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Developing Core outcome set for Women's, Newborn and Child Health: The CROWN Initiative

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Clearly defined and relevant clinical outcomes of importance to all key stakeholders are essential if clinical trials, systematic reviews and guidelines are to translate to the real-world and improve patient care. Unfortunately, we have a long way to go in perinatal and paediatric healthcare. A recent systematic review of interventions for the prevention preterm birth included 103 randomised clinical trials in which 72 different outcomes were reported. This heterogeneity of outcomes limits the synthesis and usability of research (Meher S et al., 2014), and contributes to research waste (Moher D et al., Lancet 2016). Core outcome sets (COS) have been developed to address this problem. These are the agreed *minimum* set of outcomes to be reported in all clinical trials in a specific health condition or area and are also suitable for use in clinical audit or research other than randomised trials.

The Core Outcome Measures in Effectiveness Trials (COMET) Initiative (http://www.comet-initiative.org/) involves individuals interested in "the development and application of agreed standardised sets of outcomes, known as 'core outcome sets'. Core outcomes sets are not meant to be restrictive and clinical trials would ideally include cores outcomes as well as other outcomes of interest. The COMET initiative describes a 5-step core outcome set development process (Williamson PR, Trials 2017, COMET Handbook). These involve a review of existing knowledge and consensus development approaches to agreeing the core outcome set. Similar to the publication of clear guidelines on clinical trial reporting such as CONSORT (http://www.equator-network.org/reporting-guidelines/consort/) and PRISMA for systematic reviews (http://www.equator-network.org/reporting-guidelines/prisma/), standardised guidelines have been developed for COS. COS-STAD (Kirkham et al. 2017) establishes minimum standards for the development of

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COS and COS-STAR (Kirkham 2016) provides guidance on the final reporting of COS. The importance of incorporating patient perspectives, including patient reported outcome measures (PROMs) (Macefield RC et al., 2014), in COS is increasingly recognised (Biggane et al., 2018).

The CROWN collaboration (http://www.crown-initiative.org/) involves over 54 journals related to women's and newborn health who have come together to support The CoRe Outcomes in Women's and Newborn health (CROWN) Initiative (Aims of CROWN initiative: Box 1). This group has recently published the core outcome set for studies aimed at preterm birth prevention (van 't Hooft et al., 2017) and is committed to publishing and disseminating core outcomes to improve Women's and Newborn health.

Duffy et al recently performed a systematic review of core outcomes in women's and newborn health; although this identified 49 core outcome sets registered in women's and newborn, only 3 of these related to newborn health (Duffy et al., 2017). One of these is the COIN project: Core Outcomes In Neonatology (http://neoepoch.com/core-outcomes/), which is establishing the most important outcomes for parents, children and adults who received neonatal care, healthcare professionals and researchers (Webbe J et al., 2017).

Over twenty years ago, perinatal healthcare pioneered the application of systematic reviews to improve care (Crowley P, Cochrane, 1996). We propose that women's and newborn health should again lead the way, reducing research waste and making research more relevant, by developing, disseminating and applying core outcomes sets. The journal *Pediatric Research* is delighted to demonstrate our interest in publishing core outcomes in newborn and child health, encouraging their

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use in clinical trials and furthering their wide dissemination, by becoming part of the CROWN Initiative.

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List of CROWN member journals

1 Acta Obstetricia et Gynecologica Scandinavica
2 American Journal of Obstetrics & Gynecology (AJOG)
3 American Journal of Perinatology
4 Archives of Gynecology and Obstetrics
5 Australian and New Zealand Journal of Obstetrics and Gynaecology, The
6 Best Practice & Research: Clinical Obstetrics & Gynaecology
7 Birth: Issues in Perinatal Care
8 BJOG: An International Journal of Obstetrics and Gynaecology
9 BMC Pregnancy and Childbirth
10 BMC Women's Health
11 Breast Journal, The
12 Chinese Journal of Perinatal Medicine（中华围产医学杂志）
13 Climacteric
14 Clinical Obstetrics and Gynecology
15 Clinics in Perinatology
16 Cochrane Gynaecology and Fertility Group
17 Cochrane Pregnancy and Childbirth Group
18 Contraception
19 Contraception & Reproductive Medicine
20 Current Opinion in Obstetrics and Gynecology
21 European Journal of Contraception and Reproductive Health Care, The
22 European Journal of Obstetrics & Gynecology and Reproductive Biology
23 Female Pelvic Medicine and Reconstructive Surgery
24 Fertility and Sterility
25 Fertility Research and Practice
26 Fetal Diagnosis and Therapy
27 Geburtshilfe und Frauenhelikunde
28 Ginekologia Polska
29 Gynecologic and Obstetric Investigation
30 Gynecologic Oncology
31 Gynecologic Oncology Reports
32 Gynecological Surgery
33 Human Fertility
34 Human Reproduction
35 Human Reproduction Update
36 Hypertension in Pregnancy
37 International Breastfeeding Journal
38 International Journal of Childbirth
39 International Journal of Fertility and Sterility
40 International Journal of Gynecological Cancer
41 International Journal of Gynecology and Obstetrics
42 International Urogynecology Journal
43 Journal de Gynecologie Obstétrique et Biologie de la Reproduction

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44 Journal of Family Planning and Reproductive Health Care
45 Journal of Gynecologic Oncology
46 Journal of Lower Genital Tract Disease
47 Journal of Maternal Fetal and Neonatal Medicine, The
48 Journal of Midwifery & Women's Health
49 Journal of Minimally Invasive Gynecology
50 Journal of Obstetric, Gynecologic & Neonatal Nursing
51 Journal of Obstetrics & Gynaecology
52 Journal of Obstetrics and Gynaecology Canada
53 Journal of Obstetrics and Gynecology Research
54 Journal of Ovarian Research
55 Journal of Pediatric & Adolescent Gynecology
56 Journal of Perinatal & Neonatal Nursing
57 Journal of Perinatal Medicine
58 Maternal and Child Nutrition
59 Maternal Health, Neonatology and Perinatology
60 MCN American Journal of Maternal Child Nursing, The
61 Menopause Review (Przegląd Menopauzalny)
62 Menopause: Journal of The North American Menopause Society, The
63 Midwifery
64 Nederlands Tijdschrift voor Obstetrie en Gynaecologie (NTOG)
65 Neurourology and Urodynamics
66 New Zealand College of Midwives Journal
67 Obstetrician & Gynaecologist, The (TOG)
68 Obstetrics & Gynecology
69 Paediatric and Perinatal Epidemiology
70 Pediatric Research
71 Placenta
72 Post Reproductive Health
73 Prenatal Diagnosis
74 Reproductive Health
75 Reproductive Health Library
76 Russian Journal of Obstetrics and Gynaecology
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78 Ultrasound in Obstetrics & Gynecology
79 Women and Birth
80 Women's Midlife Health

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