UNDERSTANDING HARMs OF INTERVENTIONS

Few interventions appear to be associated with no harm. Adverse effects of interventions have generally been called “risks.” “Harms”—a truer opposite of benefits—is now recognized as the preferred term. Similarly, “harm” is a more direct and appropriate term for potential problems than “safety.” Many interventions involve numerous documented harms and perhaps many other harms not yet recognized.

Truly informed decision making and informed consent or refusal are not possible without a full accounting of best current knowledge of benefits and harms. Unfortunately, there is a strong bias in favor of benefits, and comprehensive high-quality data on harms are largely unavailable.

In primary studies, harms are less likely than benefits to be:

- studied at all
- studied in enough participants and/or over a long enough period for detection
- measured with adequate definitions and methods
- reported when studied and
- referenced in titles, abstracts, and index terms.

The biases persist in systematic reviews due to this professional ethos and deficiencies of the primary studies. By contrast, women appear to have great interest in knowing about harms. For example, one-half of the participants in both U.K. and Australian surveys of postpartum women responded that “it is necessary to know every complication of an epidural before consenting to have one,” and over one-third in both groups responded that “it is necessary to know most complications...” Just 7% and 15% of women in the respective samples would be satisfied with knowledge of some complications (S. Yentis, personal communication).

The international research community has begun to actively address these concerns through research about harms of specific interventions and the adequacy of research on harms, as well as through new guidance to improve research in this area. For example, the current version of the Cochrane Collaboration’s handbook for review authors has a new appendix on including adverse effects in Cochrane reviews, and the CONSORT Group has issued an extension of their guidelines for reporting randomized controlled trials (RCTs) to address reporting of harms in RCTs. There is growing recognition that observational research may be better suited to measuring harms that are less common and/or occur long after an intervention, and work continues to strengthen the quality of such research.


FROM COCHRANE DATABASE OF SYSTEMATIC REVIEWS (CDSR), ISSUE 3, 2005

New Systematic Reviews

- Audio recordings of consultations with doctors for parents of critically sick babies
- Interventions to prevent hypothermia at birth in preterm and/or low birthweight infants
- Opioids for neonates receiving mechanical ventilation
- Oral anti-oestrogens and medical adjuncts for subfertility associated with anovulation
- Prevention and treatment of postpartum hypertension
- Relapse prevention interventions for smoking cessation
- Surgical approach to hysterectomy for benign gynaecological disease
- Thrombolytic agents for arterial and venous thromboses in neonates
- Wound drainage for caesarean section
Updated Systematic Reviews

- Breast stimulation for cervical ripening and induction of labour
- Concomitant chemotherapy and radiation therapy for cancer of the uterine cervix
- Open retropubic colposuspension for urinary incontinence in women
- Traditional suburethral sling operations for urinary incontinence in women
- Trophic feedings for parenterally fed infants

Cochrane Reviews are available by subscription to The Cochrane Library (see http://www.thecochranelibrary.com or contact emrw@wiley.com for details). Abstracts of Cochrane Reviews are available without charge at http://www.thecochranelibrary.com.

FROM DATABASE OF ABSTRACTS OF REVIEWS OF EFFECTS (DARE)

Recent Abstract Entries Assessing Quality of Systematic Reviews

- Antibiotic treatment of bacterial vaginosis in pregnancy: a meta-analysis
- Breast cancer diagnosis by scintimammography: a meta-analysis and review of the literature
- Does locoregional radiation therapy improve survival in breast cancer: a meta-analysis
- Drug treatment of hyperlipidemia in women
- Effects of aspirin consumption during pregnancy on pregnancy outcomes: a meta-analysis
- Effects of specific post-menopausal hormone therapies on bone mineral density in post-menopausal women: a meta-analysis
- Elective cervical cerclage for prevention of preterm birth: a systematic review
- The effectiveness of public health interventions to reduce or prevent spousal abuse toward women
- Free-standing midwife-led maternity units: a safe and effective alternative to hospital delivery for low-risk women?
- Hormone replacement therapy and cognition
- Multiple courses of antenatal corticosteroids: a systematic review and meta-analysis
- Physical therapy for pregnancy-related low back and pelvic pain: a systematic review
- Preconception care and the risk of congenital anomalies in the offspring of women with diabetes mellitus: a meta-analysis
- Prevention of preterm birth by cervical cerclage compared with expectant management: a systematic review
- The role of ultrasonography as an adjunct to mammography in the detection of breast cancer: a systematic review

- Systematic review of first-line chemotherapy for newly diagnosed postoperative patients with stage II, III, or IV epithelial ovarian cancer
- A systematic review of training in acute obstetric emergencies
- The effectiveness of adolescent reproductive health interventions in developing countries: a review of the evidence

DARE abstracts are available without charge from: http://www.york.ac.uk/inst/crd/darehp.htm

EVIDENCE-BASED REVIEWS FROM OTHER SOURCES


This review examined the relationship between interpregnancy interval and adverse birth outcomes in 3 studies that addressed numerous limitations of previous research and reported on over 700,000 singleton births. Controlling for key risk factors, the studies were highly consistent in finding a J-shaped curve for the proportion of mothers experiencing low birthweight: high risk for an interpregnancy interval of less than 3 months, drops off sharply to lowest risk for an interval of about 18 to 23 months, and then a linear risk increases gradually as the interval increases further.

Comment: Results of this review underscore the importance of postpartum contraception care and educational guidance for women. An interpregnancy interval of 18 to 23 months may be optimal for infant outcome, with special concern about shorter intervals.


To explore the relationship between breastfeeding and obesity in later life, the authors pooled results of 28 studies that included 298,900 participants. Overall analysis and analyses that controlled for potential confounders and looked at such factors as study size and age at outcome all found initial breastfeeding to be protective of later obesity, in comparison with formula feeding. Exclusive initial breastfeeding and longer duration of breastfeeding were associated with lower likelihood of obesity than initial mixed feeding and shorter duration of breastfeeding, respectively.

Comment: In the context of a growing epidemic of obesity and a broad range of other benefits of breastfeeding for mothers and babies, it is a priority to increase the number of mother-infant pairs meeting breastfeeding goals of the American Academy of Pediatrics and other professional organizations.
Recent Evidence-Based Reviews


Carol Sakala, PhD, MSPH, is Director of Programs at Childbirth Connection (formerly Maternity Center Association), which works with health professionals and other audiences to promote evidence-based maternity care (http://www.childbirthconnection.org). E-mail: sakala@childbirthconnection.org

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