Institution: University of Leicester		
Unit of Assessment: UoA2		
Title of case study: Reducing Stillbirth, Improving Antenatal, Perinatal and Neonatal Care, and Informing International Policy		
Period when the underpinning research was undertaken: 2000-2020		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s): 1) Prof Elaine Boyle 2) Prof Elizabeth Draper 3) Prof Brad Manktelow 4) Dr Lucy Smith	**Role(s) (e.g. job title):** 1) Professor of Neonatal Medicine 2) Professor of Perinatal & Pediatric Epidemiology 3) Professor of Medical Statistics 4) Associate Professor of Perinatal Health	**Period(s) employed by submitting HEI:** 1) 2006- present 2) 1981- present 3) 1997- present 4) 1992- present
Period when the claimed impact occurred: 2013-2020		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact

The delivery of safe, high-quality maternity and neonatal care is vital in preventing avoidable deaths and improving outcomes for children and families. For each avoidable death it is important to understand the cause and make appropriate changes to prevent reoccurrences. The Infant Mortality and Morbidity Studies (TIMMS) Research Group at the University of Leicester have driven improvements in this area across the UK and internationally through provision of an accurate evidence base, founded on novel methodologies. Their work has informed national programmes leading to 20% stillbirth reduction, changed clinical practice guidelines globally and facilitated government enquiries into some of the most significant hospital incidents of the last 20 years.

2. Underpinning research

The TIMMS Research Group at the University of Leicester has, for over 20 years, undertaken world-leading interdisciplinary research in partnership with clinicians, families and the public, investigating the causes, consequences and management of morbidity and mortality of the fetus and newborn infants, and the development of children born preterm. Their work can be broadly categorised in two interrelated themes: 'Epidemiological Research' and 'Surveillance and Confidential Enquiry'.

Epidemiological Research

TIMMS has extensive experience in the design, operation, analysis and reporting of observational studies investigating the potential causes of perinatal mortality and morbidity, the delivery of perinatal care and the developmental outcomes for children born preterm. TIMMS researchers have played an important role in key international studies, including European-wide perinatal cohorts (MOSAIC, EPICE **[G1]**, EuroPeristat), and the EPICure Studies of outcomes following extremely preterm birth (before 27 weeks of gestation) in the UK and Ireland.**[R1]** In 2015, an NIHR funded research programme led by TIMMS established the first prospective geographical population-based birth cohort of babies born late and moderately preterm (32-36 weeks gestation) along with a term-born control group. The knowledge generated by this project has been crucial in informing improvements in care, outcomes and development of the ~50,000 affected births per annum in the UK. **[R2]**

Surveillance and Confidential Enquiry

TIMMS researchers have enhanced methods for the surveillance of clinical indicators **[R3],** and extended confidential enquiries for the assessment of healthcare delivery quality **[R4]**. TIMMS lead both the perinatal arm of Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK), the national programme of work conducting surveillance and investigating the causes of maternal deaths, stillbirths and infant death **[G2]** and PICANet, the national audit of paediatric intensive care in the UK and Ireland.

As part of MBRRACE-UK, TIMMS expertise has enabled accurate recording and reporting of a wide range of complex medical data through use of their novel, internationally renowned methodologies. TIMMS lead all of MBRRACE-UK perinatal reports as authors and by provision of methods, datasets and expert review, which enable conclusions to be drawn. These reports have fundamentally changed healthcare practice and policy in the UK and internationally with TIMMS research providing the evidence base to enable the best possible outcomes.

In 2017, TIMMS partnered in an MBRRACE-UK collaboration to develop a national standardised Perinatal Mortality Review Tool (PMRT) **[G3]**. The PMRT supports high-quality systematic, multidisciplinary reviews of the circumstances and care related to each stillbirth, neonatal and postnatal death. PMRT enables active communication with parents and provides healthcare providers with a report for each death identifying contributory factors and providing action plans to prevent future avoidable deaths.

Established in 2001, PICANet provides a secure, confidential high-quality clinical database of paediatric intensive care activity (including case mix, structure and utilization) facilitating best practice, monitoring of supply/demand, treatment outcome reviews, strategic planning and further study of the epidemiology of critical illness. The PICANet database comprises almost 400,000 admission, referral and transport events and >1.32 million days of Paediatric Critical Care activity data have been reported to PICANet, providing a unique resource to drive improvements across the UK and Ireland **[G4]**.

3. References to the research

OUTPUTS

R1. Zeitlin J, **Manktelow BN**, Piedvache A, Cuttini M, **Boyle E**, van Heijst A, Gadzinowski J, Van Reempts P, Huusom L, Schmidt S, Barros H, Dillalo D, Blondel B, **Draper ES**, Maeir R.. Use of evidence based practices to improve survival without severe morbidity for very preterm infants: results from the EPICE population based cohort. BMJ. 2016:i2976.

R2. **Boyle EM, Johnson S, Manktelow B, Seaton SE**, **Draper ES**, **Smith LK**, et al. Neonatal outcomes and delivery of care for infants born late preterm or moderately preterm: a prospective population based study. Arch Dis Child Fetal Neonatal Ed. 2015; 100(6):F479-485.

R3. Mohammed MA, **Manktelow BN**, Hofer TP. Comparison of four methods for deriving hospital standardised mortality ratios from a single hierarchical logistic regression model. Stat Methods Med Res 2016;25(2):706-715.

R4. **Draper ES**, Kurinczuk JJ, **Lamming CR**, **Clarke M**, James D, **Field D**. A confidential enquiry into cases of neonatal encephalopathy. Arch Dis in Child 2002; 87(3):176-180.

GRANTS

G1. Effective Perinatal Intensive Care in Europe (EPICE) 2011 – 2015, EU FP7, UoL funding GBP285,647 (total EUR3,000,000)**, Draper ES (UK lead - PI) Manktelow B (COI), Boyle E (COI).**

G2. MBRRACE-UK 2012-2021, Healthcare Quality Improvement, GBP2,009,052. **Draper E (PI), Manktelow B (COI), Smith L (COI)**.

G3. Perinatal Mortality Review Tool, 2017-2020, Healthcare Quality Improvement, GBP35,701. **Draper E (COI)**.

G4. National Paediatric Intensive Care Database (PICANet), Healthcare Quality Improvement/ Devolved Administrations of the UK, 2001-2021, GBP2,598,341. **Draper E (PI)**.

4. Details of the impact

TIMMS research has guided the national focus on reducing stillbirth and neonatal deaths through improved maternity and child health care in the UK for over 20 years.

Improving Maternity and Child Health Care

In 2015, NHS England launched 'Spotlight on Maternity', a framework to achieve a 20% reduction in stillbirth, neonatal and maternal deaths by 2020, rising to 50% by 2025 **[E1].** The guidance rationale and recommendations are founded on five key underpinning evidence sources: two TIMMS authored MBRRACE-UK perinatal reports, two further MBRRACE-UK reports facilitated by TIMMS researchers, and 'The Report of the Morecambe Bay Enquiry' for which Draper provided crucial expertise.

The 'Spotlight' report had significant nationwide impact, forming the basis of the UK Government's 'Safer Maternity Care' guidance **[E2a]** and providing the '6 Key Drivers' that are the rationale of the NHS Improvement Maternity Programme **[E2b].**

In 2016, the MBRRACE-UK Perinatal Confidential Enquiry Report into Term, Singleton, Normally-Formed, Antepartum Stillbirth provided the rationale and evidence base for the NHS 'Saving Babies' Lives' care bundle and the updated 'Saving Babies' Lives Version Two' **[E3]**. This programme was highly successful, early adopter trusts saw an overall stillbirth reduction of 20% and term singleton stillbirths declined by 22% for a national investment of just £27million **[E3].**

TIMMS research has improved care delivery for many specific patient groups. Their MBRRACE-UK confidential enquiry into care of babies with Congenital Diaphragmatic Hernia (CDH) resulted in the formulation and implementation of a new interdisciplinary consensus guideline led by the British Association of Perinatal Medicine (BAPM) **[E4].** This led to an updated BAPM clinical practice framework for perinatal care at extreme preterm gestations, in collaboration with MBRRACE-UK (represented by Smith), Bliss, British Maternal and Fetal Medicine Society, Royal College of Obstetricians and Gynaecologists, Royal College of Paediatrics and Child Health and Sands. This guideline utilises MBRRACE-UK research extensively **[E4].**

TIMMS research has defined, guided and underpinned multiple NICE guidelines, including enabling specific provision of respiratory intervention and parent/carer support in 'Specialist Neonatal Respiratory Care for Babies Born Preterm' **[E5]** and fundamentally underpinning evidence, methodology and recommendations in 'Developmental Follow Up of Children and Young People Born Preterm' **[E5].**

TIMMS' international reach extends beyond that afforded by NICE. Their research provides the underpinning evidence for the European Standards of Care for Newborn Health ratified at the European Parliament in 2018 **[E6].** During promulgation, TIMMS research was cited extensively across the majority of the Topic Expert Groups in their formulation of these new standards, which represented an important step towards harmonising treatment and care for preterm and ill newborns across Europe.

Inspection and Surveillance of Maternity and Paediatric Care

Sound methodology is vital in monitoring and improving healthcare outcomes. Methods developed and utilised by TIMMS have been recognised as innovative and robust and are used to underpin the process and reporting of clinical indicator surveillance. Due to the significant input of TIMMS research to the methodology and expert guidance in the inquiry, the report of 'The Morecambe Bay Investigation', 2015, concludes by recommending that recording of perinatal deaths "*should build on the work of national audits such as MBRRACE-UK*" **[E7a].** This provides further evidence that TIMMS are leaders in the field, as does their subsequent input into the NHS Highland Inquiry into Perinatal Deaths at Caithness General Hospital which led to significant service reorganisation **[E7b].**

Perinatal mortality rates provided by MBRRACE-UK are included in the Care Quality Commission (CQC) inspection packs and form part of the assessment of care for Maternity Services in all NHS Trusts in England. The CQC inspection framework for maternity services defines multiple 'professional standards' and 'sector specific guidance' with explicit recommendations for organisations to utilise MBRRACE-UK reports, methodologies and

standards to effectively improve care quality **[E8].** Key metrics from PICANet are reported annually to the CQC to inform the planning of NHS hospital inspections. Through MBRRACE-UK TIMMS provide rates of stillbirths and neonatal deaths for CCG metrics in the NHS Improvement and Assessment Framework 2019/20 as an indicator of quality for care for maternity services **[E2c].**

PICANet has successfully driven patient care improvements, informed government policy and facilitated clinical practice guideline change. The project provided expertise and the primary data source for NHS service reviews in paediatric critical care, specialised surgery in children and congenital cardiac services, informed public health vaccination programmes (e.g., evaluating the maternal pertussis vaccination programme) and is the source of the NHS England PIC Specialised Services Quality Dashboard mortality metrics **[E11c].**

During the COVID-19 pandemic, PICANet was vital in the UK's national response. PICANet modelling of the minimum number of UK Paediatric Intensive Care Unit (PICU) beds required ensured ring-fencing of essential beds and enabled freeing up of non-essential PICU capacity. The project also produced the only national-level data summarising characteristics, received interventions and outcomes for COVID-19 patients admitted to PICU. This data was used by the Chief Medical Officer to inform advice regarding school re-opening following national lockdown **[E11c].**

TIMMS methodologies have been utilised globally, including in the WHO 'Maternal Health Care: Policies, Technical Standards and Service Accessibility in Eight Countries in the Western Pacific Region' guideline, where their statistical methodologies provide the data on stillbirth rates per nation to guide policy formulation **[E9].** As a member of the UNICEF Core Stillbirth Estimation Group, Smith provided expert guidance for the first ever stillbirth report by the UN Inter-Agency Group for Child Mortality Estimation. This report improves global data availability and drives political and public recognition of the issue, utilising TIMMS research extensively **[E10].**

Within eight months of launch, all NHS Trusts in England and Health Boards in Scotland and Wales delivering maternity and/or neonatal services that had experienced a perinatal death were using the PMRT (except for one small Board in Scotland) **[E11a].** In year one, 1,500 reviews were conducted, identifying 3,010 contributory factors requiring action and generating 3,050 action plans. By the end of year two >6,300 reviews of late miscarriages, stillbirths and neonatal deaths were completed with >90% identifying at least one care issue, with an average of four per death **[E11a].**

In 2020, PMRT was included as Safety Action 1 for all NHS healthcare providers in the NHS Resolution 'Maternity Incentive Scheme' **[E11b].** This scheme incentivises ten maternity safety actions, achievement of which provides substantial economic benefits to Trusts. To achieve the standards set in the framework, Trusts must use PMRT in at least 95% of suitable cases and inform MBRRACE-UK of all eligible perinatal deaths **[E11b].**

5. Sources to corroborate the impact

E1. 'Spotlight on Maternity: Contributing to the Government's national ambition to halve the rates of stillbirths, neonatal and maternal deaths and intrapartum brain injuries by 2030'

E2. Maternity Plans

(a) Department of Health 'Safer Maternity Care Action Plan' 2016.

(b) NHS Improvement 'Update on Maternity Transformation Programme' 2018.

(c) NHS Oversight Framework for 2019/20 annex 3: CCG metrics technical annex.

E3. 'Saving Babies' Lives' Policies and Reviews

(a)NHS England. Saving Babies' Lives Version Two: A care bundle for reducing perinatal mortality

(b) Tommy's Centre for Stillbirth Research 'Evaluation of the Implementation of the Saving Babies' Lives Care Bundle in Early Adopter NHS Trusts in England'. 2018.

E4. British Association of Perinatal Mortality Clinical Practice Guidelines

(a) British Association of Perinatal Mortality (BAPM). National care principles for the management of Congenital Diagphragmatic Hernia (CDH).
(b) British Association of Perinatal Mortality (BAPM). A BAPM Framework for Practice Perinatal Management of Extreme Preterm Birth Before 27 weeks of Gestation (2019)
E5. NICE Guidelines
(a) NICE Guideline (NG124) Specialist neonatal respiratory care for babies born preterm, 2014
(b) NICE Guideline 'Developmental Follow Up of Children and Young People Born Preterm' 2017.
E6. European Standards of Care for Newborn Health: EFCNI.
E7. Inquiry Reports
(a) The Report of the Morecambe Bay Investigation, 2015.
(b) NHS Highlands Board Minutes 2016, containing the Inquiry Report
E8. Care Quality Commission (CQC) Inspection framework: Maternity Framework (Acute, community, independent).
E9. WHO 'Maternal Health Care: Policies, Technical Standards and Service Accessibility in Eight Countries in the Western Pacific Region' 2018.
E10. UNICEF 'A Neglected Tragedy: The Global Burden of Stillbirths', 2020.
E11. Evaluation Reports
(a) MBRRACE-UK 'National Perinatal Mortality Review Tool First Annual Report', 2019.
(b) NHS Resolution 'Maternity Incentive Scheme: Year 3', 2020.
(c) PICANet Impact Reports 2018-2020.