182

CROWN
CORE OUTCOMES IN WOMEN'S AND NEWBORN HEALTH

Aims of the Core Outcomes in Women's and Newborn Health (CROWN) Initiative

1. Form a consortium among all women's and newborn health journals to promote core outcome sets in all areas of our specialty.

2. Encourage researchers to develop core outcome sets using robust consensus methodology involving multiple stakeholders, including patients.

3. Strongly encourage the reporting of results for core outcome sets.

4. Organise robust peer-review and effective dissemination of manuscripts describing core outcome sets.

5. Facilitate embedding of core outcome sets in research practice, working closely with researchers, reviewers, funders, and guideline makers.

Core Outcome Set

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CORE OUTCOMES IN
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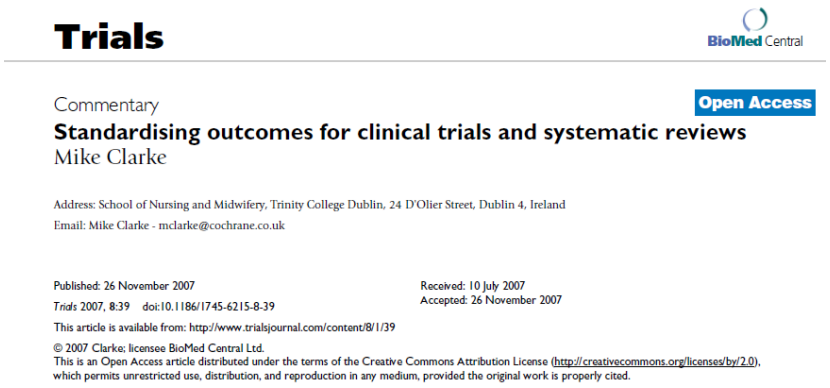
- an agreed standardized collection of outcomes which should be measured and reported in all trials for a specific clinical area developed through a systematic and transparent process



Trials

BioMed Central

Commentary

Open Access

Standardising outcomes for clinical trials and systematic reviews

Mike Clarke

Address: School of Nursing and Midwifery, Trinity College Dublin, 24 D'Olier Street, Dublin 4, Ireland
Email: Mike Clarke - mclarke@cochrane.co.uk

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Received: 10 July 2007
Accepted: 26 November 2007
This article is available from: http://www.trialsjournal.com/content/8/1/39

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Core **O**utcomes for studies on primary **P**revention **O**f **P**reterm birth

COPOP project

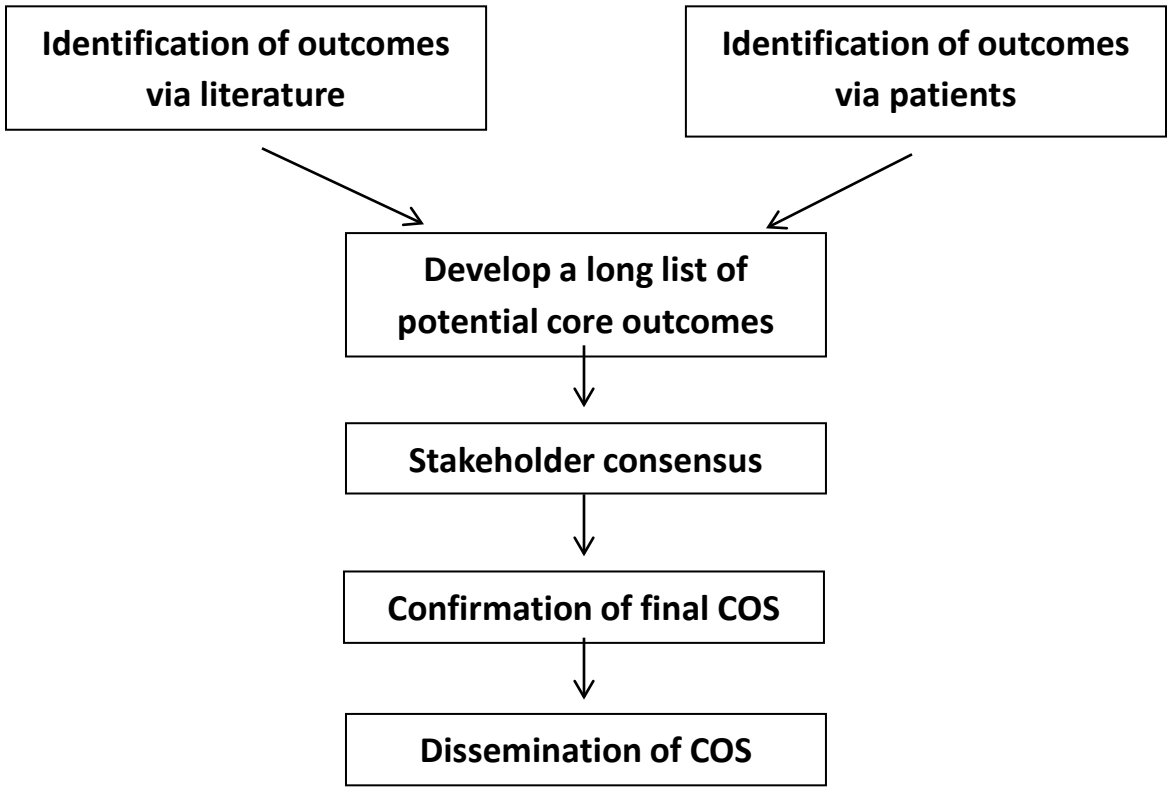
Janneke van 't Hooft

MD, PhD student Academical Medical Center, The Netherlands

Need for comparable outcomes in preterm birth studies: **core outcome set**

Aim: To identify a set of critical and important outcomes for the evaluation of preventive interventions for preterm birth in asymptomatic pregnant women.

CROWN CORE OUTCOMES IN WOMEN'S HEALTH


Identification of outcomes via literature
Identification of outcomes via patients
Develop a long list of potential core outcomes
Stakeholder consensus
Confirmation of final COS
Dissemination of COS

Development of Core Outcome Set

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CORE OUTCOMES IN WOMEN'S AND NEWBORN HEALTH

Stage 1 Identifying Potential Outcomes

Systematic Review	What outcomes have been reported before?
Qualitative Patient Interviews	What outcomes do patients want?

↓

Stage 2 Determining Core Outcomes

Delphi Method	Combining professional & patients' views

↓

Stage 3 Determining How Core Outcomes Should be Measured

Quality Assessment	Ensuring outcome measures fit for purpose
Stakeholder Consultation	Final consensus

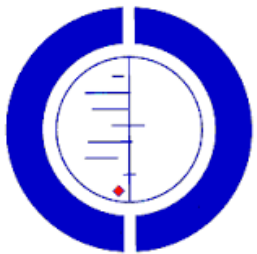
↓

Core Outcome Set

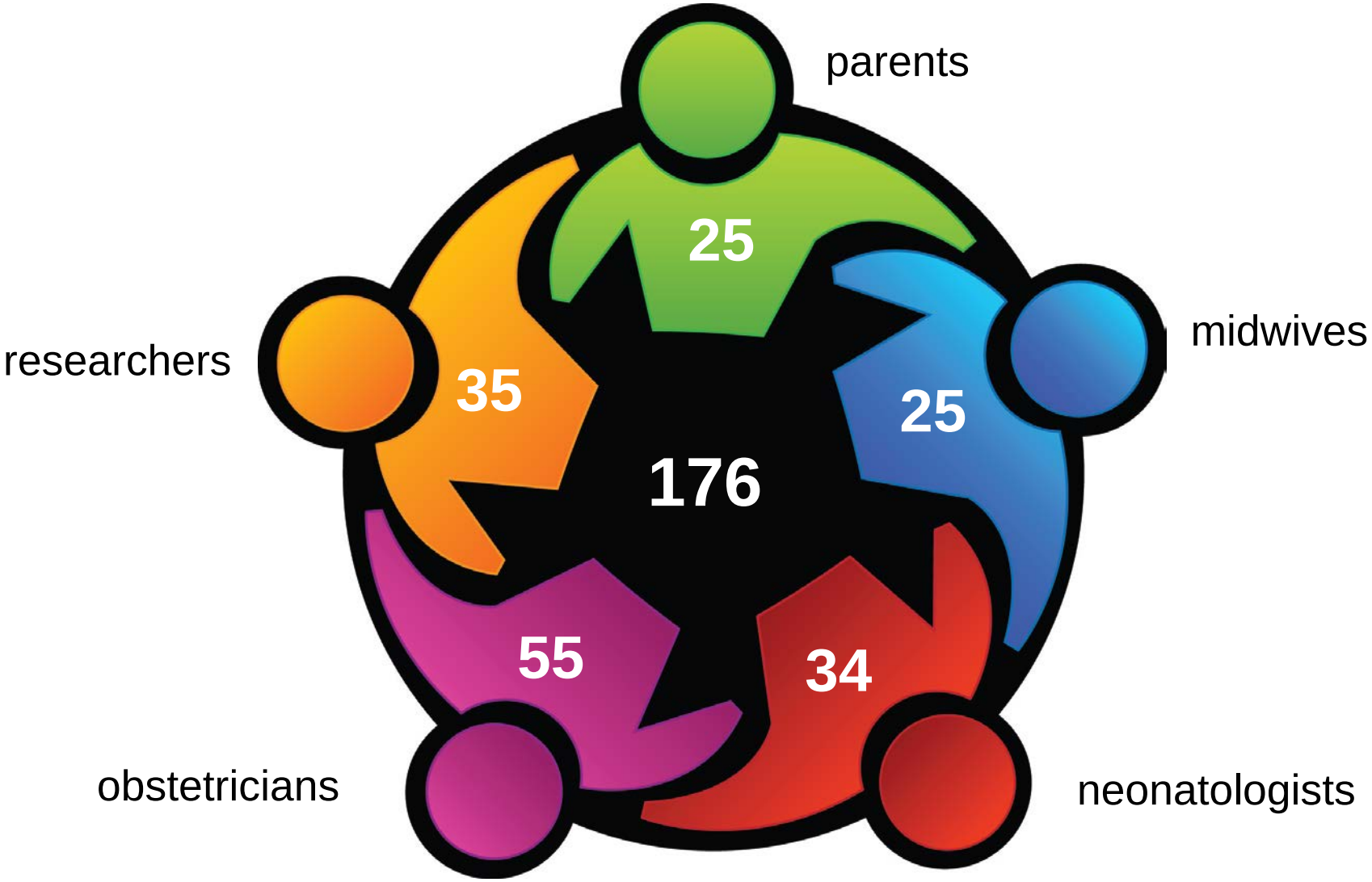
diagram courtesy of Dr James MN Duffy, modified

Collaboration

- Global Obstetrics Network (GONet)
  - Ongoing pessary trials
- Journal Editors (CROWN)
- Core Outcome Measures in Effectiveness Trials (COMET)
- Cochrane Collaboration on preterm birth
- World Health Organization (WHO)
- Patient Organizations
- Midwifery Organizations



Stakeholders



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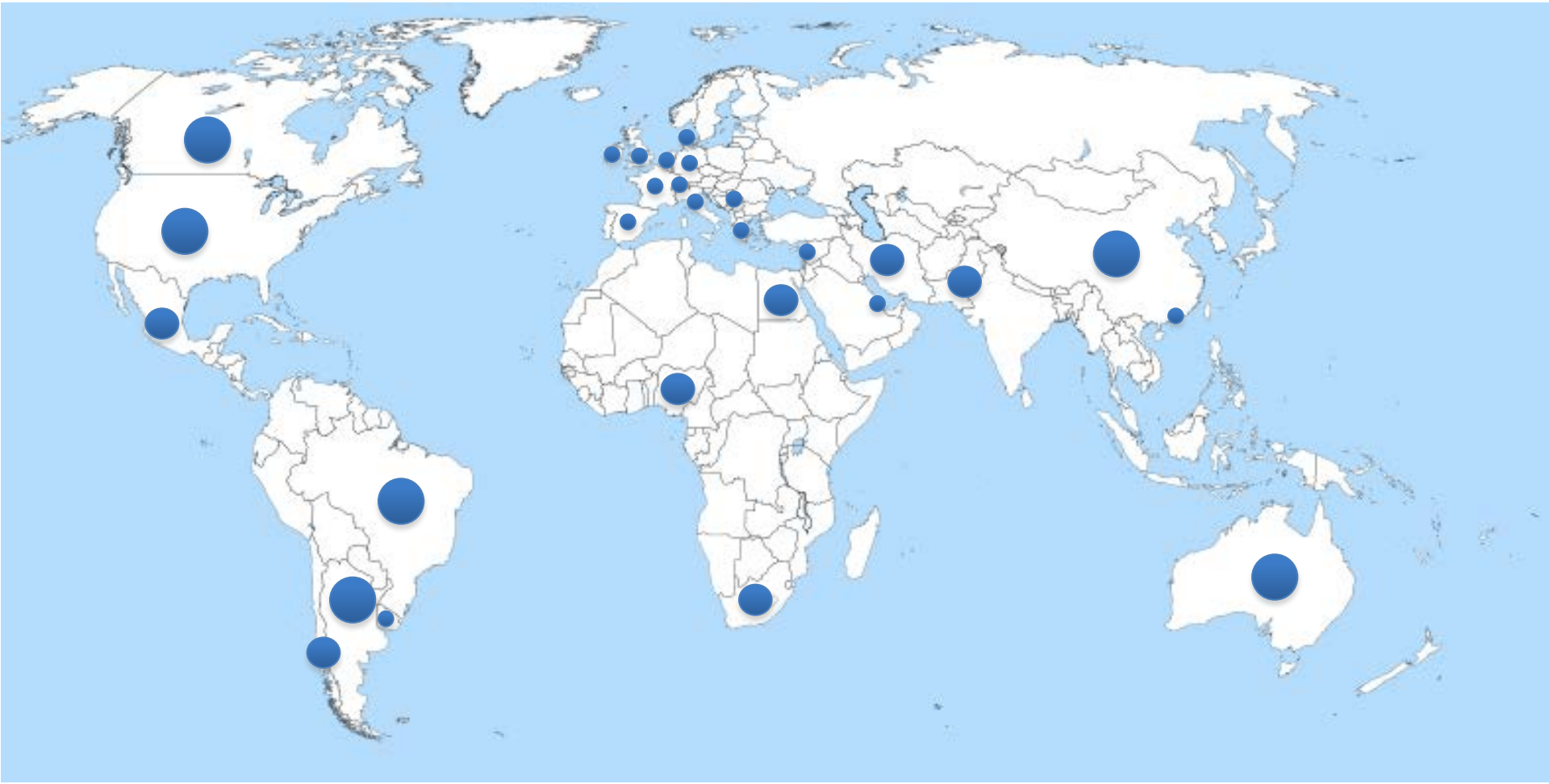

- 10 middle-income 17 high-income countries
- Healthcare providers: 60% clinical related work, 61% role in development (inter)national guidelines
- Parents: experienced preterm birth once 69%, twice 25%

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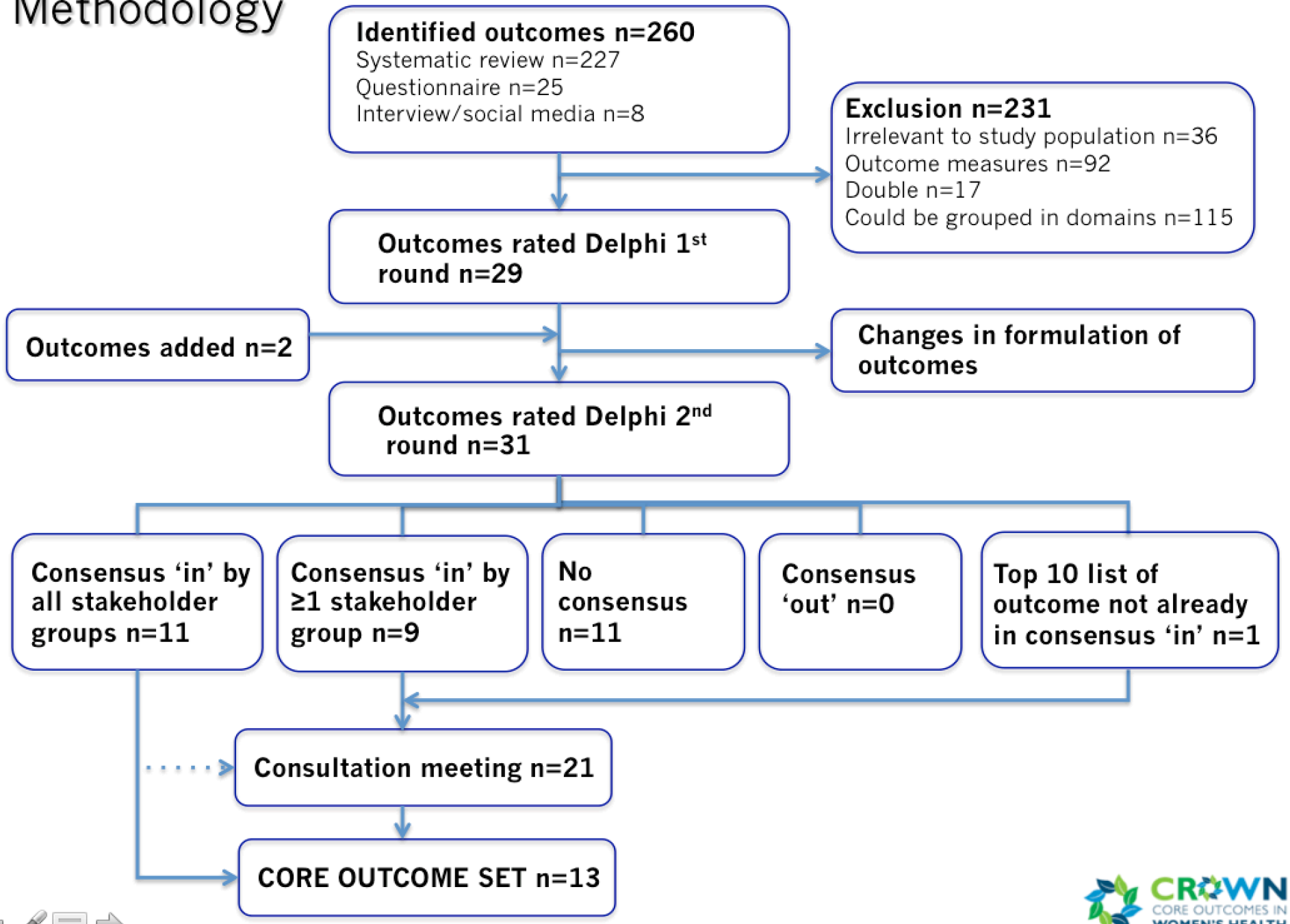
Methodology



CROWN CORE OUTCOMES IN WOMEN'S HEALTH

Core outcome set

Maternal set of outcomes	Baby set of outcomes
Maternal mortality	Offspring mortality
Maternal infection or inflammation	Offspring infection
Prelabor rupture of membranes	Gestational age at birth
Harm to mother from intervention	Harm to offspring from intervention
	Birth weight
	Early neurodevelopmental morbidity
	Late neurodevelopmental morbidity
	Gastro-intestinal morbidity
	Respiratory morbidity

CROWN
CORE OUTCOMES IN WOMEN'S HEALTH

Original Research

A Core Outcome Set for Evaluation of Interventions to Prevent Preterm Birth

Janneke van 't Hooft, MD, James M. N. Duffy, MD, Mandy Daly, MSc, Paula R. Williamson, PhD, Shireen Meher, MD, Elizabeth Thom, PhD, George R. Saade, MD, PhD, Zarko Alfirevic, MD, PhD, Ben Willem J. Mol, MD, PhD, and Khalid S. Khan, MD, PhD, on behalf of the Global Obstetrics Network (GONet)

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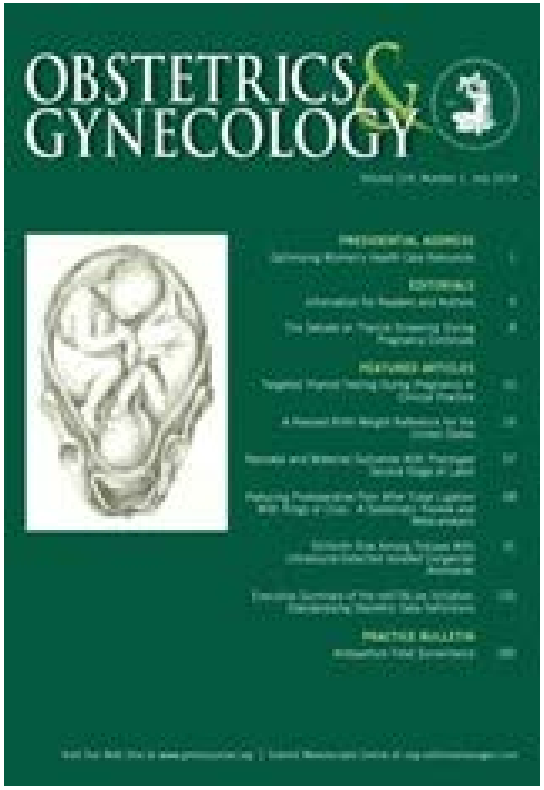

Box 1. Final Core Outcome Set of 13 Outcomes Presented as a Maternal and Neonate Set

MATERNAL SET OF OUTCOMES

1. Maternal mortality
2. Maternal infection or inflammation
3. Prelabor rupture of membranes
4. Harm to mother from intervention

NEONATAL SET OF OUTCOMES

1. Offspring mortality
2. Offspring infection
3. Gestational age at birth
4. Harm to offspring from intervention
5. Birth weight
6. Early neurodevelopmental morbidity
7. Late neurodevelopmental morbidity
8. Gastrointestinal morbidity
9. Respiratory morbidity

Steering group

Our aim is to develop a core set of outcomes that would be common to all future pre-eclampsia research.

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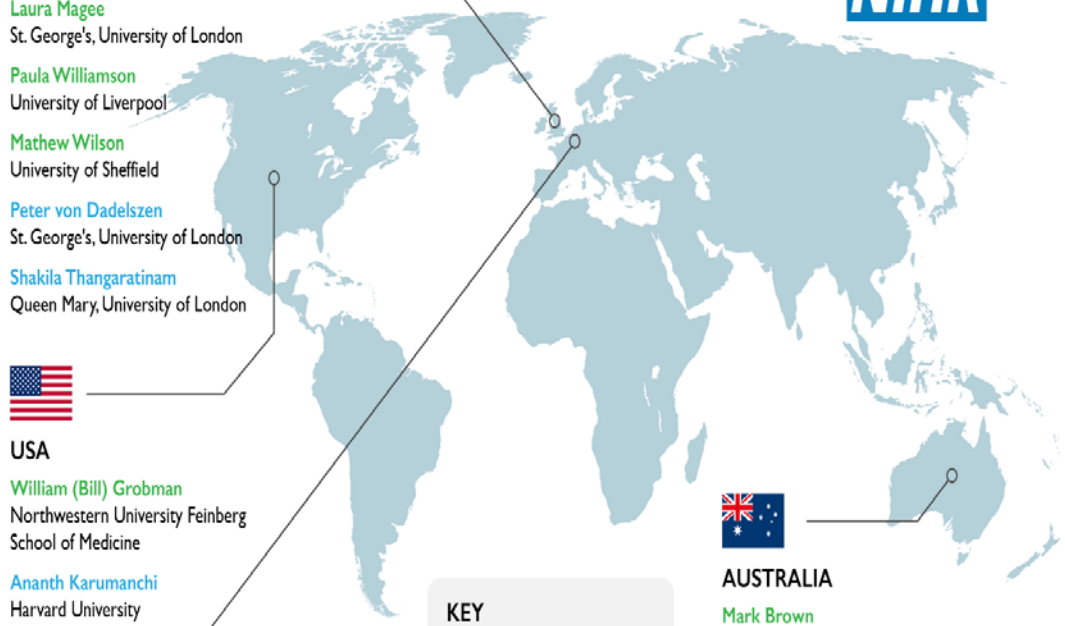
International Collaboration to Harmonise Outcomes for Pre-Eclampsia

Funded & supported by

NIHR



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Janneke van't Hooft
Academical Medical Centre

KEY

- Study management team
- Patient & public advisors
- Scientific advisors
- Implementation advisors

AUSTRALIA

Mark Brown
St George & Sutherland Hospital

Michael Stark
University of Adelaide

Ben Mol
University of Adelaide

phc.ox.ac.uk/ihope | @jamesmnduffy

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Scope: Population

Pre-eclampsia

Early onset

Late onset

Pre-eclampsia with severe features

Post-natal pre-eclampsia

etc.

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Scope: Interventions

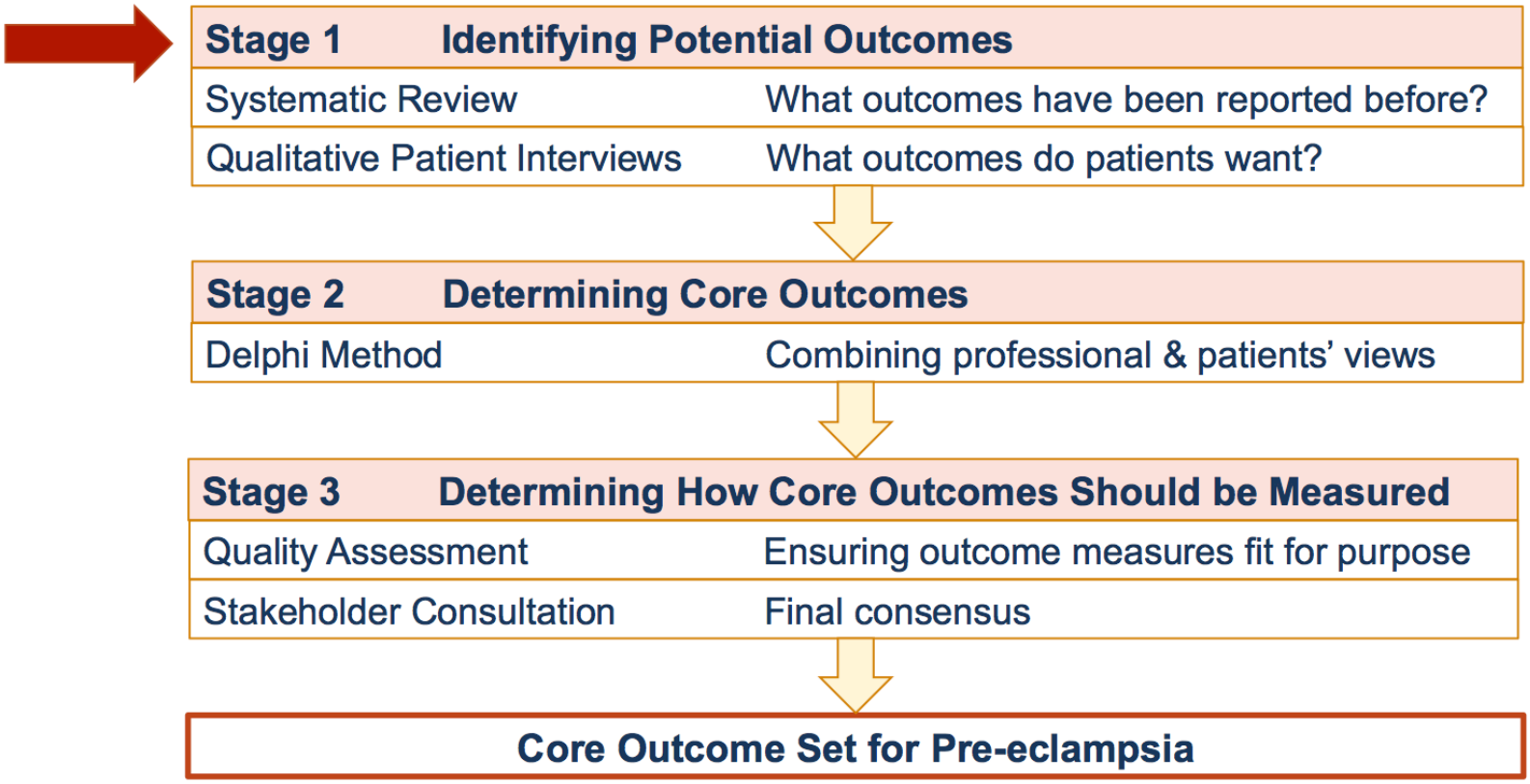
Anti-convulsants

Anti-hypertensives

Anti-oxidants

Immediate delivery

etc.


UNIVERSITY OF OXFORD
iHOPE
International Collaboration to Harmonise Outcomes for Pre-Eclampsia
Stage 1 Identifying Potential Outcomes
Systematic Review
What outcomes have been reported before?
Qualitative Patient Interviews
What outcomes do patients want?
Stage 2 Determining Core Outcomes
Delphi Method
Combining professional & patients' views
Stage 3 Determining How Core Outcomes Should be Measured
Quality Assessment
Ensuring outcome measures fit for purpose
Stakeholder Consultation
Final consensus
Core Outcome Set for Pre-eclampsia

Stage 1	**Identifying Potential Outcomes**
Systematic Review	What outcomes have been reported before?
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Core Outcome Set for Pre-eclampsia

Taking part in an interview

HYPERTENSION IN PREGNANCY

Systematic Review

Statistical Analysis

BuMP Pilot Study

iHOPE Study

iHOPE Steering Group

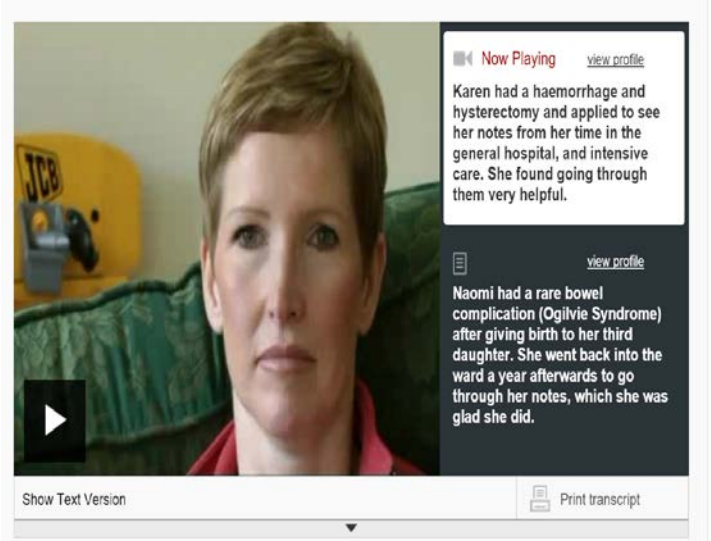
healthtalk.org/preeclampsia

Taking part in an interview

Patient reply form

Consent form

546 expressions of interest



Bronchopulmonary dysfunction

024 *She had chronic lung disease, [um] and once a month I had to go to the hospital with her overnight and they would monitor her to try and reduce the level of oxygen to wean her off it, and it was the most horrific thing in the world.*

Duration of inpatient stay

003 *She was in SCBU for eighteen days.*

001 *XXX was in a hospital for three months. Three months I walked away, every night, without my baby.*

Gestation age at delivery

003 *My aim always was to keep my baby as close to term as I could.*

012 *I didn't want her coming out early; we had to hang on as long as possible.*

018 *I was admitted in hospital for two weeks, then had the baby at thirty four weeks.*

Maternal outcomes 29 outcomes

1 Maternal mortality

3 Coagulation / haematological dysfunction
- Haemolysis, elevated liver enzyme levels, and low platelet levels (HELLP) syndrome
- Venous thromboembolism

5 Neurological dysfunction
- Cerebral haemorrhage
- Coma
- Eclampsia

6 Renal dysfunction
- Renal failure

7 Respiratory dysfunction
- Pulmonary oedema

8 Uterine dysfunction
- Antepartum haemorrhage
- Placental abruption
- Preterm birth

9 Other
- Infection
- Sepsis

10 Interventions managing morbidity
- Anticonvulsant medication
- Antihypertensive medication
- Blood product transfusion
- Other pharmacologic interventio

11 Labour and delivery characteristi
- Onset of labour
- Duration of labour
- Augmented labour
- Anaesthesia for delivery
- Mode of delivery

12 Patient reported outcomes
- Anxiety
- Depression
- Functional status pain

13 Resource utilisation
- Admission to high dependency u
- Admission to intensive care unit
- Length of stay

14 Harm
- Side effect

Examples of outcomes previously unreported in randomised trials

Maternal outcomes

10 Interventions managing morbidity
- Intravenous access
- Invasive blood pressure monitoring

11 Labour and delivery characteristics
- Anaesthesia for labour

12 Patient reported outcomes
- Confidence in role as a mother
- Bonding
- Fatigue
- Return to work

Offspring outcomes

24 Interventions managing morbidity
Confidence with breastfeeding
Any resuscitative intervention
Antibiotics
Intravenous access

26 Resource utilisation
- Admission to transitional care
- Transfer to territory neonatal unit

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International Collaboration to
Harmonise Outcomes for Pre-Eclampsia

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Core Outcome Set for Pre-eclampsia


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UNIVERSITY OF OXFORD
Researcher
Pre-eclampsia is responsible for 75,000 maternal deaths each year.
Please share your expertise so we can do better research.
Volunteer to complete an online survey: www.phc.ox.ac.uk/ihope
@jamesmnduffy


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International Collaboration to Harmonise Outcomes for Pre-Eclampsia
UNIVERSITY OF OXFORD
Midwife
Pre-eclampsia is responsible for 250,000 infant deaths each year.
Please share your expertise so we can do better research.
Volunteer to complete an online survey: www.phc.ox.ac.uk/ihope
@jamesmnduffy

Survey 1 Scoring Potential Outcomes

What outcomes have been reported before?

What outcomes do patients want?

Participants suggest additional outcomes

Survey 2 Reflecting upon participant views

Reflect and rescore outcomes

Survey 3 Finalising agreement

Reflect and rescore outcomes

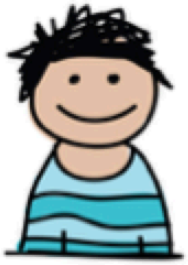
Gwyn
Anaesthetist

Riannon
Patient

Cerys
Neonatologist

Rhodri
Obstetrician

Megan
MFM specialist



Dylan
Researcher

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Core Outcome Set for Pre-eclampsia

Seeking funding	PCOS
	Subfertility
Funded	Heavy menstrual bleeding
	Stillbirth
	Abortion
1 Identifying potential outcomes	Gestational diabetes
	Cervical cancer
	Miscarriage
	Induction of labour
2 Identifying core outcomes	IUGR
	Post-partum haemorrhage
	Endometriosis
	Pre-eclampsia

2016

The Academy of Medical Sciences

NHS National Institute for Health Research

World Health Organization

b+tlc BARTS CHARITY

BMA

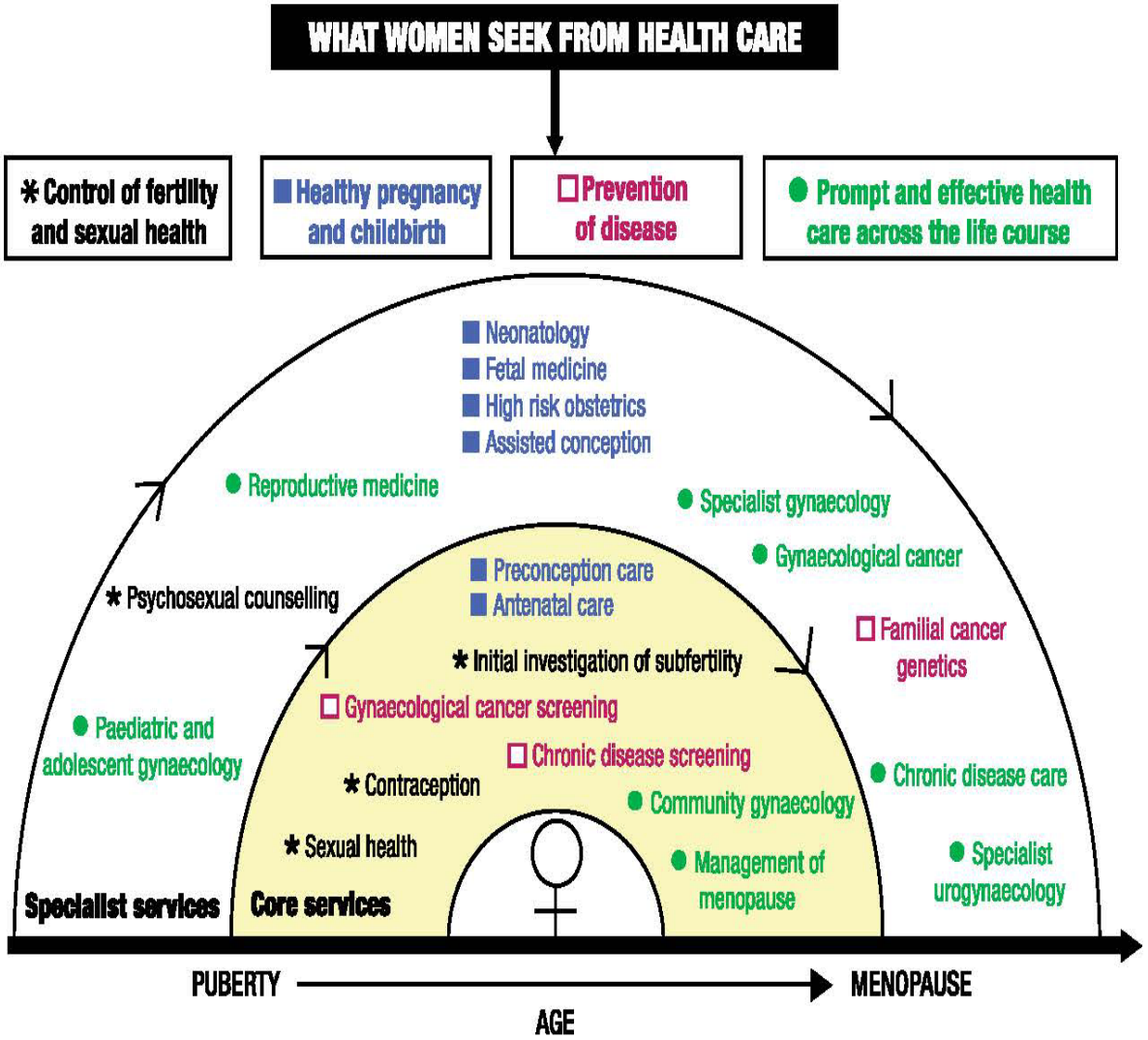
Stillbirth Foundation AUSTRALIA

Research and education to prevent stillbirth

CROWN
CORE OUTCOMES IN
WOMEN'S HEALTH

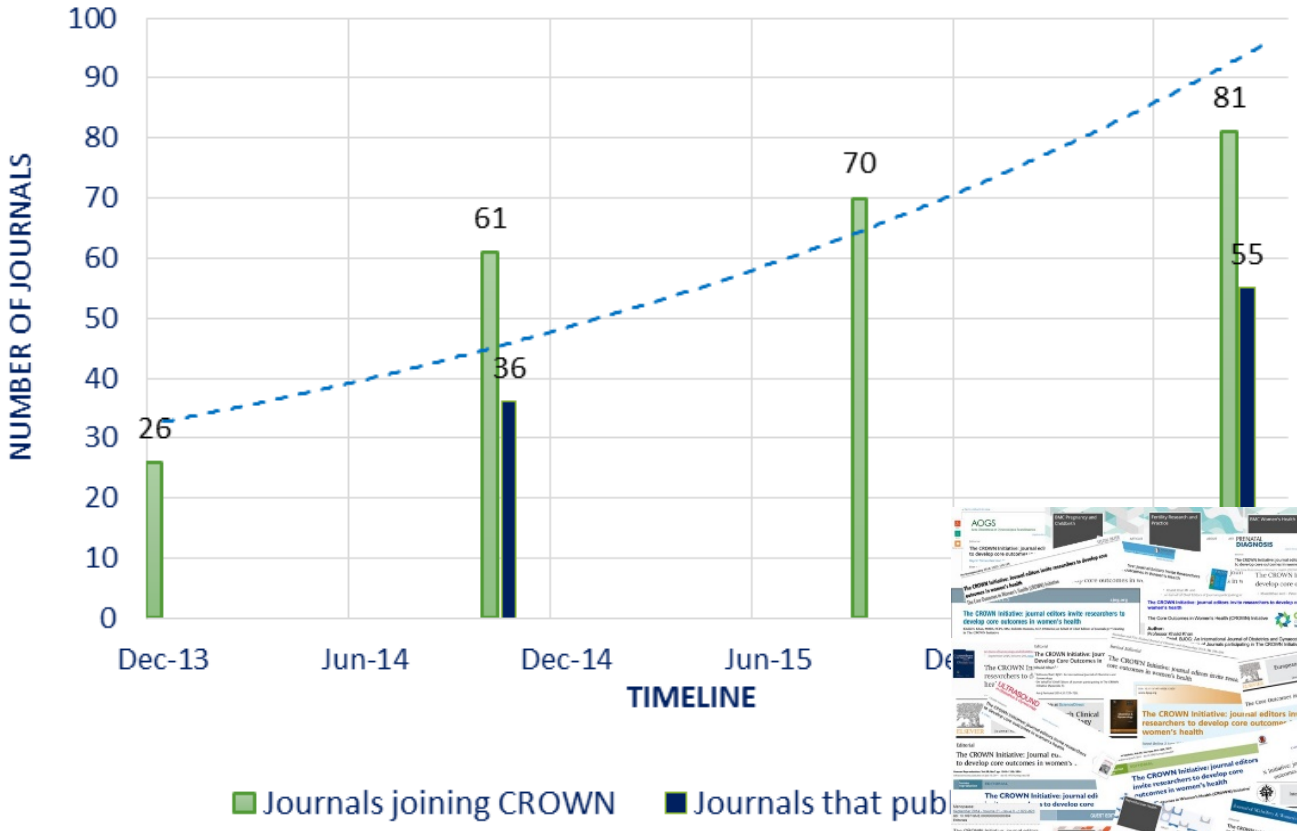
2030 vision

A core outcome set developed, disseminated, and implemented for every condition in Women's Health



Royal College of Obstetricians & Gynaecologists

The CROWN initiative



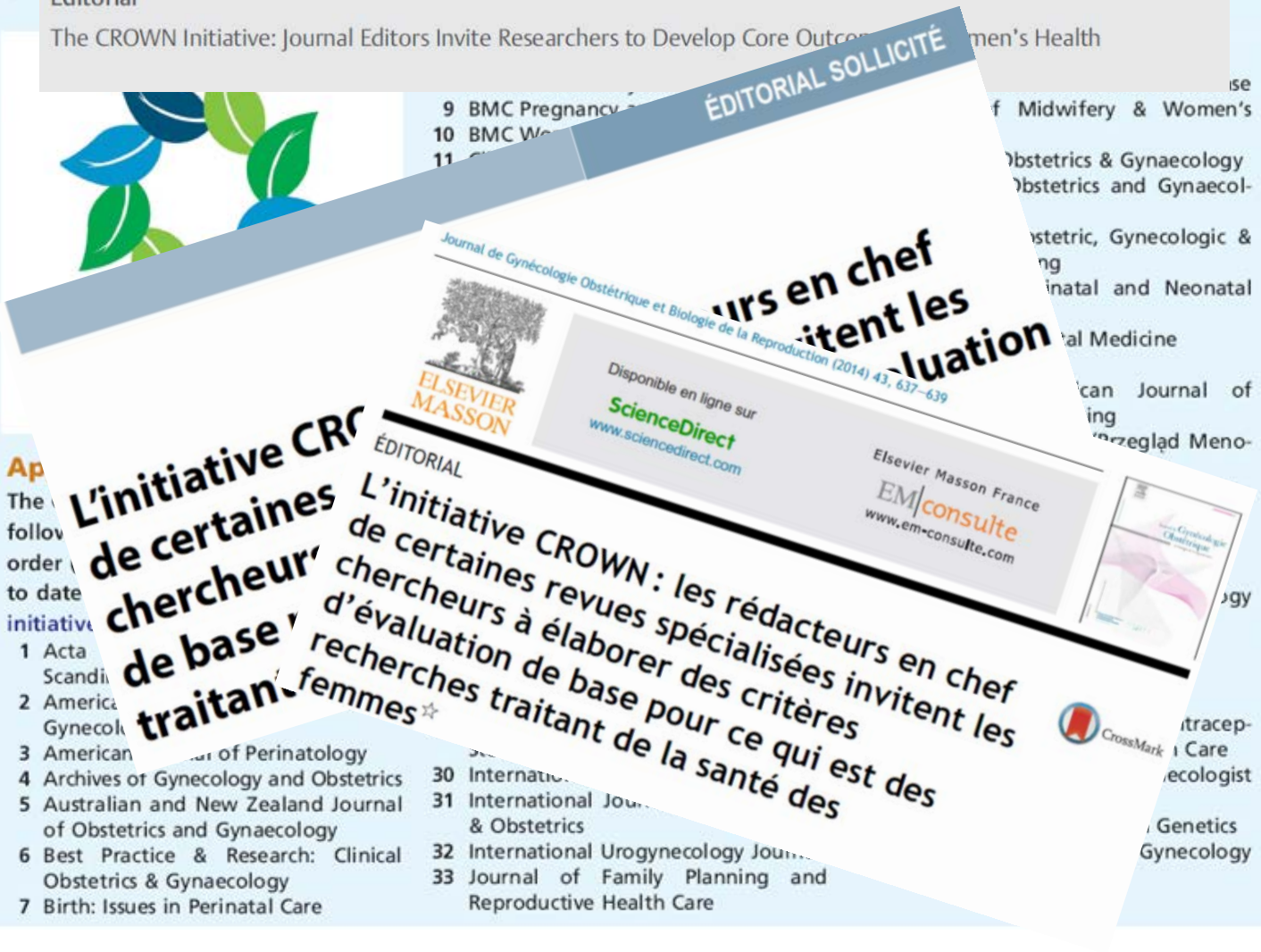
August 2016

Editorial

Die CROWN Initiative: Herausgeber laden Wissenschaftler ein, Kern-Outcomes für Frauengesundheit zu entwickeln

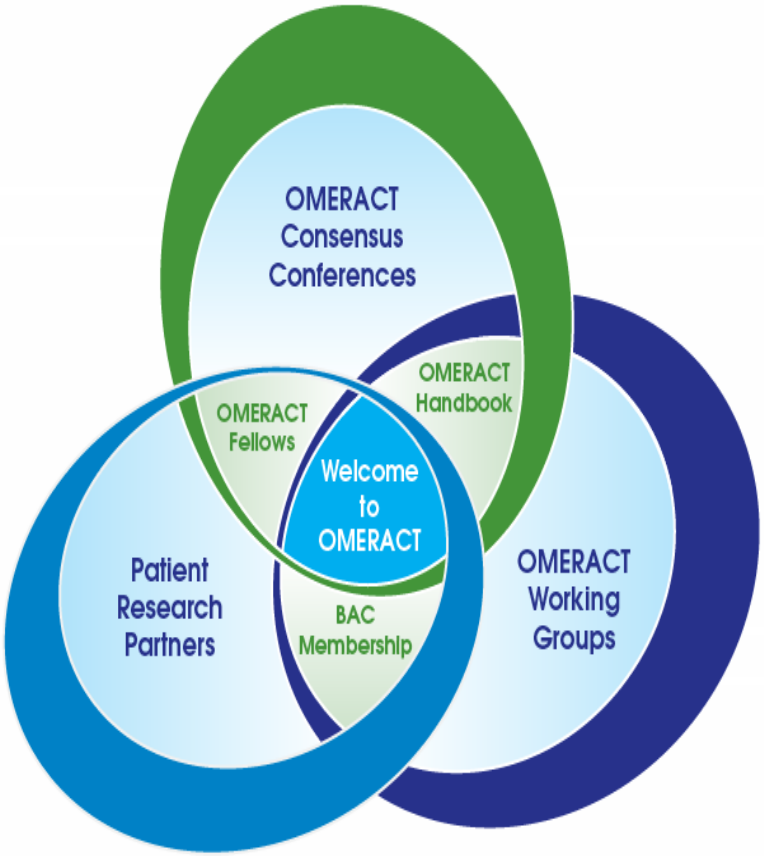
Editorial

The CROWN Initiative: Journal Editors Invite Researchers to Develop Core Outcomes for Women's Health



OMERACT
Outcome Measures in Rheumatology

CROWN
CORE OUTCOMES IN
WOMEN'S HEALTH



COMET INITIATIVE

Home | About COMET | Search | Events | Resources | Links | Contact | COMET IV Meeting

Core Outcome Measures in Effectiveness Trials

Links

Here you can find links to useful and relevant websites. If there is a link that you would like to recommend for this list, please contact us.

Relevant web links

Core outcome networks / groups / collaborations

- Outcome Measures in Rheumatology (OMERACT)
- Harmonizing Outcome Measures for Eczema (HOME)
- Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)
- Women and Babies Health and Wellbeing : Action through Trials (WOMBAT)
- Prevention of Falls Network (PROFANE)
- European Wound Management Association Patient Outcome Group (EWMA)
- Acute Dialysis Quality Initiative (ADQI)
- European Society of Cutaneous Lupus Erythematosus (EUSCLE)
- International Myositis Assessment and Clinical Studies Group (IMACS)
- Pediatric Rheumatology International Trials Organization (PRINTO)
- Core Outcomes in Women s Health (CROWN)
- IOF Research Branch
- Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)

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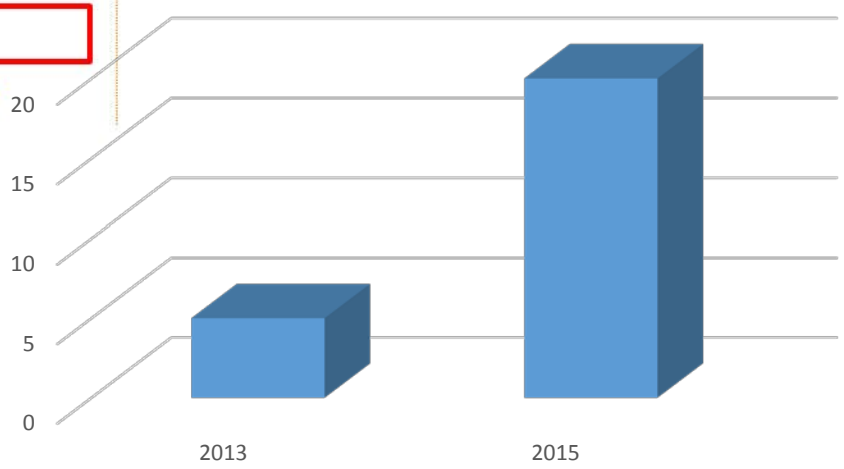
Help, I want to...

Comet Entries in Women's Health



CROWN
CORE OUTCOMES IN WOMEN'S HEALTH

www: crown-initiative.org

@CoreOutcomes

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