Institution: The University of Manchester		
Unit of Assessment: 1 (Clinical Medicine)		
Title of case study: Preventing Stillbirth and Improving the Quality of Care After a Baby Dies		
Period when the underpinning research was undertaken: January 2010 – July 2020		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	**Role(s) (e.g. job title):**	**Period(s) employed by submitting HEI:**
Alexander Heazell	Clinical Chair Clinical Senior Lecturer	2016 – present 2009 – 2016
Rebecca Jones	Honorary Senior Lecturer Senior Lecturer	2018 – present 2005 – 2018
Colin Sibley	Emeritus Professor Chair in Child Health and Physiology Professor of Child Health and Physiology	2018 – present 2015 – 2018 2004 – 2015
Period when the claimed impact occurred: 1 August 2013 – 31 December 2020		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact

Based upon University of Manchester (UoM) research, the Saving Babies Lives Care Bundle, a quality improvement programme to identify and manage risk factors for stillbirth, has been implemented nationally. Implementation reduced stillbirth by 20% in all 19 NHS Trust early adopter units, saving 161 stillbirths in these units. In 2019/20, implementation of the care bundle was incorporated into the standard NHS contract. UoM studies describing women's experiences after stillbirth and in pregnancies after loss have underpinned regional, national and international guidelines for the care of women who experience a stillbirth. Public awareness campaigns based upon our research including #sleeponside and #movementsmatter have reached >2,500,000 women in the UK and internationally.

2. Underpinning research

In 2014, the UK stillbirth rate ranked in the lowest third of high-income countries at 1 in 219 births, with 3,563 stillbirths occurring in the UK in 2014.The National Perinatal Epidemiology Unit's Listening to Parents report (2014) found that whilst quality of care for bereaved parents was generally good, there were gaps in care and variability between services. Changes were needed both to improve stillbirth rates in UK and to better help families deal with the loss of a baby.

UoM research has focussed on three main themes: i) understanding of conditions associated with stillbirth, ii) identifying risk factors for stillbirth and iii) using this information to improve the quality of clinical care to prevent stillbirths and enhance the quality of care following a stillbirth.

In the first theme, UoM researchers conducted basic scientific studies to demonstrate placental dysfunction in women with an increased risk of stillbirth including: fetal growth restriction, maternal obesity, women with a perceived reduction in fetal movements, maternal diabetes and mothers over 40 years of age. This has provided a crucial scientific basis to associate these risk factors with stillbirth [1]. Heazell also undertook systematic reviews to demonstrate the frequency and significance of placental lesions as a cause of stillbirth [2]. As a result, there is now an established link between risk factors, placental dysfunction and stillbirth.

Since 2010 UoM has developed "research clinics" to better identify placental dysfunction in women at high-risk of fetal growth restriction including women whose previous pregnancies were complicated by fetal growth restriction, hypertension or stillbirth. UoM researchers used these clinics to develop and test clinical algorithms to improve outcomes for mothers and babies and have conducted national multicentre studies to investigate the impact of better

screening and treatment for fetal growth restriction and management of reduced fetal movements.

Heazell led the largest case-control study of novel risk factors for stillbirth (Midlands and North of England Stillbirth Study, n=1,035) which demonstrated an independent association between maternal going-to-sleep position and late stillbirth [3]. UoM's subsequent collaboration in an international individual patient data meta-analysis identified underpinning mechanisms. The UoM team were co-investigators on the AFFIRM study the largest ever clinical trial of the management of reduced fetal movements (n=409,175), leading site visits, writing the protocol, analysing and disseminating study findings [4]. This study provided important data emphasising the importance of testing, after women attend with reduced movements, as detection of small infants (compared to gestational age) improved, but also indicated that unwarranted intervention may increase Caesarean section without clear benefit.

Heazell's mixed-methods study was the first to describe bereaved parents' experiences in the UK for over 20 years. This study has provided evidence for effective care practices and those that were detrimental to parents [5]. In addition, these studies demonstrated barriers and facilitators to post-mortem consent in women who have had a stillbirth, allowing care to be restructured and optimised to maximise the information obtained for parents about the cause of their baby's death [6]. Heazell's systematic review of care in pregnancies after stillbirth and cross-sectional studies describing care in pregnancies after stillbirth in the UK has led to leadership and generation of an international consensus statement for the care of women in pregnancies after stillbirth. This body of evidence has made a significant contribution to data regarding parents' experiences following the death of their baby.

3. References to the research

1. Warrander LK, Bernatavicius G, Greenwood SL, Dutton P, **Jones RL, Sibley CP**, **Heazell AEP**. Maternal Perception of Reduced Fetal movements is Associated with Altered Placental Structure and Function. *PLoS One.* 2012;7(4):e34851. DOI:10.1371/journal.pone.0034851
2. Ptacek I, Sebire NJ, Man JA, Brownbill P, **Heazell AEP**. Systematic Review of Placental Pathology Reported in Association with Stillbirth. *Placenta.* 2014;35(8):552-62. DOI:10.1016/j.placenta.2014.05.011
3. **Heazell AEP**, Li M, Budd J, Thompson JMD, Stacey T, Cronin RS, Martin B, Roberts D, Mitchell EA, McCowan LME. Association Between Maternal Sleep Practices and Late Stillbirth – Findings from the Midlands and North of England Stillbirth Case-Control Study. *BJOG: An International Journal of Obstetrics and Gynaecology*. 2018;125(2):254-262. DOI:10.1111/1471-0528.14967
4. Norman JE, **Heazell AEP**, Rodriguez A, Weir CJ, Stock SJE, Calderwood CJ, Cunningham Burley S, Frøen JF, Geary M, Breathnach F, Hunter A, McAuliffe FM, Higgins MF, Murdoch E, Ross-Davie M, Scott J, Whyte S; AFFIRM investigators. Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): a stepped wedge, cluster-randomised trial. *Lancet.* 2018;392(10158):1629-1638. DOI:10.1016/S0140-6736(18)31543-5
5. **Heazell AEP**, Siassakos D, Blencowe H, Burden C, Bhutta ZA, Cacciatore J, Dang N, Das J, Flenady V, Gold KJ, Mensah OK, Millum J, Nuzum D, O'Donoghue K, Redshaw M, Rizvi A, Roberts T, Toyin Saraki HE, Storey C, Wojcieszek AM, Downe S; Lancet Ending Preventable Stillbirths Series study group; Lancet Ending Preventable Stillbirths investigator group. Stillbirths: economic and psychosocial consequences. *Lancet.* 2016;387(10018):604-16. DOI:10.1016/S0140-6736(15)00836-3
6. **Heazell AEP**, McLaughlin MJ, Schmidt EB, Cox P, Flenady V, Khong TY, Downe S. A Difficult Conversation? – The Views and Experiences of Parents and Professionals on the Consent Process for Perinatal Post-mortem after Stillbirth. *BJOG: An International Journal of Obstetrics and Gynaecology*. 2012 119(8):987-97.

DOI:10.1111/j.1471-0528.2012.03357.x

4. Details of the impact

Pathways to impact

- **Parliamentary POST notes:** UoM research cited informing MPs about stillbirth issues (POSTbrief 21 July 2016, Bereavement Care, POSTNOTE 527, May 2016, Infant Mortality and Stillbirth in the UK).
- **Heazell presented to All Party Parliamentary Group on Baby Loss (2016):** Co-chair described Manchester's hospitals as displaying best practice with their stillbirth-specific integrated pathway.
- **Patient guidance:** UoM research informed patient-information leaflets from the Royal College of Obstetricians and Gynaecologists (RCOG), Kick's Counts, Tommy's (for NHS England), StillAware (Australian charity) and #movementsmatter campaign (published 24 Oct 2016, >65,100 YouTube views).
- **International #sleeponside campaign:** Launched in 2018, by Tommy's, to educate mothers about sleeping position in late pregnancy [3]. Tommy's estimate this reached >2,500,000 women globally.

Reach and significance of the impact

20% reduction in stillbirth followed Saving Babies Lives Care Bundle's introduction in 19 UK early adopter trusts

In 2014, NHS England launched the four element Saving Babies Lives Care Bundle. The third element focussing on Reduced Fetal Movements was authored by Heazell and underpinned by UoM research [Ai]. In 2018, UoM conducted the SPiRE study to determine the bundle's impact on pregnancy outcomes. Stillbirths were reduced by 20% over the implementation period (2015-2017) [Aii]. UoM's findings informed the bundle's second iteration (released March 2019) which included the sleep on side message [Ai, 4]. National Clinical Director for Maternity and Women's Health, NHS England noted, "*Heazell's research contribution was an important factor in allowing us to make these positive changes. In my view, the development and subsequent evaluation is an excellent example of how translational research can be used to effect positive change in NHS services*" [B]. Implementing the bundle was included in NHS planning guidance and incorporated into the standard NHS contract for 2019/20.

Influence on Australian Safer Baby Bundle

UoM findings influenced the Australian Safer Baby Bundle (SBB), launched in 2019. Heazell was an international advisor. SBB handbook states it is *"based on the approach used in the UK Bundle Versions One and Two*" [Ci,3,4]. Victoria's Secretary of Department of Health and Human Services confirmed, "*There is no question that we would not have been able to develop the Safer Baby Bundle without the resources and insights…generously shared by Professor Heazell…an example of how sharing research insights can rapidly enable application internationally*". He confirmed, "*initial evaluation of the care bundle in 21 Victorian maternity services is that it has been associated with a reduction in stillbirth by 27%"* [Cii].

National/international clinical guidance

UoM reduced fetal movements work was cited as best practice in: guidance from RCOG (reviewed 2014 and 2017) [Di]; Perinatal Society of Australia and New Zealand [Dii]; American College of Obstetricians and Gynecologists [Diii]; national Perinatal Confidential Enquiries into stillbirth (2015 [Ei], 2017 [Eii]).

Creation of North West Regional Stillbirth Care Pathway

Initiated in 2014/5, updated in 2018, UoM's research was cited in North-West regional stillbirth care pathway guidelines [5,6,Fi, Fii]. A pathway audit in August 2016 demonstrated 25% more women were: receiving information; being cared for in labour more safely; and accessing investigations to determine the cause of stillbirth [Fiii].

Creation of National Perinatal Post Mortem Consent Package and Bereavement Care Pathway

In January 2013, Sands (Stillbirth and Neonatal Death Charity) launched a perinatal post mortem consent package and training programme. Sands confirmed Heazell's *"research informed the development of the...package and substantially aided our efforts in producing this important resource, which benefits both health professionals and parents*" [G,6]. A 2016 maternity unit audit of UK's bereavement care provision demonstrated 52 UK Trusts use the package and, of these, 85% believed it had improved staff confidence [H].

In 2017, Sands launched a national bereavement care pathway (NBCP) and audit tools, stating UoM "*research into post-mortem consent, the value of investigations and parent's experiences following stillbirth was instrumental in informing Sands as we developed and launched the…documents*" [G,5]. A 2020 NBCP progress report documented, within the pilot sites, that 76% of professionals aware of the pathway agreed that bereavement care improved during the pilot [I]. The pathway was rolled out nationally in October 2018. Sands confirmed, by August 2020, 52% of English sites have fully committed to NBCP and 99% have engaged with NBCP in some way [G]. Additionally 5 Scottish NHS Boards are currently piloting the NBCP as early adopters [G].

In 2014, 'Listening to Parents after Stillbirth' reported only half of women whose baby died before labour felt involved in decision making and confident about decisions made at the time. By contrast, NBCP's 2020 progress report found 89% felt decisions they made in hospital were the right ones at the time, 89% felt communication was sensitive and they received information about relevant support organisations. 92% agreed they were treated with respect [I], demonstrating NBCP's positive impact for these parents.

Improved care delivered in pregnancies after stillbirth

A clinic model for care in pregnancies after stillbirth was developed from UoM's systematic review of women and families' needs in these pregnancies. Over 800 families have been treated at Manchester's Rainbow Clinic since January 2014, which provides specialist care for pregnant women who have previously had a stillbirth and supports partners and family. It was cited in a Parliamentary debate as an example of excellent care [Ji].

Manchester's Rainbow Clinic has improved clinical outcomes. A 2016 review showed it had reduced: preterm birth (10% *vs* 21%); and low birthweight infant numbers (9% *vs* 18%) [Jii]. An independent study by NEF Consulting found clinic attendance reduced anxiety and post-natal depression [Jiii]. It also demonstrated the Rainbow Clinic gave tangible healthcare financial benefits of GBP6.10 of benefit per pound invested solely from clinical outcomes [Jiii].

Twelve satellite Rainbow Clinics have opened in the UK to date, delivering the UoM care model with a further 25 in development. Further afield, UoM researchers are working with care providers wishing to adopt the model in Melbourne (Australia), Toronto (Canada) and Wisconsin (USA).

5. Sources to corroborate the impact

A. Saving Babies Lives Care Bundle and related testimony;

i. Saving Babies Lives Care Bundle- for reducing perinatal mortality. Version 1 March 2016, version 2 Mar 2019. ***Heazell was lead contributor to element 3 (Reduced Fetal Movements).***

ii. SPiRE Report. Widdows K, Roberts SA, Camacho EM, Heazell AEP. Evaluation of the implementation of the Saving Babies' Lives Care Bundle in early adopter NHS Trusts in England. Maternal and Fetal Health Research Centre, University of Manchester, Manchester, UK. 2018. ISBN number: 978-1-5272-2716-3 – ***version 2 of the Saving Babies Lives Care Bundle was adapted to address issues raised in the SPiRE report.***

B. Testimonial from National Clinical Director for Maternity and Women's Health, Acute Medical Directorate, NHS England and NHS Improvement, September 2020- ***confirming importance of Heazell's research to positive change in NHS.***

C. Australian Safer Baby Bundle;

i. Handbook and Resource Guide, Centre of Research Excellence Stillbirth, Australia, October 2019. – ***Heazell was an international adviser to the Australian safer baby bundle operational committee. Handbook cites UoM references 3 and 4.***

ii. Testimonial from Secretary of Department of Health and Human Services, Victoria State Government, Australia. 2 December 2020- ***confirms importance of UoM work to development of SBB and positive early outcomes in Victoria, Australia***.

D. Clinical Guidances on Reduced Fetal Movements;

i. UK: RCOG Greentop Guideline 55 Reduced Fetal Movements (updated February 2017) - ***cites UoM research (Heazell J Obstet Gynaecol 2009).***

ii. Australian and New Zealand: PSANZ Clinical practice guideline for the care of women with decreased fetal movements for women with a singleton pregnancy from 28 weeks' gestation (September 2019) - ***cites UoM reference 4.***

iii. American: ACOG Obstetric Care Consensus: Management of Stillbirth (March 2020) – ***cites UoM reference 4.***

E. National Perinatal Confidential Enquiries(MBRRACE-UK);

i. Term, singleton, intrapartum stillbirth and intrapartum-related neonatal death. November 2017 - ***cites UoM reference 2.***

ii. Term, singleton, normally-formed, antepartum stillbirth November 2015- ***cites UoM reference 2.***

F. North West Regional Stillbirth Care Pathway;

i. Management of Stillbirth Guideline, V3 March 2018 - ***cites UoM reference 5, co-authored by Heazell.***

ii. Guideline for the Management of Stillbirth 2014 ***– cites UoM research, co-authored by Heazell.***

iii. Regional Evaluation 2014-16. "Improved management of stillbirth using a care pathway" Tomlinson AJ, Martindale E, Bancroft K, Heazell A. *International Journal of Health Governance* 2018;23(1):18-37- ***demonstrating improvements following pathway introduction.***

G. Testimonial from Sands NBCP Lead for the UK and Sands Research and Prevention Lead, September 2020 - ***confirming the importance of UoM work to NBCP and post mortem consent package.***

H. Sands Audit of bereavement care provision in UK maternity hospitals 2016 – ***showing widespread use of Sands post mortem consent package and improvements to staff confidence in trusts used.***

I. National Bereavement Care Pathway Progress Report June 2020 – ***confirming impact and effectiveness of NBCP introduction for parents and professionals.***

J. The Rainbow Clinic; ***- developed from UoM systematic review of women's needs***

i. ***Cited in parliamentary debate*** as centre of excellence, 26 March 2014.

ii. The Manchester Rainbow Clinic: a dedicated clinical service for parents who have experienced a previous stillbirth improves outcomes in subsequent pregnancies. Abiola JW, Stephens L, Harrison L, et al. *BJOG:* 2016;123:46 May 2016 -***demonstrates improved clinical outcomes.***

iii. Independent review of the social return on investment of Rainbow Clinic by NEF Consulting, February 2018 - ***shows benefits for women of reduced anxiety and post-natal depression.***