

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



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Clinical trials, systematic reviews and guidelines compare beneficial and non-beneficial outcomes following interventions. Often, however, various studies on a particular topic do not address the same outcomes, making it difficult to draw clinically useful conclusions when a group of studies is looked at as a whole (Williamson et al., 2012). This problem was recently thrown into sharp focus by a systematic review of interventions for preterm birth prevention, which found that among 103 randomised trials, no fewer than 72 different outcomes were reported (Meher & Alfirevic, 2014). There is a growing recognition among clinical researchers that this variability undermines consistent synthesis of the evidence, and that what is needed is an agreed standardised collection of outcomes – a *core outcomes set* – for all trials in a specific clinical area (Williamson et al., 2012). Recognising that the current inconsistency is a serious hindrance to progress in our specialty, the editors of over 50 journals related to women's health have come together to support The CROWN (CoRe Outcomes in Women's health) Initiative (Table 1).

Development of consensus is required around a set of well-defined, relevant and feasible outcomes for all trials concerning particular obstetric and gynaecologic health conditions, such as preterm birth, incontinence, infertility and menstrual problems. With so many subspecialties involved, this is no easy task. Duplication of effort can be avoided by working with the Core Outcome Measures in Effectiveness Trials (COMET) Initiative, which is working towards core data sets for all medical specialties (Williamson, Altman, Blazeby, Clarke, & Gargon, 2011). Production of trustworthy core outcome sets will require engagement with patients, healthcare professionals, researchers, industry and regulators, and the employment of scientifically robust consensus methods (Williamson et al., 2012). The data for these core outcome sets, once agreed upon, should be collected in trials and reported in publications as standard practice in the future.

Journal editors now invite researchers to take the lead in beginning this work. What will we do as editors to support them and their colleagues? First, we are drawing wide attention to The CROWN Initiative by publishing this editorial in the journals listed below. We shall ensure that the global research community, which includes our many reviewers, is aware of the need for core outcome sets. Submissions which describe development of core outcome sets, if deemed acceptable after peer review, will be effectively disseminated.

Our collaboration is not for enforcing harmony at the expense of innovation. To quote from the COMET home page, "The existence or use of a core outcome set does not imply that outcomes in a particular trial should be restricted to those in the relevant core outcome set. Rather, there is an expectation that the core outcomes will be collected and reported, making it easier for the results of trials to be compared, contrasted and combined as appropriate; while researchers continue to explore other outcomes as well" (COMET, 2014). We also expect that as new or superior ways of capturing outcomes emerge, core outcome sets will themselves need updating.

Producing, disseminating and implementing core outcome sets will ensure that critical and important outcomes with good measurement properties are incorporated and reported. We believe this is the next important step in advancing the usefulness of research, in informing readers, including guideline and policy developers, who are involved in decision-making, and in improving evidence-based practice.

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Table 1: Aims of the CROWN Initiative

1. Form a consortium among all gynaecology-obstetrics and related 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.

www.crown-initiative.org

REFERENCES

- Core Outcome Measures in Effectiveness Trials Initiative. (2014). COMET initiative home. Retrieved from <http://www.comet-initiative.org/>
- Meher, S., & Alfirevic, Z. (2014). Choice of primary outcomes in randomised trials and systematic reviews evaluating interventions for preterm birth prevention: a systematic review. *BJOG*, 121. doi:10.1111/1471-0528.
- Williamson, P. R., Altman, D. G., Blazeby, J. M., Clarke, M., Devane, D., Gargon, E., & Tugwell, P. (2012). Developing core outcome sets for clinical trials: issues to consider. *Trials*, 13, 132.
- Williamson, P. R., Altman, D. G., Blazeby, J. M., Clarke, M., & Gargon, E. (2011). The COMET (Core Outcome Measures in Effectiveness Trials) Initiative. *Trials*, 12(Suppl 1), A70. doi:10.1186/1745-6215-12-S1-A70.

The CROWN Initiative includes the following journals, in alphabetical order (correct on 13th May 2014, up to date list available at www.crown-initiative.org):

Acta Obstetrica et Gynecologica Scandinavica
American Journal of Obstetrics & Gynecology
American Journal of Perinatology
Archives of Gynecology and Obstetrics
Australian and New Zealand Journal of Obstetrics and Gynaecology
Best Practice & Research: Clinical Obstetrics & Gynaecology
Birth: Issues in Perinatal Care
BJOG: An International Journal of Obstetrics and Gynaecology
BMC Pregnancy and Childbirth
BMC Women's Health
Climacteric
Clinical Obstetrics and Gynecology
Clinics in Perinatology

Cochrane Menstrual Disorders and Subfertility Group
Cochrane Pregnancy and Childbirth Group
Contraception
Current Opinion in Obstetrics and Gynecology
European Journal of Obstetrics & Gynecology and Reproductive Biology
Fertility and Sterility
Fetal Diagnosis and Therapy
Ginekologia Polska
Gynecological Surgery
Gynecologic Oncology
Gynecologic Oncology Reports
Human Fertility
Human Reproduction
Human Reproduction Update
Hypertension in Pregnancy
International Journal of Fertility and Sterility
International Breastfeeding Journal
International Journal of Gynecology & Obstetrics
International Urogynecology Journal
Journal of Family Planning and Reproductive Health Care
Journal of Gynecologic Oncology
Journal of Lower Genital Tract Disease
Journal of Midwifery & Women's Health
Journal of Obstetrics & Gynaecology
Journal of Obstetrics and Gynaecology Canada
Journal of Obstetric, Gynecologic & Neonatal Nursing
Journal of Perinatal & Neonatal Nursing
Journal of Perinatal Medicine
Maturitas
MCN The American Journal of Maternal Child Nursing
Menopause Review (Przegląd Menopauzalny)
Menopause: The Journal of The North American Menopause Society
Neurourology and Urodynamics
Obstetrics & Gynecology
Paediatric and Perinatal Epidemiology
Placenta
Prenatal Diagnosis
Reproductive Health
The Breast Journal
The European Journal of Contraception and Reproductive Health Care
The Obstetrician & Gynaecologist (TOG)
Twin Research and Human Genetics
Ultrasound in Obstetrics & Gynecology

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