Institution: Swansea University
Unit of Assessment: 3b - Allied Health Professions, Dentistry, Nursing and Pharmacy: Nursing
Title of case study: Improved breastfeeding rates through evidence-based guideline changes

1. Summary of the impact

The societal, economic and health benefits of breastfeeding include reduced infections in infants, cancers in mothers, cardiovascular disorders in both, and costs to the NHS (UNICEF UK 2012). Breastfeeding initiation rates in England improved from 66.2% in 2005/6 to 73.7% in 2010/11. Swansea work improved services, health and welfare because we:

- identified for the first time the need to **restrict doses of epidural opioid analgesia** during labour (R1)
- **helped midwives** identify mothers in greatest need of breastfeeding support (R2)
- developed public and professional awareness of the impact of drugs in labour on breastfeeding.

We recommended that doses of analgesia be minimised and mothers receiving multiple medicines in labour targeted for additional breastfeeding support (R1-3). These recommendations reached most midwives and students in the English-speaking world through **NICE** (National Institute for Health and Care Excellence), *Intrapartum Care Guideline* 2007 (C1 p.123) and our textbooks (R4, 5). NICE guidelines form the basis of hospital policies and procedures in the UK and beyond. Doses were lowered (details below) and breastfeeding rates improved.

2. Underpinning research

The benefits of breastfeeding to infants and mothers underlie World Health Organisation and UK government policies on infant nutrition. Our group explored the impact of drugs in labour on infant feeding. Literature searches for the standard midwifery textbook (R4) suggested that it is biologically plausible that analgesics and uterotonics routinely administered in labour adversely affect the complex, and incompletely understood, physiology of breastfeeding. These hypotheses were supported in a series of cohort studies undertaken in Swansea.

1. A cohort of first time mothers delivering in Singleton hospital 2000, data extracted from patient records (n=425) (R1)
2. Analysis of the Cardiff Births Survey 1989-1999 (n=48,366) (R2)
3. An internet survey (n=284) (R3)

We were the first to report:

1. A dose-response relationship between epidural fentanyl and reduced breastfeeding rates by up to 40% (R1)
2. A reduction of 6-8% in breastfeeding rates in women receiving intramuscular oxytocin or Syntometrine® for routine prophylaxis of *post partum* haemorrhage (R2).
3. Birth complications, accompanied by medications, are associated with breastfeeding discontinuation for physical (pain and difficulties), but not psychosocial (lifestyle, support, body image and embarrassment) reasons (R3).

This work questions practices which have remained unchallenged and unchanged since the widespread introduction of epidural fentanyl and routine administration of uterotonics in the third stage of labour in the 1980s. Identification of previously unsuspected adverse drug reactions is an important strategy for harm avoidance.

Infant feeding data have been collected in <3% of trials of pain relief in labour (Cochrane 2012, Issue 3. Art. No.: CD009234), and <20% of trials covering the third stage of labour (Cochrane 2011 Issue 11. Art. No.: CD007412), increasing the significance of our observation studies. A dose-response relationship is an important quality indicator (J Clin Epidemiol. 2011 64; 1311-6). Accordingly, our work has been disseminated widely, and informed the Cochrane overview (Cochrane 2012, Issue 3. Art. No.: CD009234), and recommendation that breastfeeding be included as an outcome for all future trials in the Cochrane Pregnancy and Childbirth group.

Ours is the only cohort with fentanyl doses, although others have linked epidurals to reduced breastfeeding. A SCOPUS search (20.6.2012) of the key terms “feeding” “dose” “epidural” found no earlier data exploring the dose/response relationship between opioid analgesia and infant feeding. Oxytocin for labour augmentation has been implicated in smaller studies, but we are the only group using a large naturalistic cohort to report the impact of routinely administered oxytocin

on breastfeeding. Ergometrine alone reduces breastfeeding, but we are the only group reporting an association in combination with oxytocin.

Key researchers: Sue Jordan, Swansea university 1992-present, reader.
Alan Watkins, Swansea university 1986-present, associate professor in statistics
Gareth Morgan, Swansea university 2002–present, professor of paediatrics
Simon Emery, ABMU HB, 1989-present, consultant obstetrician and gynaecologist
Amy Brown, Swansea University, 2005-present, senior lecturer. **All work in Swansea.**

3. References to the research

R1. Jordan S., Emery S., Bradshaw C., Watkins A., Friswell W. 2005 The Impact of Intrapartum Analgesia on Infant Feeding. *BJOG:* 112, 927-34. (By 31.7.13, 40 citations, Impact factor (IF) 3.76, 3rd in field for article influence score (Thompson ISI 2012).

R2. Jordan S, Emery S, Watkins A, Evans J, **Storey M, Morgan G**. 2009 Associations of drugs routinely given in labour with breastfeeding at 48 hours: analysis of the Cardiff Births Survey. BJOG; 116(12) 1622-30 (see REF outputs) (13 citations)

R3. Brown AE., Jordan S. 2013 Impact of Birth Complications on Breastfeeding duration: an internet survey. *J. Ad. Nursing.* 69(4):828-39 DOI: 10.1111/j.1365-2648.2012.06067.x IF 1.53

R4. Jordan S. 2002, 2010 *'Pharmacology for midwives: the Evidence Base for Safe Practice'* Palgrave/ Macmillan, Basingstoke 1st & 2nd edition ISBN-13: 978-0-230-21558-0 pp. 486

R5. Jordan S. 2011 Pharmacology and the midwife In: MacDonald S., Magill-Cuerden J. (eds) 2011 *Mayes' Midwifery: A text book for Midwives* pp.123-136. 14th edition Elsevier, Edinburgh.

R6. Jordan S. 2006 Infant feeding and analgesia in labour *Int. Breastfeeding J.*: 1: 25 doi: 10.1186/1746-4358-1-25 (11 citations).

Grants supporting this work:

G1. Jordan *et al.* 2005 was supported by Welsh Office of Research and Development: Emery and Jordan, 2002-3, *An exploration of the drugs administered during normal labour on infant feeding*, £9,560.

G2. PhD studentship, Brown: *Maternal control of milk feeding*. ESRC 2005-2009, £45,000.

G3. National Institute Social Care and Health Research Wales, Research Development Group for Pregnancy, childbirth, infant feeding and medicines, £9,000, PI Jordan.

4. Details of the impact

Low breastfeeding rates are an intransigent public health problem with multiple causes (R6). Our work identifying links between medicines in labour and reduced chances of breastfeeding has focused on one aspect of this complex aetiology - iatrogenic harm.

Public and professional awareness was raised by: 1) The media, including front page of *The Times* 1.9.2009: and "Concern over painkillers led the NHS to revise its guidelines on epidurals", BBC, *Daily Mail, Western Mail, Reuters,* UNICEF baby friendly website, BMJ, NCT journal; 2) 7 clinical guidelines and 7 books for clinicians; 3) 56 citations by 31.7.13 in midwifery, obstetrics, paediatrics, anaesthetics, public health, chiropractice, pharmacy publications. The standard textbooks (R4,5) ensure that our research recommendations reach most midwifery students working in English, Farsi and Indonesian: 40 of 65 UK midwifery courses have adopted our textbook (R4). The >5,800 and >3,800 copies of the English 1st & 2nd editions sold reach most of the UK's 35,000 midwives and many in Australasia, USA, Ireland and Malta (July 2013). Accordingly, when labour has been extensively medicated, practitioners are now aware of the need for additional support and time to allow the body to eliminate medicines. The impact on education is evidenced by suggestions that the book makes "care safer for mothers and babies" (C9). Citing our work in R1, West & Marasco (2009 p.59 C2) advise: "*epidurals (...) can temporarily diminish infants' nursing behaviours (...); it may take a little more work to get breastfeeding started*". The position is summarised by the National Childbirth Trust (**NCT**): "*NCT has been concerned about use of opioids during labour and their impact on women's experiences of establishing breastfeeding, breastfeeding initiation and continuation for many years. We consider the work in Swansea, which centred on the impact of drugs in labour on breastfeeding, to be really important. The recommendation to minimise doses of epidural fentanyl was adopted by NICE in the Intrapartum Care guidelines, and the literature indicates that doses are now lower. Breastfeeding rates have improved, for a number of reasons. Lower doses of opioids may be contributing to women having more positive experiences of feeding in the very earliest days, and to this*

improvement in rates. The associations between medicines and breastfeeding rates, together with knowledge of the importance of breastfeeding, persuaded the Cochrane group to include infant feeding as one of the core outcomes for future trials in childbirth. NICE recommendations were based on Swansea work." (C8)

Incorporation into Guidelines Citing our work on the association between the dose of fentanyl and breastfeeding, 7 guidelines (C1-7) recommend restrictions on epidural fentanyl doses. Our recommendations (R1) against high doses and the need for further research were adopted by NICE: the NICE Evidence statement reports the association between the dose of fentanyl and the success of breastfeeding, and indicates *"a need for studies (...): to assess the impact of low-dose epidurals with opioids (fentanyl) on neonatal outcomes, including resuscitation and breastfeeding."* (NCC 2007 p.123 C1). Recommendations (p.14 C1) include informing women that "*opioids may interfere with breastfeeding*".

The US Academy of Breastfeeding Medicine Protocol (2008 p.129 C2), citing our work (R1), states: "*consideration should be given to the type and dose of analgesia. Higher doses of intrapartum fentanyl may impede establishment of breastfeeding*." Also citing R1 and a small trial, Reynolds recommends: "*When prolonged epidural analgesia using local anaesthetic-opioid combination is extended for emergency section, it is unwise, for the baby's sake, to give further opioid epidurally or systemically until after delivery*" (Best Pract Res Clin Obstet Gynaecol. 2010;24(3):289-302 p.298). Also, if epidurals are contraindicated, the more rapidly metabolised remifentanil is now selected, as it is less likely to enter the foetus and depress neonates' behavioural responses.

Practice changes NICE now recommends initiation of epidural analgesia with bolus doses of 10-30mcg fentanyl (C1 p.137). Previously, analgesia was initiated with bolus doses of 100mcg (Anesth Analg. 2000; 91(2):374-8): in 2003 a bolus of 50mcg was considered 'ultra low dose' (J Obstet Gynecol Neonatal Nurs.;32(3):322-31). In local hospitals, epidural fentanyl total doses now range 40-240 mcgs. In the COMET trial, in 2000, 155/757, 20.5% parturients received >200mcgs epidural fentanyl and 41/757, 5.4% received >300mcgs (Anaesthesia. 2010; 65(2):145-53).

Changes in Breastfeeding Rates Publication of our work (R1 in 2005) and guidelines citing it (2007) were followed by improved breastfeeding initiation in England between 2005 & 2010 (Figures from Dept. of Health Statistics).

Breastfeeding Initiation	% (95% CI)	OR increase each year from 2005	Breastfeeding at 6-8 weeks	% (95% CI)
2005/06	66.2 (66.1-66.3)		2008/09 Q1	48.7 (48.4-49.0)
2010/11	73.7 (73.6-73.8)	1.076 (1.074-1.077)	2009/10 Q1	50.3 (50.0-50.5)
2011/12	74.0 (73.9-74.1)	1.066 (1.065-1.068)	2011/12 Q1	49.1 (48.9-49.4)

The deceleration in improvement from >1% to <0.5% pa after 2010 intimates that the impetus for improvement was discrete and sustainable. Similarly, 6-8 week data (only available from 2008/9) indicate improvement to 2009/10, but not thereafter. The quinquennial Infant Feeding Surveys from 1980 indicate that breastfeeding rates deteriorated when epidural fentanyl and routine uterotonics were introduced in the 1980s, and recovery was co-temporaneous with our work.

Alternative explanations, and commonly held beliefs regarding strategies to improve breastfeeding rates, are not supported by evidence from industrialised countries. 1) Well-conducted trials suggest that psychosocial interventions and support do not improve rates (BMJ. 2009;338; 392-5 & 338; 388-92). 2) Systematic reviews indicate that lay support confers no advantages in the UK (BMJ 2012; 344:d8287), and benefits of any support are minimal or non-significant in countries with low or intermediate initiation rates, particularly when only studies with low risk of bias are considered (Cochrane 2007 Jan 24(1):CD001141; 2012 May 16(5) CD001141). 3) Lay support is difficult to obtain, due to limited supply of altruistic mothers and inadequate administrative support (Soc Sci Med. 70(5):769-778). 4) Delivery in 'baby friendly' hospitals does not improve breastfeeding rates at 1 month (Int J Epidemiol.;35(5):1178-86). Without evidence for the efficacy or effectiveness of other feasible strategies to improve breastfeeding, awareness of the impact of drugs in labour (*via* NICE and other guidelines, textbooks, press coverage, UNICEF and NCT), and subsequent decreases in fentanyl doses, are important.

Health gains Before 2005, high fentanyl doses affected at least 3-4% of the 750,000 infants born each year in the UK: in our hospital, 4% primiparae received over the current maximum dose of epidural fentanyl. Practice and dose changes related to our work were important in the 7.5%

increase in breastfeeding initiation 2005-2010 and the subsequent reduction in admissions for diarrhoea and gastroenteritis (A09) (Hospital episode statistics 2012). A 2-4% increase in breastfeeding rates **improves health** by reducing UK infant hospital admissions for diarrhoea and lower respiratory tract infections by 2% and 1%. An extra 2-4% UK women breastfeeding for 3 months decreases childhood obesity by 1% (R2); underlying mechanisms (Brown et al., *Paediatric Obesity* 7; 382-90) and preventive strategies (Brown et al. 2011, *JAN* 67; 1993-2003) are incorporated in several guidelines (NCT, UNICEF, US Surgeon General). Breastfeeding also has measurable impact on: necrotising enterocolitis, sudden infant death, asthma, leukaemia and cardiovascular disease in infants, breast & ovarian cancer in mothers, and diabetes in infants & mothers (UNICEF UK, 2012).

Cost savings Improved infant and maternal health translate into cost savings. Increase in any breastfeeding at 6 months by 2-4% saves >£1m pa from reduced gastrointestinal, respiratory and ear infections. Reducing the number of women who never breastfeed by 2-4% saves >£3m in breast cancer expenditure over the lifetime of the cohort, exclusive of quality adjusted life years. Where 1% of those who "never breastfeed" initiate breastfeeding, the associated small increase in infants' average IQ results in a gain of over £278 million in economic productivity over the lifetime of each annual birth cohort (UNICEF UK, 2012).

In summary, identification of the association between medicines administered in labour and breastfeeding *raised public and professional awareness of a health risk and engendered practice changes, including lower doses of opioid analgesics*. Subsequently, breastfeeding initiation rates increased 2005-2010 (66.2-73.7%). This represents a ***significant avoidance of harm***.

5. Sources to corroborate the impact

The work is cited in 7 clinical practice guidelines:

C1. NCC/ National Collaborating Centre for Women's and Children's Health, commissioned by NICE (2007) *Intrapartum care; care of healthy women and their babies during childbirth: clinical guideline.* London: RCOG Press 2007. P. 122-3, section 6.5, ref. 187 http://www.gserve.nice.org.uk/nicemedia/pdf/IntrapartumCareSeptember2007mainguideline.pdf

C2. Academy of Breastfeeding Medicine (ABM) clinical protocol 5. Breastfeeding Medicine: official journal of the ABM; 2008 Jun;3(2):129-32 Also: National Guideline Clearinghouse 2009 Peripartum breastfeeding management for the healthy mother and infant at term. US. Dept Health & Human Services http://www.guideline.gov/content.aspx?id=13406 Accessed 30.7.13

C3. New Zealand College of Midwives (Inc.) 2011 NZCOM Consensus Statement: Prescribing and administration of Narcotic Analgesia in Labour [Auckland?], New Zealand, http://www.midwife.org.nz/quality-practice/consensus-statements-and-guidelines accessed 8.4.13

C4. West D, Marasco L 2009 The breastfeeding mother's guide to making more milk New York, McGraw-Hill@9780071598583 0071598588 ISBN-10:007159857X |ISBN-13:978-0071598576

C5. Hey E. (2007) Neonatal formulary and Drug Use in the First Year of Life. 5th edition. Wiley Blackwell / BMJ Books, Oxford.

C6. Royal College of Midwives 2012 Evidence-based Guidelines for Midwifery-led Care in Labour: Early Breastfeeding http://www.rcm.org.uk/college/policy-practice/evidence-based-guidelines/ accessed 18.7.13

C7. Ministerio De Sanidad Y Política Social. Guía de Práctica Clínica sobre la Atención al Parto Normal (clinical practice guidelines on normal childbirth care). Servicio Central de Publicaciones del Gobierno Vasco; 2010. ref 356 p.235-7 Available: http://www.msssi.gob.es/organizacion/sns/planCalidadSNS/pdf/equidad/guiaPracClinPartoCompleta.pdf. accessed 1.8.13

C8. Head of Research and Information, NCT, Acton, London, e mail 27.3.13 - 15.32

C9. Senior Lecturer, School of Nursing and Midwifery, De Montfort University, UK, e mail 30.7.13

C10. 26 news reports: The Times 1.9.2009. Media citations include: BBC, *Daily Mail, Western Mail, Reuters,* BMJ, NCT journal: Dodds R. 2010, UNICEF baby friendly website, http://www.unicef.org.uk/BabyFriendly/Search/?SearchText=Jordan *News Digest*. 49(1) 20 accessed 1.8.13. I**nvitations**: HTA panels; NICE stakeholders for intrapartum care guidelines; Cochrane Groups; Keynote addresses: 2010 Patient safety conference. Groote Schuur Hospital, Cape Town; RCN Congress seminar 2008; editorial boards: International Breastfeeding Journal, International Nursing Review, Journal of Nursing Management, Open Nursing Journal.