

EVIDENCE-BASED MEDICINE

REPRODUCTION, PREGNANCY & BIRTH

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Evidence-based medicine

- use of current **best evidence** in **making decisions** about the care of **individual patients**.

Evidence-based clinical practice

- an approach to decision-making in which the clinician uses the **best evidence** available, in **consultation** with the patient, to **decide the option** which suits that patient best.

Evidence-based health care

- use of current **best evidence** in making decisions about the care of individual patients or the **delivery of health services**

Evidence-based public health/social intervention?

BENEFITS OF EBM

- Allows clinicians to draw the **objective experience** of many researchers working with accepted scientific standards.
- Improves **efficacy and efficiency**.
- Decreases the use of **ineffective** clinical practices.
- Promises to **better inform** patients and clinicians about clinical practices by offering collectively agreed and publicly available information about **treatment options**.
- Provides a **scientific basis** for the construction of **clinical guidelines and health care policy**.

Romana, H.-W. (2006). Is Evidence-Based Medicine Patient-Centered and Is Patient-Centered Care Evidence-Based? *Health Services Research*, 41(1), 1-8. doi: 10.1111/j.1475-6773.2006.00504.x

CLINICAL GUIDELINES



The Royal Australian
and New Zealand
College of
Obstetricians
and Gynaecologists

What clinical guidelines do

- Describe the care of individuals by healthcare professionals
- They are based on the best available evidence of clinical practice and cost effectiveness (individual experience???)
- They focus on the management of core conditions or diseases (rare and complex cases???)



NICE National Institute for
Health and Care Excellence

What clinical guidelines do not do

- Replace clinical judgement



Expert judgment

- The practice of evidence-based medicine requires integrating individual clinical experience with the best available research evidence.

White, B. (2004). Making evidence-based medicine doable in everyday practice. *Fam Pract Manag*, 11(2), 51-58.

Gabbay, J. and A. le May (2004). "Evidence based guidelines or collectively constructed "mindlines?" Ethnographic study of knowledge management in primary care." *BMJ* **329**(7473): 1013

Without clinical expertise, practice risks becoming tyrannized by evidence, for even excellent external evidence may be inapplicable or inappropriate for an individual patient.

Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients

Sackett, D. L., et al. (1996). "Evidence based medicine: what it is and what it isn't." BMJ 312(7023): 71-72.

Reproduction, pregnancy and birth

Use of current *best evidence* in
health care / medicine / practice
to

provide care for women/couples,
pregnancies and babies



<http://www.meganmarlene.com/>



PRACTICAL EXAMPLES OF EBM

Neural tube defect incidence and folic acid Supplement

- Before 1990, prevalence of neural tube defects about **2 per 1,000 births** (AIHW National Perinatal Statistics Unit, 2004)
- In early to mid-1990s, Australia started to promote folic acid through **fortification of selected foods and folic acid supplements** (Bereznicki, Jackson, & Peterson, 2006) (AIHW National Perinatal Statistics Unit, 2004).
- In 2001, the estimated birth prevalence of neural tube defects was **0.5 per 1,000 births** (AIHW National Perinatal Statistics Unit, 2004).

Current recommendations:



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and Gynaecologists

- Folic acid should be taken for **a minimum of one month before conception**
- For the **first 12 weeks of pregnancy** in a minimum daily dose of **0.4mg daily** to aid the prevention of neural tube defects
- A **5mg daily** dose for those with **high risk** of neural tube defect or a mal-absorption risk (RANZCOG, 2014)

PRACTICAL EXAMPLES OF EBM

HPV AND CERVICAL CANCER



- Pre1980 – link between cervical cancer and high number of sexual partners (STI link)
- 1980 - development of HPV DNA testing for cellular specimens
- 1990 - accumulation of epidemiological evidence on HPV and cervical cancer
- 2002 – HPV association is present in virtually all cervical cancer cases worldwide. It is the right time for **medical societies and public health regulators** to consider this **evidence** and to define its **preventive and clinical implications**.
- Bosch FX, Lorincz A, Muñoz N, Meijer CJ, Shah KV. The causal relation between human papillomavirus and cervical cancer. J Clin Pathol. 2002 Apr;55(4):244-65.

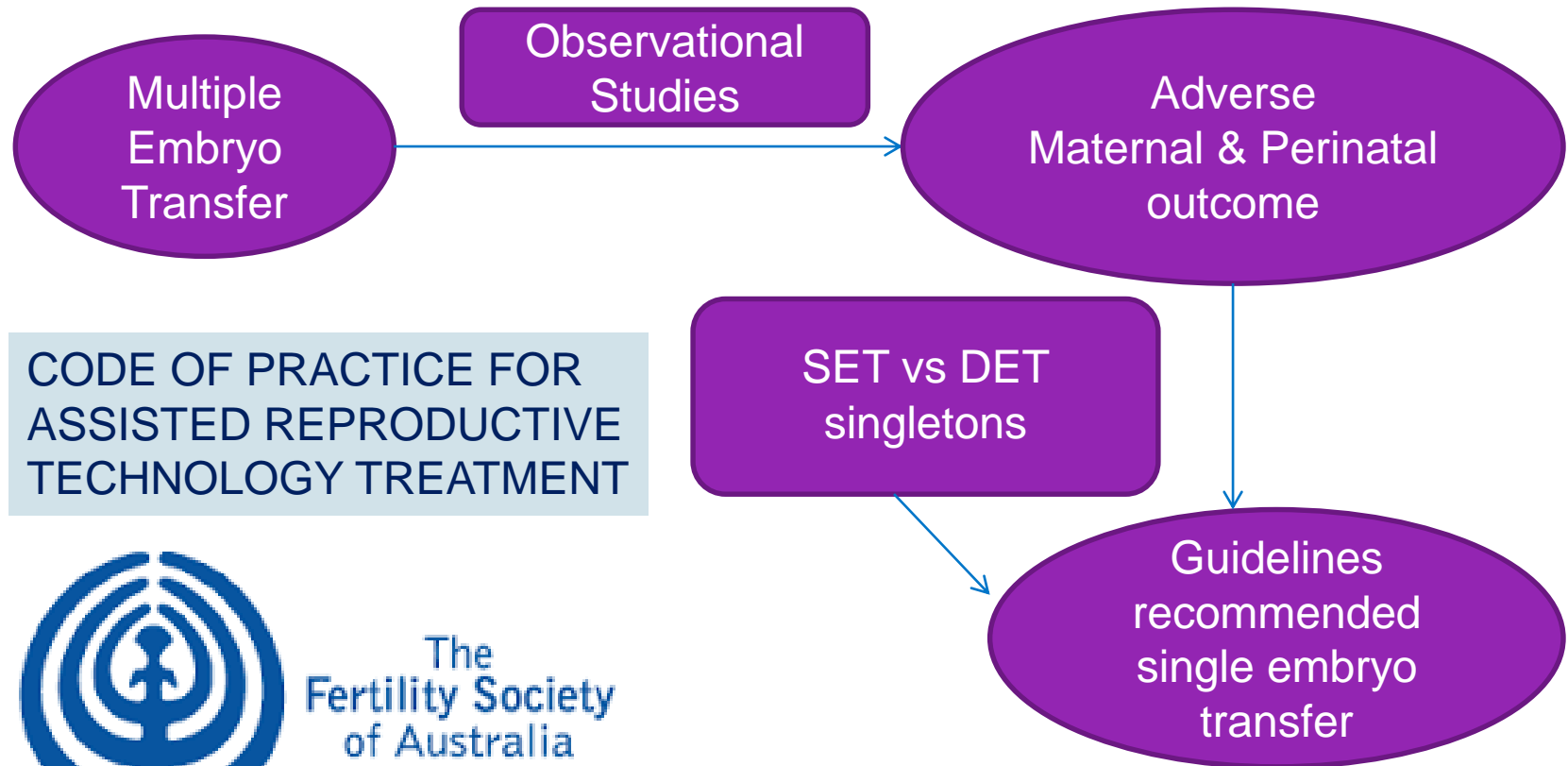
The role of HPV in Cervical Cancer

- In 1991 HPV vaccine developed by **Australian Professor Ian Frazer**
- Before 2007, **no national vaccine program** to prevent cervical cancer
- In 2007 Australia was **the first country** to introduce HPV vaccination program on national level to prevent cervical cancer.(Tabrizi et al., 2012)
- Prevalence of HPV **6.7%** in 2010-2011 vs **28.7%** in 2005-2007
- “a substantial decrease in vaccine-targeted genotype HPV is evident, and should, in time, translate into reductions in **HPV-related lesions** (Tabrizi et al., 2012).
- In 2008 Prof Harald zur **Hausen** awarded **Nobel Prize**



PRACTICAL EXAMPLES OF EBM

MULTIPLE PREGNANCY AND EMBRYOS



PRACTICAL EXAMPLES OF EBM

Clomiphene --- Infertility

- Oral clomiphene citrate - **ovulation induction** for **unexplained infertility**.
- Clomiphene → **multiple pregnancies & ovarian cancer**
- Multiple pregnancies → high risk of **maternal and perinatal morbidity and mortality**
- Clomiphene → **birth defects** (Davis 2012 NEJM)

From: National Institute for Health and Care Excellence
. Fertility: assessment and treatment for people with
fertility problems. London: NICE; 2013. CG156.

www.nice.org.uk/guidance/cg156/evidence/cg156-fertility-full-guideline3 (accessed 6 October 2015).

NICE National Institute for
Health and Care Excellence

CLOMIPHENE AND IVF

NICE Recommendations

- **Do not offer** clomiphene to women with unexplained infertility.
- **Inform** women that clomiphene citrate **does not increase** the chances of a pregnancy or a live birth.
- **Advise** women with unexplained infertility who are having regular unprotected sexual intercourse to try to conceive for a total of **2 years**
- Offer **IVF treatment** to women with unexplained infertility after 2 years

NICE National Institute for
Health and Care Excellence

Assessment and treatment for people with fertility problems

- In 2004 NICE guideline define an upper and a lower age limit **(23-39 years)** for IVF treatment.
- However, the lower age limit was **not based on evidence**.
- Meta analysis shows that an **increase in female age leads to a decrease in pregnancy rates** (van Loendersloot et al, 2010).
- NICE 2013 Recommendation: **Inform women** that the chance of a live birth following IVF treatment falls with rising female age.

From: National Institute for Health and Care Excellence . Fertility: assessment and treatment for people with fertility problems. London: NICE; 2013. CG156. www.nice.org.uk/guidance/cg156/evidence/cg156-fertility-full-guideline3 (accessed 6 October 2015).

PRACTICAL EXAMPLES OF EBM

of Breech presentation

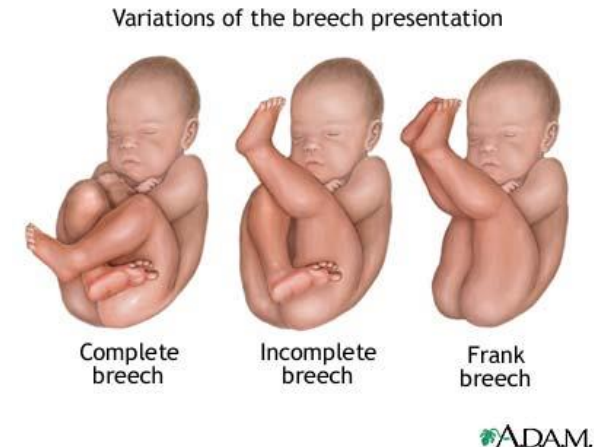
Controversial - manage and plan delivery in breech presentation

A RCT in 2000: perinatal mortality and neonatal morbidity were **lower in the planned CS** (Hannah et al., 2000)

Change of practice: **90%** of breech presentations at term had **CS** (RANZCOG, 2013)

Some experts: **planned vaginal delivery** of the singleton breech at term may be an option (RANZCOG, 2013).

Chinese herbs – moxibustion 2012 Cochrane



<http://birthwithoutfearblog.com/2010/10/29/breech-babies-is-another-variation-of-normal/>

PRACTICAL EXAMPLES OF EBM

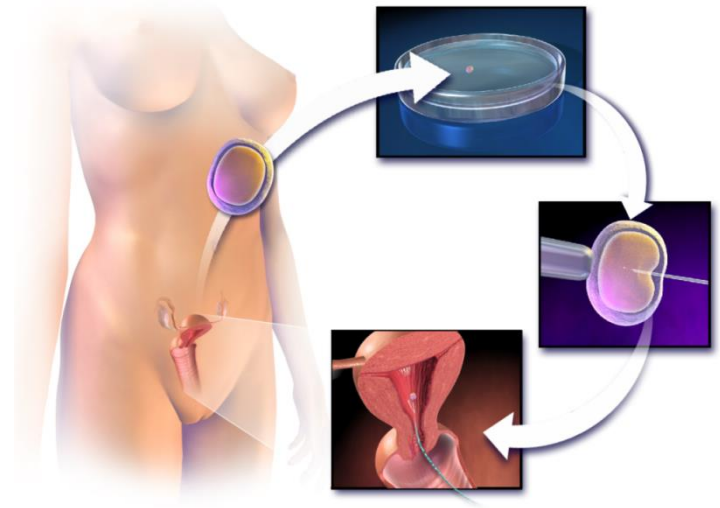
Intra-cytoplasmic sperm injection (ICSI)

Evidence: retrospective cohort studies

Congenital malformations associated with **ICSI** (Davis 2012 NEJM)

Controversial:

ICSI procedure itself vs the **subfertility** of couples





ASRM recommendation:

- i. **It is unclear** whether the increased prevalence of birth defect observed in ICSI offspring relates to the procedure itself, or to the subfertility characteristics of couples who require ICSI to conceive.
- ii. Couples considering ICSI should **be informed** about the associated potential risks.

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QUESTIONS & DISCUSSION