

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

The Core Outcomes in Women's Health (CROWN) Initiative

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On behalf of Chief Editors of Journals participating in The CROWN Initiative listed at the end of this article.

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Clinical trials, systematic reviews, and guidelines compare beneficial and nonbeneficial 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 randomized 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 standardized collection of outcomes—a “core outcomes set”—for all trials in a specific clinical area (Williamson et al., 2012). Recognizing 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 (Box 1).

Development of consensus is required around a set of well-defined, relevant, and feasible outcomes for all trials concerning particular obstetric and gynecologic 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 toward 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



Box 1. Aims of The CROWN Initiative

1. Form a consortium among all gynecology-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. Organize 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

Key words: Bias (Epidemiology); Clinical trials; Consensus; Endpoint determination/standards; Evidence-based medicine; Guidelines; Research design/standards; Systematic reviews; Treatment outcome.

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 that 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 (www.comet-initiative.org): “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.” 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. ♦

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):

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| 1. Acta Obstetrica et Gynecologica Scandinavica | 29. International Journal of Fertility and Sterility |
| 2. American Journal of Obstetrics & Gynecology | 30. International Breastfeeding Journal |
| 3. American Journal of Perinatology | 31. International Journal of Gynecology & Obstetrics |
| 4. Archives of Gynecology and Obstetrics | 32. International Urogynecology Journal |
| 5. Australian and New Zealand Journal of Obstetrics and Gynaecology | 33. Journal of Family Planning and Reproductive Health Care |
| 6. Best Practice & Research: Clinical Obstetrics & Gynaecology | 34. Journal of Gynecologic Oncology |
| 7. Birth: Issues in Perinatal Care | 35. Journal of Lower Genital Tract Disease |
| 8. BJOG: An International Journal of Obstetrics and Gynaecology | 36. Journal of Midwifery & Women's Health |
| 9. BMC Pregnancy and Childbirth | 37. Journal of Obstetrics & Gynaecology |
| 10. BMC Women's Health | 38. Journal of Obstetrics and Gynaecology Canada |
| 11. Climacteric | 39. Journal of Obstetric, Gynecologic & Neonatal Nursing |
| 12. Clinical Obstetrics and Gynecology | 40. Journal of Perinatal & Neonatal Nursing |
| 13. Clinics in Perinatology | 41. Journal of Perinatal Medicine |
| 14. Cochrane Menstrual Disorders and Subfertility Group | 42. Maturitas |
| 15. Cochrane Pregnancy and Childbirth Group | 43. MCN The American Journal of Maternal Child Nursing |
| 16. Contraception | 44. Menopause Review (Przegląd Menopauzalny) |
| 17. Current Opinion in Obstetrics and Gynecology | 45. Menopause: The Journal of The North American Menopause Society |
| 18. European Journal of Obstetrics & Gynecology and Reproductive Biology | 46. Neurourology and Urodynamics |
| 19. Fertility and Sterility | 47. Obstetrics & Gynecology |
| 20. Fetal Diagnosis and Therapy | 48. Paediatric and Perinatal Epidemiology |
| 21. Ginekologia Polska | 49. Placenta |
| 22. Gynecological Surgery | 50. Prenatal Diagnosis |
| 23. Gynecologic Oncology | 51. Reproductive Health |
| 24. Gynecologic Oncology Reports | 52. The Breast Journal |
| 25. Human Fertility | 53. The European Journal of Contraception and Reproductive Health Care |
| 26. Human Reproduction | 54. The Obstetrician & Gynaecologist (TOG) |
| 27. Human Reproduction Update | 55. Twin Research and Human Genetics |
| 28. Hypertension in Pregnancy | 56. Ultrasound in Obstetrics & Gynecology |

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