Using routinely collected data to evaluate the performance and quality of English NHS maternity services

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Declaration

I, Hannah Ellin Knight, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Full name Hannah Ellin Knight

Signed

Date: 20th April 2018

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Dedication

This thesis is dedicated to my son, who is due to be born this summer. Though he is currently the size of an aubergine, he has given me a deeper and more personal understanding of the data I have analysed over the last few years. Like all expectant mothers, I hope for his safe entry into this world. This thesis seeks, in a small way, to help turn this hope into a reality for more women and their babies.

Table of Contents

Acknowledgements

First and foremost, I would like to thank my supervisors, David Cromwell and Ipek Gurol-Urganci, for their expert guidance over the last five years. It has been a long but rewarding journey. Thank you for bearing with me as I juggled PhD and work commitments. I am privileged to call you my colleagues, and hope that the submission of this thesis marks just the 'end of the beginning' of our collaboration.

In addition to my supervisors, I would like to thank the range of clinical and methodological experts who kindly contributed to this research: Jan van der Meulen, Gordon Smith, Sam Oddie, Katie Harron, Lynn Copley, Tahir Mahmood, David Richmond and Allan Templeton.

I am indebted to all the unnamed midwives, doctors, maternity support workers, ward clerks, and clinical coders who enter data into NHS electronic maternity and patient administration systems on a daily basis, and to the women and babies whose data I have been fortunate to analyse. I am also grateful to the 19 NHS trusts who participated in the Maternity Indicators Pilot Project and agreed for their data to be included in this PhD thesis. In addition, I would like to thank NHS Digital for their help in supplying and linking the data.

Whilst being able to conduct this work 'part-time' has had many benefits, five years of evening and weekend studying has been undeniably demanding and I am much indebted to my husband, family, friends and colleagues for their patience, support and encouragement throughout this process. I look forward to spending more time with all of you in the near future.

Abstract

This 'publication style' thesis comprises a collection of research papers, each of which seeks to address a different element of the overall aim: to determine the extent to which electronic data, captured routinely as part of clinical care and hospital administration, can be used to evaluate the performance and quality of English NHS maternity services.

These routine data sources present opportunities for research groups to examine whether current practice and outcomes in NHS maternity services meet guidelines and standards, and to guide research and initiatives to improve the quality of maternity care at a regional and national level. However, the difficulty faced by clinicians, managers and service users in interpreting some of the currently available maternity statistics highlights the need to improve the usefulness of the information being produced to evaluate NHS maternity services.

The first part of this thesis comprises a review of the advantages and limitations of existing routinely collected data sources for these purposes. The review identifies three key challenges relating to 1) the handling of missing or inconsistent information, 2) the definition of key exposure, outcome and confounding variables relevant to maternity care and 3) adjustment for confounding variables.

In the second part, novel techniques are developed to address current weaknesses in the secondary analysis of these data. The findings show that these new methods can be used to derive accurate information on two key data items: 1) the method of delivery and 2) the parity status of women, although misclassification rates are higher for some subgroups of women. This section demonstrates that overall the quality of administrative data is sufficient to support the evaluation of maternity care but that some organisational-level statistics are sensitive to inconsistencies in the data. Consequently, it is recommended that publications of quality indicators should describe how data were prepared and analysed, in order for results to be replicable.

In the third part, a series of retrospective cohort studies are described that illustrate how these new methodological techniques can be used to overcome the three challenges identified in the part 1.

The first study calculated rates of attempted and successful vaginal birth after caesarean section, which had not previously been done using administrative data at national and provider-level basis (Chapter 6), and found that among women who attempted a trial of labour for their second birth, almost two-thirds successfully achieved a vaginal delivery. A second study evaluated a clinical intervention (induction of labour) designed to prevent rare outcomes such as perinatal mortality which are impractical to investigate by experimental methods (Chapter 7); it found that bringing forward the routine offer of induction of labour from the current recommendation of 41±42 weeks to 40 weeks of gestation in nulliparous women aged >=35 years might reduce overall rates of perinatal death.

A third study examined an important health policy question about when staff should be present on the labour ward (Chapter 8) and involved the linkage of administrative, staffing and clinical datasets. The study found no difference in the rate of maternal and neonatal morbidity according to the presence of consultants on the labour ward. A final study examined whether administrative data provided a cost effective way of monitoring perinatal outcomes using a composite indicator of adverse outcomes. The study found that a measure developed in Australia could be adapted to English data, and had good concurrent and predictive ability (Chapter 9).

The thesis concludes that hospital administrative datasets, linked with other sources of clinical data where necessary, are a valuable resource for population-based service evaluations. Taken together, the novel techniques developed, validated and applied as part of this programme of work, advance our understanding of the ways in which routinely collected maternity data can and cannot be used to support the evaluation of maternity services. Whilst these data are not perfect and there is certainly a need to improve their completeness and consistency, this research demonstrates that it is possible to develop techniques to identify and manage data errors, and methods to clearly define key exposure, outcome and confounding variables. Together, these allow answers to be found to many potential questions about maternity care.

List of Tables

Chapter 4

Chapter 5

Chapter 6

Chapter 7

Chapter 8

Chapter 9

List of Figures

Chapters 1-3

Chapter 4

Chapter 5

Chapter 6

Chapter 7

Chapter 8

Chapter 9

Abbreviations

AHRQ	Agency for Healthcare Research and Quality
BMI	body mass index
CI	confidence internal
CS	caesarean section
CPAP	continuous positive airway pressure
ERCS	elective repeat caesarean section
IMD	Index of Multiple Deprivation
IV	intravenous
HES	Hospital Episode Statistics
HIE	hypoxic ischaemic encephalopathy
HSCIC	Health and Social Care Information Centre
ICD-10	International Classification of Diseases, 10th Edition
IQR	interquartile range
IVH	intraventricular haemorrhage
MIS	maternity information system
NAOI	Neonatal Adverse Outcome Indicator
NHS	National Health Service
NHSLA	National Health Service Litigation Authority
NICE	National Institute of Health and Clinical Excellence
NMPA	National Maternity and Perinatal Audit
NNT	number needed to treat
NRES	National Research Ethics Service

ONS	Office for National Statistics
OPCS-4	Office of Population Censuses and Surveys Classification of Interventions and Procedures, version 4
OR	odds ratio
PPH	postpartum haemorrhage
RCOG	Royal College of Obstetricians and Gynaecologists
RCM	Royal College of Midwives
RCT	randomised controlled trial
RR	risk ratio
SD	standard deviation
SES	socioeconomic status
UK	United Kingdom
VBAC	vaginal birth after caesarean section

I. Overview of thesis

1.1. Thesis structure

This 'publication style' thesis comprises a collection of research papers, each of which seeks to address a different aspect of the overall aim: to determine the extent to which electronic data captured routinely as part of clinical care and hospital administration can be used to evaluate English NHS maternity services.

This introductory chapter provides an overview of the thesis as a whole, including the aims and objectives of the work. Chapter 2 provides background context for the work carried out. The overall methodology and data sources are described in Chapter 3.

The papers in chapters 4 and 5 are methodological in nature and seek to demonstrate how the analysis of routinely collected maternity data can be improved through the application of novel techniques for data validation and handling of missing data.

Chapters 6, 7 and 8 each contain a case study that demonstrates how the novel techniques developed in the methodological chapters can be applied to answer important clinical and health policy questions in the field of maternity care.

Chapter 9 demonstrates how a composite adverse neonatal outcome indicator developed using Australian routine data can be translated, adapted and validated using routinely collected, linked English hospital data.

Finally, Chapter 10 draws together the findings from the research carried out and makes a series of recommendations.

1.2. Contributions of the candidate

I have spent the last six and a half years working within the Clinical Quality department at the Royal College of Obstetricians and Gynaecologists (RCOG). My role has evolved during this time, but a consistent theme has been the design, management, analysis and reporting of a programme of work to provide maternity services in the UK with clinically meaningful and methodologically robust performance measures, that can be used to inform quality improvement initiatives.

As part of my contract with the RCOG, I had the opportunity to pursue a PhD alongside my job, with the aim of supporting the overall programme of work and at the same time advancing my academic development. The work contained within this thesis has been informed by, and is related to, the RCOG programme of work, but is not a formal project output.

I have designed and undertaken the analyses contained within this thesis myself, with appropriate guidance from my supervisors. My contributions and those of other authors are given at the start of each chapter.

1.3. Funding

The PhD was funded, in-part, by the RCOG, who were also my employers throughout the time I undertook this work. The RCOG played no part in the design and conduct of the research, nor the interpretation and presentation of the results.

1.4. Thesis aim and objectives

The broad aim of this thesis is to advance understanding of the ways in which *routinely collected maternity data* (a term which I use to refer to data that are routinely collected for either clinical or hospital administrative purposes) can and cannot be used to support the evaluation of English NHS maternity services.

The objectives of the research described in this thesis were:

1. To review the advantages and limitations of existing hospital administrative and clinical datasets, for the purposes of evaluating patterns of care and outcomes among hospital-based maternity services;

2. To develop techniques to address current weaknesses in the secondary analysis of these data, particularly in relation to the handling of missing or inconsistent information. This work sought to overcome concerns about data quality related to key data items, including mode of birth and parity. These data items are particularly important for the construction of maternity statistics and yet suffer from high data incompleteness;

3. To demonstrate how the novel techniques developed in objective 2 can facilitate applied research aiming to answer clinically relevant questions in maternity care. Specifically:

    - To define a subgroup of women giving birth following a primary caesarean section, and investigate the demographic and obstetric factors associated

with the uptake and success of vaginal birth after caesarean section (VBAC) in this group.

- To define a subset of hospitals with good quality data, and to define appropriate comparison groups that allow an examination of the association between induction of labour at term and selected maternal and perinatal outcomes in nulliparous women aged 35 years and over.

- To link three different sources of routinely collected data (hospital administrative data, electronic maternity records and obstetric staffing rotas) to determine whether rates of obstetric intervention and outcome change "out-of-hours," i.e., when consultants are not providing dedicated, on-site labour ward cover.

4. To evaluate the feasibility of constructing a composite indicator for severe adverse neonatal outcome. Such a measure could overcome reliance on individual diagnosis codes that may suffer from issues of low statistical power and under-recording in routine data.

1.5. Other outputs

Over the period that I conducted this research, I have also contributed to the production of the following reports and research articles. Although not a formal part of this thesis, much of this work draws on and has been shaped by the research I have undertaken as part of my PhD:

a) Geary RS*, Knight HE*, Carroll FE, Gurol-Urganci I, Cromwell DA, van der Meulen JH. A step-wise approach to developing indicators to compare the performance of maternity units using hospital administrative data. BJOG 2017; https://doi.org/10.1111/147-1-0528.15013. (*joint first authors)

b) NMPA project team. National Maternity and Perinatal Audit: Clinical Report 2017. RCOG London, 2017.

c) Harron KL, Doidge JC, Knight HE, Gilbert RE, Goldstein H, Cromwell DA, van der Meulen JH. A guide to evaluating linkage quality for the analysis of linked data. Int J Epidemiol. 2017 Oct 1;46(5):1699-1710. doi: 10.1093/ije/dyx177.

d) NMPA Project Team. National Maternity and Perinatal Audit: Organisational report 2017. RCOG: London, 2017.

e) Knight HE, Gurol-Urganci I, Mahmood T. Audit in Medical Research. In O'Brien S and Fiona Broughton-Pipkin F (eds) Introduction to research methodology for specialists and trainees. Cambridge University Press: Cambridge, 2017.

f) Carroll FE, Knight HE, Cromwell DA, Gurol-Urganci I, van der Meulen JH. Patterns of maternity care in English NHS trusts 2013/14. RCOG: London, 2016.

g) In 2014 I was seconded to the Department of Health for 9 months to provide analytical support and expertise to the Morecambe Bay Investigation into the management, delivery and outcomes of maternity and neonatal care at the Trust over a 10 year period. Kirkup B. The Report of the Morecambe Bay Investigation. The Stationary Office: London, 2015.

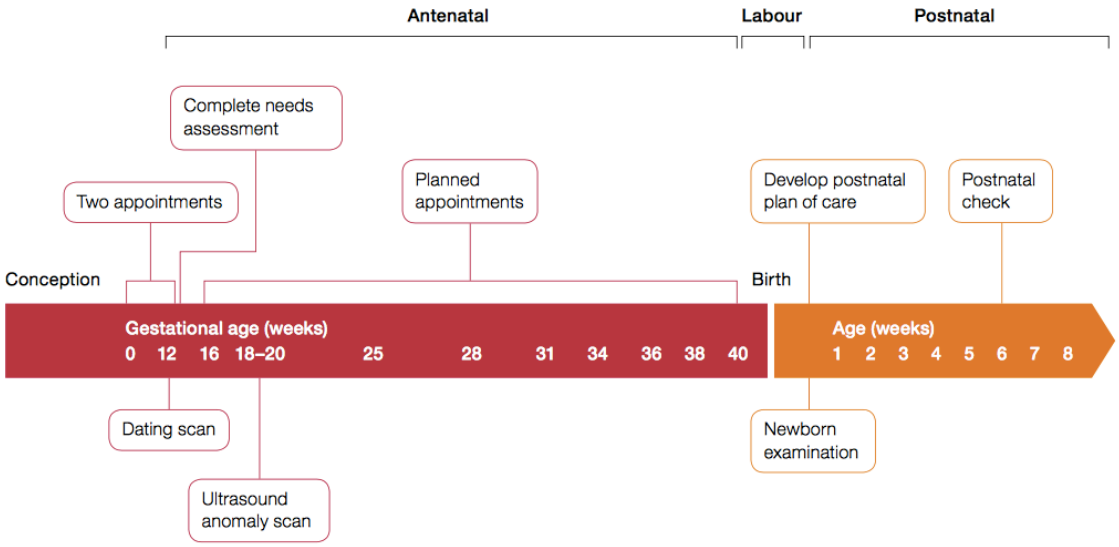
h) Knight HE, Cromwell DA, van der Meulen JH, Gurol-Urganci I, Richmond D, Mahmood TA, Dougall A, Johnson S. Patterns of maternity care in English NHS hospitals 2011/12. RCOG: London, 2013.

2. Background

2.1. Maternity services in England

Pregnancy is a time of sustained contact with the health service. The NHS maternity care pathway is complex and spans contraception services, pre-pregnancy care through to antenatal and delivery care and then early years and mainstream and specialist children's services (Figure 1).

Figure 1. The NHS maternity care pathway in England



Source: National Audit Office[1]

Pregnancy and birth are among the most common reasons for contact with the NHS, and obstetric admissions are the leading cause of hospitalisation for women in England, accounting for 636,401 discharges in 2016/17.[2] For many women, pregnancy is their first experience of being a regular user of the health service. The maternity care pathway therefore represents a unique opportunity for health professionals to support women to maximise their own health, as well as their child's health and development, during

pregnancy, birth and beyond, through the promotion of healthy lifestyles and potential interventions.[3 4]

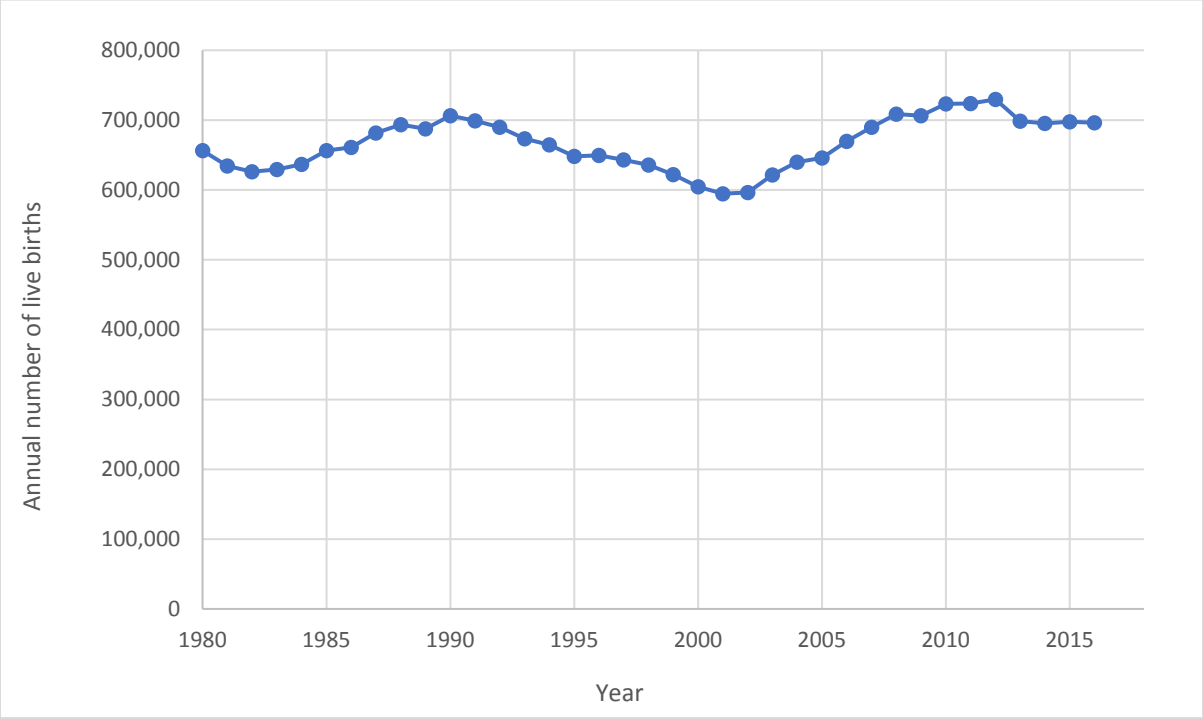
Pregnant women receive care from a variety of different health professionals. All women see a midwife for their first antenatal ('booking') appointment. Midwives then act as the care coordinator for the remainder of the pathway and as lead professional for those at low risk of complications. For women at higher risk or undergoing medical procedures, care is also provided by doctors, led by consultant obstetricians. Care of healthy babies is provided by midwives, while neonatal doctors and nurses provide care to babies who need additional support, for example because they are born prematurely or have clinical conditions or concerns.

Since the early 1990s, maternity care policy in England has promoted women's choice of place of birth. There are three types of location in which women can give birth: obstetric units (OU), midwifery units (MU) (either alongside an obstetric unit [AMU] or freestanding [FMU]) and at home. The number of AMUs in England has quadrupled since 2007, from 26 to 106. 68% of obstetric units are now co-located with a midwifery unit.[5] Despite the increasing availability of midwifery units and national policy that now recommends that women at low risk of complication should be encouraged to plan to give birth in a midwifery-led setting,[6 7] the proportion of women giving birth in these settings is around 14%. An estimated 2% of women give birth at home, with the remainder (84%) giving birth in an OU.[8] Significant variation between services in the use of midwifery-led settings has also been reported (4-31%).[8]

2.2. Challenges facing maternity services

There have been considerable fluctuations in the number of women giving birth in England over the last four decades (Figure 2). Between 2001 and 2012 the annual number of births rose at a rate of approximately 2% per year to its highest level in over 40 years. In 2013 the number of births per annum fell slightly to just under 700,000 and has remained at this level for the last four years.[9]

Figure 2. Annual number of live births in England and Wales between 1980 and 2016



Source: Office for National Statistics[9]

At the same time as increasing birth numbers, there has been increasing pressure on the frontline NHS workforce due in part to challenges with recruitment and staff retention in the wake of austerity, the Brexit referendum vote and the lessons learned from the Mid Staffordshire hospital scandal.[10] [11] Maternity staffing is no exception. The ratio of midwives

to births has fallen,[12] with significant between-unit variation in the number of beds per rostered midwife.[5] In 2017, 88% of obstetric units reported a gap in their middle grade obstetric rota and 83% reported that locum cover was required to staff their middle grade rotas in the previous 3 months.[5] The level of continuity of carer (i.e. seeing the same midwife throughout the antenatal, intrapartum and postnatal period) that maternity services provide is low, regardless of which model of midwifery staffing is used.[5]

Another challenge facing maternity services is that the characteristics of women giving birth are changing. An increasing number of pregnancies are occurring to women over the age of 35, obese women, and women with co-morbidities.[1 4 9 13] An increase in the rate of multiple births associated with fertility treatment [14] has also led to greater need for specialist care. The rising number of women born outside the UK also presents issues for maternity services related to language and social expectations of care.[9]

The NHS spends around £2.6 billion each year on maternity services, which represents around 3% of health spending.[1] This is about the same proportion as a decade ago. Nearly a fifth of the maternity budget is spent on clinical negligence cover, which totalled £482 million in 2012-13. Maternity care accounts for around a third of the total NHS clinical negligence bill, higher than any other clinical specialty, and the total cost of claims is rising.[1]

Despite the increasing clinical, staffing and financial pressures on maternity services, giving birth in England is likely to be safe for the overwhelming majority women and babies.[15] The rate of stillbirth in England is 3.93 per 1,000 births, while 8.8 women per 100,000 die during pregnancy or shortly after giving birth.[13 16] The overall perinatal mortality (stillbirth or the death of a baby up to 28 days after birth) in England has also fallen from 9.37 to 7.11 per

1000 births between 2003 and 2015.[9] However, stillbirth rates in England remain higher than in many other European countries where rates below 2 per 1000 have been achieved.[17 18]

In 2008, the Kings Fund report '*Safe births: everybody's business*' concluded that, whilst the majority of births are safe, "some births are less safe than they could or should be."[15] There have been a series of reports documenting cases of inadequate care over the last decade,[15 19 20] and the safety and the quality of care delivered by maternity units still continues to attract a high level of public interest. For example, a 2017 confidential enquiry report into term, intrapartum-related perinatal deaths found that that in 80% of cases, different care might have prevented the baby's death.[21] There is also evidence of substantial variation in maternal and perinatal mortality within England across women from different socioeconomic and ethnic backgrounds.[13 16]

Rates of other more common birth outcomes such as emergency caesarean section, obstetric haemorrhage and severe perineal tears have also been shown to vary among hospitals, even after accounting for differences in maternal clinical and demographic characteristics between areas.[5 22 23] This variation is a source of concern because it suggests the care that women receive is dependent upon where they live, and implies that NHS resources may not be being used in the most efficient way.

In 2017, almost half of Care Quality Commission (CQC) inspections of maternity services resulted in assessments that were either rated 'inadequate' (7%) or 'requires improvement' (41%).[24] A recent report by the National Audit Office concluded that there was "significant and unexplained local variation in performance against indicators of quality and safety, cost, and efficiency."

In conclusion, like many NHS services, maternity services have been under sustained pressure over the last decade. Several new policy initiatives have been introduced in recent years aimed at improving the safety, effectiveness and experience of maternity care, reducing unnecessary intervention, and reducing inequalities.[1 4 25]

In order to understand the extent to which maternity services are coping with this increased pressure and judge the success of new policy initiatives, clinically meaningful and technically robust methods of measuring and evaluating the performance of services are required. Such information would allow the NHS to examine whether current practice in maternity care meets guidelines and standards, and to compare service provision and maternal and neonatal outcomes among providers. The next section of this thesis will consider the challenges that valid and accurate measurement poses, and explain the rationale for this thesis.

2.3. Evaluating the performance and quality of maternity services

2.3.1. Measuring quality in health care

The importance of measurement in healthcare has been understood for at least 150 years. In 1863, Florence Nightingale in the 3rd edition of her Notes on Hospitals wrote about the need for hospital-level statistics on surgical complication rates, "If wisely used, these statistics would tell us more about the relative value of particular operations and modes of treatment than we have any means of ascertaining at present."[26]

This drive towards measuring outcomes in healthcare of course needs to be done with the well-known adage originally penned by William Bruce Cameron in mind: "Not everything that can be counted counts, and not everything that counts can be counted."[27]

Quality in healthcare is a multifaceted concept, not amenable to a single performance measure or simple metric. There is broad agreement that the key domains of quality are: effectiveness, capacity, safety, patient-centeredness, equity, access and timeliness,[28] yet within each clinical specialty, there is varying agreement about what aspects of care should be evaluated within these domains.

The accurate measurement of the processes and outcomes of care is now seen as crucial for guiding service improvement.[29-32] Such information aims to fulfil various roles: informing policy making at regional and national levels; supporting clinicians and providers to improve care through comparative benchmarking; identifying unexpected levels of performance to protect public safety, and providing consumer information to facilitate choice of maternity care provider.

2.3.2. Measuring quality in maternity care

Maternal and perinatal health statistics are considered to be among the best indicators of the effectiveness of an entire health system, because pregnant women require a system that functions well 24 hours a day across the whole range of services, from community care to the most specialised of hospital treatments.[33]

The RCOG defines high quality women's health care as "a medical service which focuses on [women's] needs, is safe and effective and meets their expectations".[3] However, the

evaluation of maternity care extends beyond this because there are two individuals to consider: the mother and the baby. Furthermore, the needs of mother and baby are not always aligned during pregnancy and sometimes a careful balance between the two has to be sought by the care team. For example, pre-eclampsia is a condition that can arise during the third trimester, characterised by hypertension and proteinuria. Left untreated, it can develop into life-threatening eclampsia. The only cure for pre-eclampsia is to end the pregnancy by delivering the baby. However, in practice most women with this condition continue their pregnancy under close observation until 37 weeks of gestation to minimise the risks to the baby associated with preterm delivery.[34]

As this example illustrates, what constitutes 'good' quality maternity care is therefore highly dependent upon the individual context, which includes a woman's individual preferences as well as factors such as parity, past obstetric history, fetal presentation, length of gestation, and the presence of pre-existing or pregnancy-related clinical conditions.

There are three major categories of measure that can be applied to the different domains of quality in healthcare. Quality measures may cover the *structure* of care (the setting in which care is organised and delivered); the *processes* of care (what was done, to whom and when) or the *outcomes* of the care received.[31] These categories of measure each have relative strengths and weaknesses. Outcome measures are of greater intrinsic interest, but are often hard to interpret because differences in outcome across organisations may not necessarily reflect differences in the quality of care.[35] Conversely, process measures are only appropriate as direct measures of the quality of care if there is strong evidence for a particular treatment or intervention: the more patients without contraindications who receive a proven therapy, the better.[35]

Process measures are important in maternity care because the ability to provide an appropriate response to emergency situations is one of the pillars of a high-quality service. Obstetric emergencies, such as fetal distress or dystocia, may develop rapidly and without warning, often in previously uncomplicated pregnancies, and quick decisions have to be taken by the care team about which intervention to use. However, using process indicators to measure quality in maternity care is problematic because the most common obstetric interventions (e.g. induction of labour; caesarean section) are not associated with an 'optimal' rate, and cannot be compared against a national standard or benchmark.

Outcome measures are crucial in the assessment of patient safety, but they also pose problems for monitoring the quality of maternity care, because poor outcomes are relatively rare. Maternal mortality may act as a sentinel indicator but the signal to noise ratio is too low to be used for quality improvement.[36] Perinatal mortality is a more common outcome, yet only a minority of cases have a known cause[37] and it is therefore not necessarily appropriate to use these cases to make judgments on quality of care.

Instead, many quality indicators in maternity care are based on obstetric complications, such as severe postpartum haemorrhage or perineal lacerations. However, again not all of these complications are preventable and statistical power can also be an issue with some of these rarer morbidities, particularly if rates are stratified by maternal characteristics, or derived for small maternity units. Several composite indicators of maternal and neonatal morbidity have been developed and now require further validation.[38-41]

Outcomes include not only mortality and morbidity, but also women's experience of care. It is also important to reflect not only what outcomes are important for an individual mother

and her baby during the current pregnancy, but how decisions taken in one pregnancy can impact on future pregnancies the mother may have. In a publicly funded health system such as the NHS, there are also wider health policy economic considerations about maximising outcomes for the greatest number of women and babies.

Perhaps the most commonly used maternity indicator, the overall caesarean section rate, is one of the most difficult to interpret. Lower caesarean section rates are often assumed to reflect better care. However, there is also a threshold below which the caesarean section rate is too low and babies may be harmed. One problem is that there are no established guidelines for determining this threshold. A second problem is that as maternal request for caesarean section is now an option supported by national guidance,[42] this measure may no longer be a reliable marker of quality of care but rather one of patient choice. The caesarean section rate is also complicated by the fact that it can be considered both a process of care and an 'outcome' of other processes of care further downstream, for example induction of labour.

Several techniques have been proposed that could aid the interpretation of the caesarean section rate, for example, stratification by type of caesarean section or specific delivery characteristics,[43 44] or statistical adjustment that takes into account risk factors for caesarean section among different populations.[45 46] However, these techniques have not yet been applied to national maternity statistics for England; instead official maternity statistics for England continue to publish the overall caesarean section rate in each hospital.[2]

Exploring variations in maternity care without a full understanding of the clinical complexities may lead to erroneous conclusions. For example, a higher proportion of women in the South of England have a caesarean section than in the North,[47] which has been used as

evidence by some commentators that women from more affluent areas are "too posh to push".[48] However, further exploration of the data demonstrated little variation between NHS trusts in rates of elective caesarean section.[45] Most variation in overall rates of caesarean section was associated with rates of emergency caesarean section, which reflects how clinicians respond to emergency situations during labour (e.g. fetal distress or dystocia) rather than the choices that women make about how they want to deliver their baby.

It is partly due to the complexity illustrated by this example that there is an ongoing debate about what information should be used to evaluate the quality of maternity care.

2.3.3. Rationale for thesis

There has been growing interest in performance monitoring and quality improvement in maternity care, both in the UK and elsewhere. Many performance indicators for maternity care have been proposed, although little consensus has been reached within the specialty on a "minimum core set". A review of guidance documents produced by the RCOG revealed 290 quality indicators covering 96 clinical categories, with up to 18 definitions for each category.[49]

It is not clear why progress towards a consensus has not been made in this field, which is concerning because medical errors are more common in maternity care than other medical specialties.[50] Maternity litigation claims, as a group, are the most expensive clinical negligence claims reported to the NHS Litigation Authority (NHSLA) and the second highest by volume.[51] Furthermore, when errors are made these have the potential to adversely affect the lives of two individuals, as well as those of the wider family and society.

The starting point for the work contained in this thesis was a recognition that a growing number of organisations in England were beginning to use routinely collected data for evaluating maternity services, and/or producing information about local services for the public. These organisations included both public sector and voluntary organisations (such as the CQC, NHS Digital and Birthchoice UK), as well as commercial companies (such as Dr Foster Intelligence and CHKS). Routine data were also being used more regularly by academics to conduct research in maternity care.[45 52]

However, the information produced by some of these groups was often difficult to interpret because the analysis either failed to adequately take into account some of the challenges described in section 2.3.2, or failed to describe how the common pitfalls of using this type of data were tackled. For example, the comparative statistics published by NHS Digital and Birthchoice UK were not presented in a way that revealed how much variation might be due to the influence of random fluctuations, and also did not use methods to take into account differences in the case mix between hospitals. In other specialties with more established performance monitoring,[53] it is widely accepted that conclusions about quality of care can only reasonably be drawn after differences due to these factors have been removed.

The difficulty faced by clinicians, managers and service users in interpreting some of the currently available maternity statistics highlights the need to improve the usefulness of the information being produced on NHS maternity services. This thesis focuses on several of the methodological issues which have not been given due attention in some of the previous publications to make use of routinely collected maternity data.

Despite the inherent conceptual and practical challenges, the development of methods for defining key processes and outcomes in maternity care using routinely collected data would

not only guide research and initiatives to improve the quality of maternity services at regional and national level, but would support obstetricians and midwives through comparative benchmarking and the ability to monitor safety and identify unexpected levels of performance. These data, together with appropriate structural indicators and measures of maternity service user experience, would also provide information that would help women choose their maternity care provider.

3. Thesis methodology and data sources

3.1. Overview of thesis methodology

The studies within this thesis were based on retrospective cohort design, and make use of routinely collected data sources. In this thesis, the term *routinely collected data* is used to refer collectively to hospital administrative data and data collected as part of routine clinical care.

While some commentators have argued that experimental methods are the gold standard for evaluation and that observational methods hold little value, it is increasingly accepted that observational studies may provide a complementary approach for evaluating effectiveness in healthcare, and that "policymakers need data from both approaches when making decisions about health services."[54]

Like any study design, retrospective cohort studies have both advantages and limitations.[55] The specific pros and cons of using routinely collected data for retrospective cohort studies in maternity care are discussed further in section 3.3, with particular emphasis on the following elements: clarity of population definition, measurement of outcome and exposure variables, and measurement of confounders.

More generally, an advantage of retrospective, population-based cohort studies is that they can offer large, representative samples impossible to achieve with experimental methods, in which the type of patients, providers and settings that consent to participate are often atypical. This is particularly important for studies in maternity in which adverse outcomes are often rare.

Retrospective cohort studies also have the advantage over experimental methods of maintaining the integrity of the context in which care is delivered, which helps to ensure they have good external validity. External validity refers to the extent to which results of a study can be generalised to other situations and to other people. This is an important concept in health services research that aims to evaluate the effectiveness of interventions within real health systems.

On the other hand, the retrospective nature of the data used in these studies, which has often not been collected primarily for the purposes of the research, means that the recording of risk factors may not cover all relevant confounders, and/or that the quality of the data on confounding variables may be insufficient. The ability to draw causal conclusions based on the results (i.e. the internal validity of the study) may therefore be undermined because of the role of unrecognised confounding factors.

Finally, an advantage of cohort studies is that the exposure has been recorded before the outcome occurs, which can allow the temporal sequence of risk factors and outcomes to be assessed. There is usually no reason to suspect that systematic differences in recording will exist between groups of patients. However, this is an important assumption to test through validation studies or sensitivity analyses when designing a retrospective cohort study using routine data.

3.2. Data sources used in this thesis

Before discussing the advantages and limitations of using routinely collected data for retrospective cohort studies, the two sources of data used in this thesis (Hospital Episode

Statistics (HES) and data from electronic maternity IT systems) will be briefly described in turn.

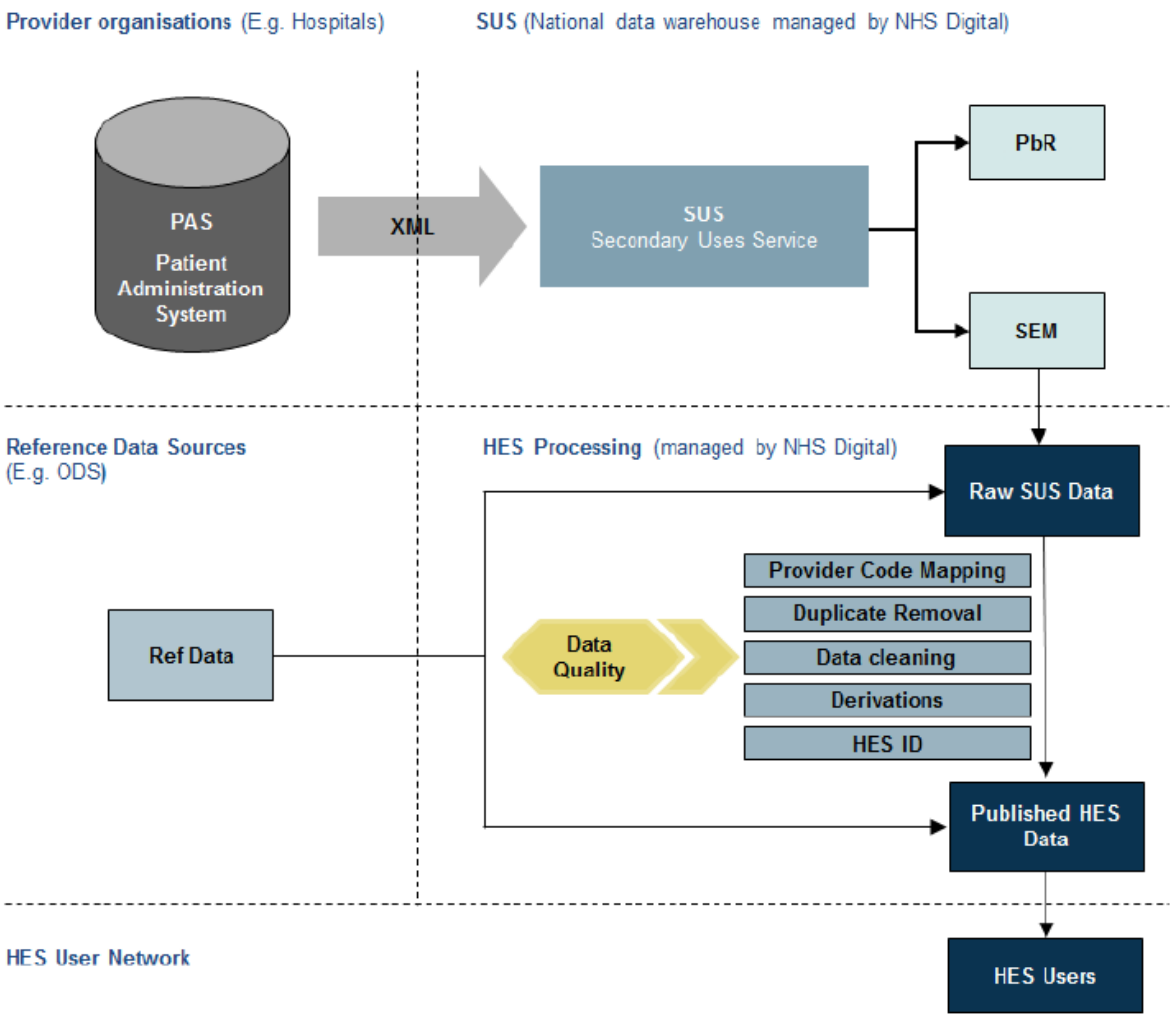
Although both data sources constitute routinely collected data, they serve different primary purposes. The primary purpose of hospital administrative datasets like HES is that they support the allocation of resources to hospitals for the care they deliver, and the data are typically entered into patient administration systems by clerical coders from discharge summaries. In contrast, during direct clinical care, data are also routinely collected in clinical information systems for the purpose of monitoring the patient's condition, and aiding continuity of care and referrals between professionals. As this thesis illustrates, both types of data can be processed and used for other purposes, known collectively as 'secondary uses' of data.

Capturing electronic data once at the point of care, with extracts available for secondary use is advantageous both in terms of efficiency and cost-effectiveness. Avoiding duplication in data capture reduces the burden on frontline clinicians and administrative staff, and reduces the time lag between when data are captured and when they are available for other, non-clinical purposes. Users of secondary data include the national governments and regulatory bodies, academic researchers and commercial healthcare organisations.

3.2.1. Hospital Episode Statistics (HES)

HES is a data 'warehouse' that includes records of all admissions, A&E attendances and outpatient appointments at NHS hospitals in England, accounting for over 125 million records per financial year.[56] The data are extracted from the patient's notes and entered onto local patient administration systems by clinical coders (Figure 3).

Figure 3. Overview of the data flows from healthcare providers into the HES dataset

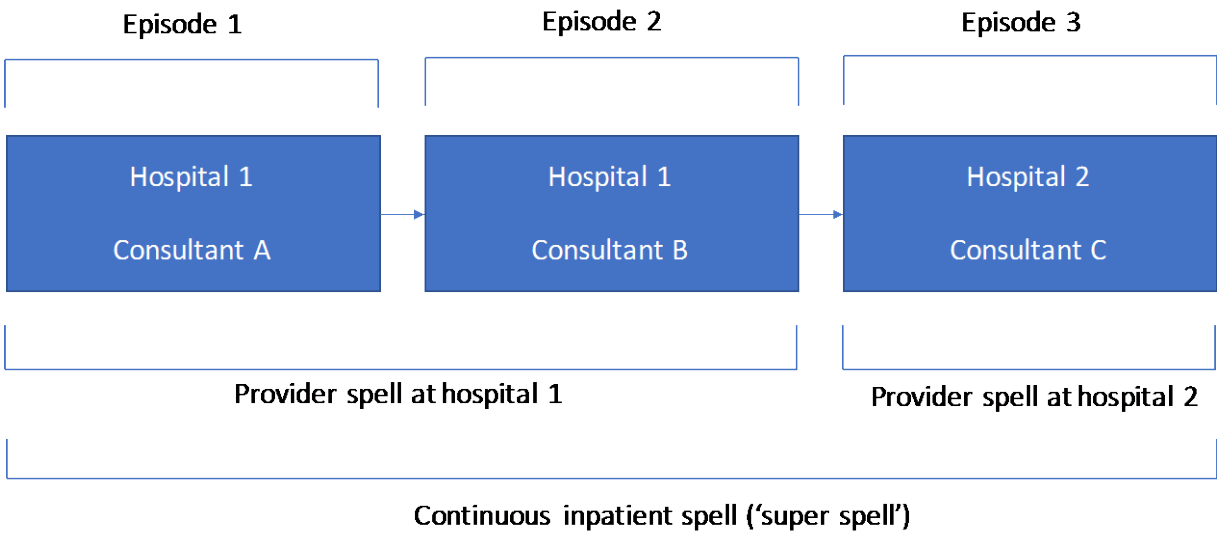


Source: NHS Digital. "The processing cycle and HES data quality"

The basic unit of activity in HES is the finished consultant episode, covering the period a patient is under the care of one consultant. A patient's entire stay in hospital is known as a provider spell. A provider spell can be made up of one or more episodes of care delivered by the provider NHS organisation. If the patient is transferred to another hospital, dies or is discharged, the episode and the provider spell end. If a patient is transferred directly from one hospital provider to another, this results in a continuous inpatient spell or ‘super-spell’.

The relationship between episodes, provider spells and continuous inpatient spells is summarised in Figure 4.

Figure 4. Demonstration of how episodes, providers spells and continuous inpatient spells relate to each other



In the HES inpatient database, each record contains data on the patient demographics (for example, age, sex, ethnicity, postcode), the episode of care (for example, hospital name, date of admission and discharge) and clinical information. Diagnoses for each patient are recorded using the International Classification of Diseases, 10th edition (ICD-10).[57] Procedures performed during an episode are coded using the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures, 4th revision (OPCS).[58]

In addition, each episode related to the delivery of a baby can capture details about the labour and delivery (for example, mode of delivery, gestational age and birthweight) in supplementary data fields known as the HES 'maternity tail'. For multiple births, each maternal delivery record can hold up to 9 baby tails (up to 6 prior to 2002). For babies' birth

episodes, a similar 'baby tail' exists. For an individual mother-baby pair, the two 'tails' should contain the same information; however, there is no routine linkage of maternal and baby records within HES: the maternal NHS number is not available on the baby record or vice versa. The maternity (or baby) tail is not compulsory and the level of data completeness varies across NHS trusts. The level of data completeness has improved over time,[52 59] but varies between different NHS trusts: in 2014, data on onset of labour and gestational age were available in 85% and 82% of all delivery episodes, respectively. The majority of records missing this information were from trusts that failed to submit any 'maternity tail' information for births under their care.

One of the advantages of HES is that each patient is assigned a unique identifier (the HESID). This makes it possible for researchers to study longitudinal patterns of care, such as rates of unplanned readmission following a particular procedure, as well as enabling the tracking of patients between hospitals without needing access to any personal identifiers. HESID is assigned using a deterministic rule-based algorithm based on NHS number, local patient identifier, sex, date of birth and postcode.

For the purposes of the work contained within this thesis, HES records were defined as relating to a delivery (i.e. belonging to the mother) if 'method of delivery' information was found in any procedure field (OPCS codes R17 - R25) and/or the maternity tail field. For the analyses in which HES birth records (i.e. records belonging to the baby) were used (see Chapters 8 and 9), births were identified by the presence of ICD-10 codes Z37-Z38, HRG codes N01-N05 (neonates) or HES fields relating to episode type, method of admission, age at start of episode and level of neonatal care.

3.2.2. Maternity Information Systems (MIS) Pilot

The majority of NHS hospitals in the UK use electronic Maternity Information Systems (MIS) to capture detailed demographic and clinical information related to each pregnancy and delivery under their care. These databases often include data from antenatal booking through to postnatal care. Although each MIS collects slightly different information, there is sufficient similarity between MIS to allow a minimum dataset to be developed.

This thesis used a dataset created as part of the RCOG MIS Pilot Project. Building on a successful feasibility study conducted in 7 NHS trusts in South West England, the MIS Pilot Project aimed to assess the feasibility of creating a multi-centre dataset using electronic maternity records for the purpose of developing clinically meaningful performance indicators for maternity care. A secondary aim of the pilot was to assess the feasibility of linking this dataset with HES data for a subset of women giving birth in English NHS trusts.

The MIS pilot began by contacting trusts to request their interest in participating. A survey was disseminated to all Clinical Directors of UK trusts / health boards with a maternity service (n = 164) (Appendix 1), and respondents were asked for information about their MIS and whether their organisation would be interested in participating in the pilot study.

Ninety trusts responded positively and 25 were shortlisted on the basis of their size, geographic location, and type of MIS. Telephone calls were conducted with the clinical director and lead midwife for informatics at each trust to determine their ability to supply the required data item and their willingness to participate in the pilot. Following these telephone calls, 19 of the 25 trusts confirmed that they were able to participate. Each trust

supplied a retrospective 12-month extract of patient-level MIS data in accordance with a pre-defined specification (Appendix 2).

In order to collect patient identifiable data (NHS number, date of birth, post code) required for linkage with HES without informed consent from individual women in the cohort, it was necessary to seek relevant regulatory approval (Section 251) and to prepare data sharing agreements with each of the participating units (Appendix 3). Permissions were also granted for the database to be used for the purposes of this thesis.

The individual NHS trust extracts were cleaned and pooled to create a single database comprising 112,458 infants born between 1 April 2012 and 31 March 2013, representing approximately 15% of the total number of births in the UK during this period.

The participating maternity units ranged in size from 1,800 to 9,800 deliveries per year. Two were large specialist women's hospitals, 15 were teaching/university hospitals, and two were district general hospitals. Fifteen of the maternity units were located in England, one in Scotland, one in Wales, and two in Northern Ireland. All had an obstetric unit able to provide the full spectrum of obstetric care.

For the births in English units, MIS records were linked with the HES database by the HSCIC Data Linkage and Extract Service using a deterministic linkage algorithm based on the following patient identifiers: NHS number, date of birth, postcode and sex. 99.8% of mothers and 99.1% of babies in the MIS cohort could be linked with a HES birth record, giving a total match rate of 99.4%. 82.4% of the linked records matched exactly on all four identifiers (match rank 1).

A linked MIS/HES dataset has the advantage of containing more detailed information than either data source alone. For example, the MIS dataset contains information on maternal and neonatal outcomes that are not captured in HES, and HES contains information on events that happen after discharge from maternity services, for example, admission to neonatal care.

3.3. Why use routinely collected data for evaluating maternity care?

Although they have some important limitations, routinely collected data sources are often ideal for conducting retrospective cohort studies. In countries in which routinely collected datasets exist, these are attractive data sources for evaluating health interventions and services due to their often large sample sizes, lack of selection bias, and the relatively low costs of accessing these data compared to conducting primary data collection.

Turning specifically to routinely collected maternity data, in countries with national birth registers such as Sweden and Finland, these datasets cover the whole population and therefore minimise the possibility of selection bias.[60] In England, more than 96% of all deliveries occur in NHS hospitals and are captured by HES.[6] Home births should in theory also be recorded in HES but in practice are often missing. Although these account for only a small proportion (approximately 3%) of all births, they represent an important group and their absence limits the purposes for which HES can be used. Home births are recorded in the ONS birth register and, in the majority of hospitals, are entered on to the local electronic maternity record system. Linkage with these datasets therefore offers opportunities to capture these missing births and provide a truly population-based sample.

The HES dataset captures multiple procedures and diagnoses at the patient level, providing a rich description of patient characteristics and clinical risk factors for cohort studies. Many variables relevant for defining processes and outcomes of maternity care are recorded in HES, in particular in the diagnosis and procedure fields and in the 'maternity tail'. However, not all relevant information is captured and the level of clinical detail that would be needed for some questions to be adequately addressed is insufficient. For example, several important risk factors for maternal and neonatal outcomes, such as maternal BMI at booking, smoking and alcohol consumption, are not recorded in HES. This means they cannot be taken into account as possible confounders, although record linkage can extend the range of data items available and thus can improve the validity and quality of hospital administrative data. For example, MIS data routinely contains information about maternal risk factors that are captured at the booking appointment (BMI, smoking, alcohol use) as well as several outcomes important that are not available in HES, including estimated blood loss at delivery and the baby's Apgar score at 5 minutes.

In addition to limitations related to the level of clinical detail available in HES, concerns have been expressed about the accuracy and completeness of diagnosis and procedure coding,[19] which call into question its credibility as a reliable source of maternity data and limit its usefulness for cohort studies. For example, in a letter published in the BMJ in 2012, Brennan et al. (2012) expressed their surprise at finding over 17,000 *male* inpatient admissions to obstetric services between 2009 and 2010.[61] This letter generated widespread concern that basic information, in this case the sex of the patient, was being erroneously entered on a large scale. However, a reply from the database administrators revealed that almost all of these episodes were related to male newborns and were therefore likely to have been birth-

related episodes treated by associate specialties, rather than data entry errors.[62] This example highlights how, at first glance, routine data can be misleading if not subjected to careful data quality checks and systematic analysis.

A recent systematic review of discharge coding accuracy in HES data found that primary diagnosis accuracy has improved from 73.8% to 96.0% in the ten years since the introduction of Payment by Results.[63] Nonetheless, there are important issues around the standardisation of data definitions among units submitting data to a national data warehouse. Divergent coding practices can undermine meaningful comparisons and lead to inappropriate incentives and penalties being given to hospitals. Discrepancies in coding tend to occur where confusion exists about the definition of a particular data item. For example, in maternity care, uncertainty can be caused by the different ways in which the terms 'elective' and ‘emergency' caesarean section are used. The term 'elective' is variously used to describe a caesarean with no medical indication or a prelabour caesarean. In other situations, the terms 'elective' and 'emergency' are used to reflect a measure of the urgency. A similar problem exists around induction of labour, specifically in the distinction between induction (initiation) and augmentation (speeding up) of labour, both of which are performed using similar drugs and procedures. Lack of clarity around important clinical definitions such as these can lead to over- or under-estimation of the true rate.

The methodological element of this thesis will focus on some specific challenges that have not been given due attention in some of the previous publications to make use of routinely collected maternity data. These specific issues are summarised below:

1. *Assessing data completeness and accuracy*

In all epidemiological research, the problems arising from missing data need to be considered and dealt with appropriately. These investigations should involve evaluating the completeness and distribution of key data fields. Although an advantage of cohort studies is that the exposure is usually recorded before the outcome occurs, in routinely collected data sources an important issue that must be considered and tested is selective data incompleteness in different subpopulations. For example, data may be more likely to be entered electronically into the hospital discharge summary for a patient if a procedure was performed that is chargeable for reimbursement or if something unusual happened during the admission. Conversely, if a baby is born very prematurely and is transferred straight to the neonatal unit, data may not get entered onto the maternity system used to populate the birth record on the hospital's administrative system. The assumption that data are missing at random can often be tested through validation studies or sensitivity analyses.

Other methods to examine the internal consistency of routinely collected data include developing coding frameworks that combine diagnosis, procedure and administrative codes to assess miscoding. In this way, records with implausible values and hospitals with divergent coding practices can be identified and excluded from the analysis. Chapter 4 describes an example of this type of approach applied to the information on method of delivery available in English hospital administrative data.

Alternatively, if problems of data incompleteness or inconsistency are identified, methods to improve completeness that draw upon the unique features of the dataset can sometimes be developed. For example, there may be an alternative source of information within the database, or it may be possible to construct a replacement variable using a longitudinal

'look-back' approach. Chapters 4 and 5 describe the development of techniques in relation to missing information on method of delivery and parity in the HES database.

2. Defining obstetric populations and outcomes

Evaluating maternity care requires that key obstetric events can be reliably identified in the data source. The most fundamental event to be able to define is the birth episode itself, but other obstetric characteristics and outcomes will also be important depending on the specific question being asked.

As discussed above, routine datasets often provide a rich description of patient characteristics and clinical risk factors but can be limited by the amount of detail available or data completeness. Attention needs to be given to selecting the most appropriate combination of codes to define important groups of women, which often involves working with clinical experts to develop coding frameworks that combine diagnosis, procedure and administrative codes to minimise under- or over-ascertainment and reduce misclassification bias. Chapters 4 to 9 all include examples of this type of work. For example, in Chapter 7 it was necessary to apply the 'look-back' technique described in Chapter 5 to define a group of women having their second baby following a primary caesarean section, and to seek clinical input to be able to exclude those women with contraindications for VBAC. Likewise, in Chapter 8, the appropriate comparison group for examining the association of induction of labour with perinatal mortality also required careful consideration and construction.

Attempts should also be made to examine the concurrent validity of these definitions, for example by comparing the prevalence of a condition within the dataset to known national

prevalence rates. An example of this type of work can be found in Chapter 9 in relation to severe adverse neonatal outcomes.

3. Adjusting for confounders

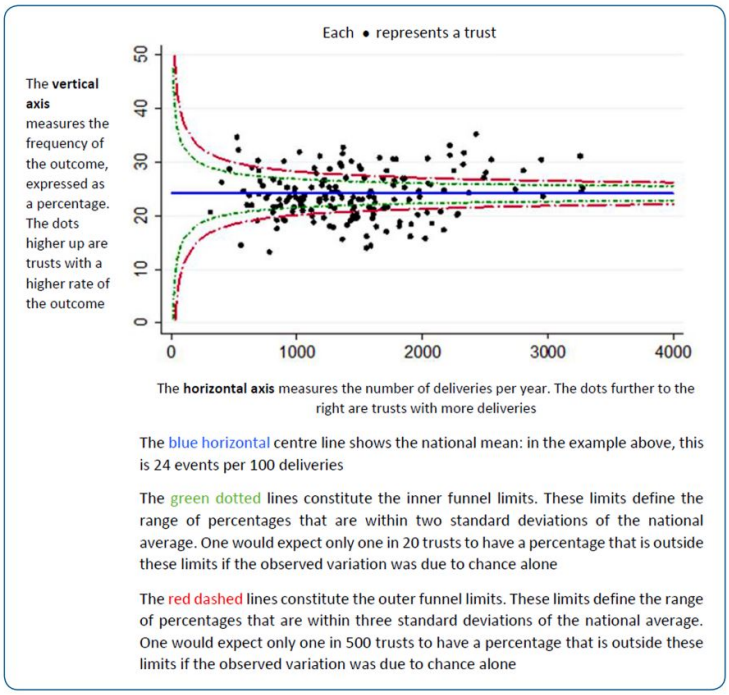
As discussed in section 3.1, being able to take confounding factors into account is a vital element of a well-conducted observational study. This may involve developing multivariate regression models to adjust for maternal characteristics or obstetric risk factors. Chapters 6 to 9 all include examples of controlling for case mix between maternity providers, as well as discussions on the limitations of routine data for this purpose when not all relevant risk factors can be identified in the data.

Routine data is good at capturing certain characteristics, however a particular limitation of HES maternity data is that for information governance restrictions there is no direct link between the mother's and the baby's record. This prevents an examination of how maternal characteristics or obstetric risk factors impact on neonatal outcomes. However, as described in Chapters 8 and 9, this limitation can be partially overcome through data linkage.

Presentation of data using funnel plots

A funnel plot is a graphical method for comparing the performance of institutions using cross- sectional statistics. The main advantage of this technique is that it takes the size of each institution into account. This is important because the amount by which a trust's indicator value may vary from the national mean is influenced by random fluctuations that are related to the number of deliveries at its maternity unit (Figure 5).

Figure 5. Interpretationof a funnel plot



The control limits within funnel plots highlight how much of the variation among organisations is over and above what would be expected due to chance alone. Several of the funnel plots presented in this thesis show evidence of a phenomenon known as overdispersion. Overdispersion occurs when there is a greater degree of variability among providers than can be explained by chance and the existence of a few outlying units. Important explanations for overdispersion are differences in data quality, limitations of risk-adjustment methods and clinical uncertainty.

3.4. Ethics

The research contained within this thesis is exempt from UK National Research Ethics Service (NRES) approval because it involves the secondary use of existing datasets of anonymised data for service evaluation: http://www.hra.nhs.uk/documents/2016/06/defining-research.pdf. All record-level data used in my research was de-identified and drawn solely from two sources. Approvals for the use of HES data were obtained as part of the standard NHS Digital data access process. The use of the RCOG MIS dataset for the purposes of this thesis is covered by a Data Sharing Agreement with each of the participating NHS trusts and a Section 251 approval (Appendix 3).

Development of techniques to analyse routinely collected maternity data

In Chapter 3, the advantages and limitations of routinely collected maternity data for evaluating hospital-based maternity services were reviewed (thesis objective 1) and a case was made for careful handling of these data in order for robust conclusions to be drawn. Particular challenges related to internal validity were highlighted: 1) assessing data completeness and accuracy, 2) defining obstetric populations and outcomes and 3) adjusting for confounders

In this section, the focus moves to thesis objective 2: the development of techniques to address current weaknesses in the secondary analysis of routine maternity data. The themes within this section relate particularly to the handling of missing or inconsistent information and the definition of obstetric populations.

4. Data quality assessment and validation: an illustration using method of delivery data

This chapter comprises a published paper based on a detailed analysis of the completeness and consistency within HES of a particularly key data item for maternity services: the method of delivery. This single piece of information is required for the construction of a great number of different maternity statistics, either to define the numerator (for example, the caesarean section rate), the denominator (for example, the rate of severe perineal tears among instrumental deliveries), or both.

In the HES database, method of delivery can be entered twice: 1) as a procedure code in the core HES database, and 2) in the supplementary maternity tail. 87% of delivery records have both data items present, but it is not clear which is the preferred data source, and no standard definitions of method of delivery are available for secondary users of HES. It is therefore critical that the impact of different ways of handling missing or inconsistent data is considered when selecting methods to define groups of women that have given birth by a particular method.

Statement of authorship

This chapter has been written as a published paper:

Knight HE, Gurol-Urganci I, Mahmood TA, Templeton A, Richmond D, van der Meulen JH and Cromwell DA. Evaluating maternity care using national routine datasets: How are statistics affected by the quality of data on method of delivery? BMC Health Serv Res 2013 30;13:200.

The authors have certified that:

a. they meet the criteria for authorship in that they have participated in the conception, execution or interpretation of at least that part of the publication in their field of expertise
b. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
c. there are no other authors of the publication according to these criteria;
d. potential conflicts of interest have been disclosed to granting bodies, the editor or publisher of journals or other publications and the head of responsible academic unit;
e. they agree to the use of the publication in the student's thesis and its publication on the LSHTM Research Online database consistent with any limitations set by publisher requirements.

Contributor	**Statement of contribution**
H.E. Knight	Conceived and conducted the research; designed and implemented the statistical analysis; wrote the first draft of the manuscript; modified the manuscript as suggested by co-authors and reviewers
Signature & Date:	H Knight 20.04.18
D.A. Cromwell, I. Gurol-Urganci, J.H. van der Meulen	Developed the research idea; advised on study design, statistical methods and analysis; supervised the research; assisted in editing the manuscript
T. Mahmood, A. Templeton, D. Richmond	Technical input into the clinical aspects of the work; interpreted the results from a clinical perspective; commented on the manuscript

Principal Supervisor Confirmation:
I have sighted email or other correspondence for all co-authors confirming their authorship.

Signature & Date:

20th April 2018

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Hannah Knight
Principal Supervisor	David Cromwell
Thesis Title	To what extent can routinely collected data be used to evaluate the performance and quality of English NHS maternity services?

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	BMC Health Services Research		
When was the work published?	30 May 2013		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
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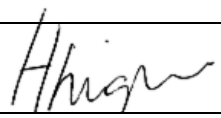
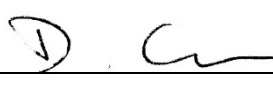
For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	see page 50

Student Signature:  **Date:** 20.04.18

Supervisor Signature:  **Date:** 20.04.18

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RESEARCH ARTICLE Open Access

Evaluating maternity care using national administrative health datasets: How are statistics affected by the quality of data on method of delivery?

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Abstract

Background: Information on maternity services is increasingly derived from national administrative health data. We evaluated how statistics on maternity care in England were affected by the completeness and consistency of data on "method of delivery" in a national dataset.

Methods: Singleton deliveries occurring between April 2009 and March 2010 in English NHS trusts were extracted from the Hospital Episode Statistics (HES) database. In HES, method of delivery can be entered twice: 1) as a procedure code in core fields, and 2) in supplementary maternity fields. We examined overall consistency of these data sources at a national level and among individual trusts. The impact of different analysis rules for handling inconsistent data was then examined using three maternity statistics: emergency caesarean section (CS) rate; third/fourth degree tear rate amongst instrumental deliveries, and elective CS rate for breech presentation.

Results: We identified 629,049 singleton deliveries. Method of delivery was not entered as a procedure or in the supplementary fields in 0.8% and 12.5% of records, respectively. In 545,594 records containing both data items, method of delivery was coded consistently in 96.3% (kappa = 0.93; $p < 0.001$). Eleven of 136 NHS trusts had comparatively poor consistency (<92%) suggesting systematic data entry errors. The different analysis rules had a small effect on the statistics at a national level but the effect could be substantial for individual NHS trusts. The elective CS rate for breech was most sensitive to the chosen analysis rule.

Conclusions: Organisational maternity statistics are sensitive to inconsistencies in data on method of delivery, and publications of quality indicators should describe how such data were handled. Overall, method of delivery is coded consistently in English administrative health data.

Keywords: Administrative health data, Maternity statistics, Method of delivery, Procedure codes, HES

Background

Countries which have administrative health data collection systems are increasingly using this information to produce maternity statistics at both local and national levels [1-3]. In the US, the Agency for Healthcare Research and Quality (AHRQ) developed a set of quality indicators based on administrative health data which included several areas of obstetric care [2]. These indicators have supported both national and local quality initiatives, and have been piloted in other developed countries including the UK, Canada, Spain, and Australia [4]. However, data quality remains a key concern for users of administrative maternity data and validation exercises are required to determine its accuracy and reliability prior to analysis [5].

In England, maternity statistics are produced by a number of organisations using the Hospital Episode Statistics (HES) database [6-9]. HES contains records on all patients

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admitted to English NHS hospitals, with data being extracted from local patient administration systems. The core fields of a HES record hold data on patient demographics and can capture up to 20 diagnoses and 24 procedures per episode of care. Delivery records can also capture supplementary data on the pregnancy and delivery, such as length of gestation, onset of labour, method of delivery and birth weight, for up to 9 babies. Not all delivery records contain this supplementary information (the 'maternity tail'), although the percentage of records with a complete maternity tail has improved over time.

A number of quality indicators for hospital maternity services require method of delivery for their construction, for example the caesarean section rate (where it is required for the numerator), and the rate of third/fourth degree perineal tears amongst women delivering vaginally (where it is used in the denominator). Despite the importance of data on method of delivery, there is no current information on the quality of this data in HES. This is of concern because there are two ways in which method of delivery can be recorded in HES, and it is not clear which is the preferred data source. Until 2006, the UK Department of Health published figures on the consistency of the two sources of method of delivery for each hospital [10]. In addition, the Department of Health used to conduct extensive cleaning of HES data before its release for secondary analysis, but this has been replaced by a simpler data validation process.

This paper describes an evaluation of how statistics on maternity care in English hospitals are affected by the completeness and consistency of data on method of delivery. The completeness and internal consistency of HES method of delivery data were evaluated at a national level and by NHS trust (hospital organisation). We then assessed how different analysis rules for handling poor quality HES data influenced a selection of maternity statistics.

Methods

We extracted from the HES database records of women who delivered in English NHS acute trusts between 1 April 2009 and 31 March 2010. Records were defined as relating to a delivery if "method of delivery" information was found in any procedure field and/or the maternity tail field. Table 1 maps the Office of Population Census and Surveys (OPCS) procedure codes R17-25 on to the maternity tail codes used to define method of delivery [11]. The definitions for each category are equivalent. However, the OPCS codes are entered by clinical coders based on the discharge notes, whereas the maternity tail data is typically populated directly from the electronic maternity information system, which is completed by midwives.

The analysis was limited to singleton deliveries. Records were excluded if they contained an International Classification of Diseases (ICD-10) diagnosis code for a multiple delivery (O30.1, Z37.2-.7 or Z38.3-.8) in any diagnosis field or the record contained data on more than one baby in the maternity tail.

Method of delivery was defined using a seven-category classification (Table 1). Both OPCS and maternity tail coding systems define 'elective caesareans' as prelabour caesarean sections and 'emergency caesareans' as an intrapartum caesarean sections. On inspection, a small number of hospitals had a value of "9" (other) in the maternity tail field for *all* deliveries, or seemed to have used this code to indicate an 'unknown' method of delivery. Consequently, if an NHS trust had values of "9" in the maternity tail field for more than 5% of their delivery episodes, all these values was re-coded as missing.

Data analysis

To examine data completeness for each NHS trust, we calculated the proportion of women for whom the method of delivery was recorded in a) the procedure fields, and b) the maternity tail. This analysis included all singleton delivery records. The subsequent analysis of coding consistency was restricted to women whose records contained information on method of delivery in both sources.

The mean rate of coding consistency was calculated by dividing the number of records with a consistent mode of delivery recorded in both the procedure field and the maternity tail by the total number of records containing valid information in both fields. We measured the overall level of coding agreement at a national level using the unweighted kappa (k) statistic. This measure ranges from 0 (a level of agreement no greater than would be obtained by chance) to 1 (perfect agreement). Values of k above 0.80 are generally considered to indicate excellent agreement [12].

We used funnel plots to examine variation among NHS trusts in the consistency of method of delivery coding [13,14]. The inner and outer control limits set at two

Table 1 Correspondence between OPCS procedure delivery codes and maternity tail "delmeth" delivery codes

OPCS code	Delmeth code	Method of delivery description
R17	7	Elective caesarean section
R18, R25.1	8	Emergency caesarean section
R19, R20	5, 6	Breech vaginal delivery
R21	2, 3	Forceps delivery
R22	4	Vacuum delivery
R23, R24	0, 1	Cephalic vaginal delivery without instruments
R25.2, R25.8, R25.9	9	Other method of delivery, including destructive operation to facilitate delivery

Both coding systems define elective caesareans as prelabour caesarean sections and emergency caesareans as intrapartum caesarean sections.

and three standard deviations above and below the national average, respectively. The limits also took into account a measure of over-dispersion. This was derived using the random-effects method and incorporated 10% winsorisation to prevent the limits being widened excessively by extreme outliers [14]. The 0-5th percentiles were winsorised to the 5th percentile and the 95-100th percentiles were winsorised to the 95th percentiles.

We selected three maternity statistics to investigate the impact of using different analysis rules for handling inconsistent data. These were selected to represent the various categories of maternity statistic that require method of delivery:

- Emergency caesarean section rate (where method of delivery is the numerator);
- Third and fourth degree perineal tear rate amongst instrumental deliveries (where method of delivery is the denominator), and
- Elective caesarean section rate for breech presentation (where method of delivery affects both numerator and denominator).

Breech presentation was defined using ICD-10 codes O32.1, O64.1, O80.1 and O83.0-1 and/or OPCS or maternity tail codes for breech vaginal deliveries. We defined third and fourth degree tears as records with an ICD-10 code for third or fourth degree perineal laceration (O70.1; O70.2) and/or an OPCS procedure code for their repair (R32.1; R32.2).

Five versions of each statistic were produced using different analysis rules for dealing with inconsistencies in the method of delivery data (see Table 2 for definitions). To investigate the impact of these different rules on trust-level maternity statistics, we used mean-difference plots [15] to assess the agreement between two sets of figures, namely, figures derived using data on method of delivery from only the procedure fields (the approach currently used by the NHS Information Centre) [10] and figures derived using only those records for which the procedure and maternity tail data were in agreement (the most restrictive of the five analysis rules). STATA 11 (TX: StataCorp LP) was used for all statistical calculations.

Table 2 Impact of mode of delivery definition on resulting maternity statistics: three case studies

Definition rule	Numerator	Denominator	# Trusts	Rate (%)
Emergency caesarean section rate				
1	89,572	624,199	151	14.35
2	75,370	550,763	140	13.68
3	70,298	525,192	140	13.39
4	81,964	573,497	140	14.29
5	82,701	578,223	140	14.30
Third and fourth degree perineal tear rate amongst instrumental deliveries				
1	5,049	76,161	144	6.63
2	4,260	64,661	136	6.59
3	3,965	60,281	135	6.58
4	4,640	70,268	133	6.60
5	4,686	71,205	133	5.58
Elective caesarean section rate for breech presentation				
1	11,852	23,640	147	50.14
2	10,066	21,691	139	46.41
3	9,378	17,834	138	52.58
4	10,919	21,776	136	50.14
5	10,928	21,851	136	50.01

Key to definition rules.
1 = Use all episodes with an OPCS method of delivery code & base method of delivery definitions on OPCS codes alone.
2 = Use all episodes with a delmeth code & base method of delivery definitions on delmeth codes alone.
3 = Use only episodes in which both OPCS and delmeth codes are present and in agreement; base method of delivery definitions on agreed method of delivery code.
4 = Use all episodes with an OPCS method of delivery code excluding those from trusts with a poor agreement rate; base method of delivery definitions on OPCS codes alone.
5 = Use all episodes excluding those from trusts with a poor agreement rate; base method of delivery definitions on OPCS codes, or delmeth codes if OPCS codes are missing.

Results

Completeness of method of delivery codes

We identified 629,049 singleton deliveries in 151 English NHS trusts between 1 April 2009 and 31 March 2010. Among these, 545,594 records (86.7%) had method of delivery entered in both the procedure and maternity tail fields (Figure 1).

Method of delivery was mostly commonly entered as a procedure code, being omitted in just 4,850 records (0.8%) overall. All but four NHS trusts had a "method of delivery" procedure code in more than 95% of their deliveries, and in no trust was this code available in less than 90% of deliveries. In contrast, 78,605 records (12.5%) had method of delivery missing from the maternity tail. Only 96 of the 151 NHS trusts had a maternity tail "delivery" code in more than 95% of their deliveries, and seven NHS trusts had no information on delivery method in the maternity tail of their records.

Overall coding consistency

Among the 545,594 singleton deliveries with information in both the procedure and maternity tail fields, method of delivery was coded consistently in 96.3% records (kappa = 0.93, $p < 0.001$) using the seven category coding framework (Table 3). The overall rate of each delivery method differed by between 0 and 0.5% (e.g. the overall emergency caesarean section rate was 13.9%

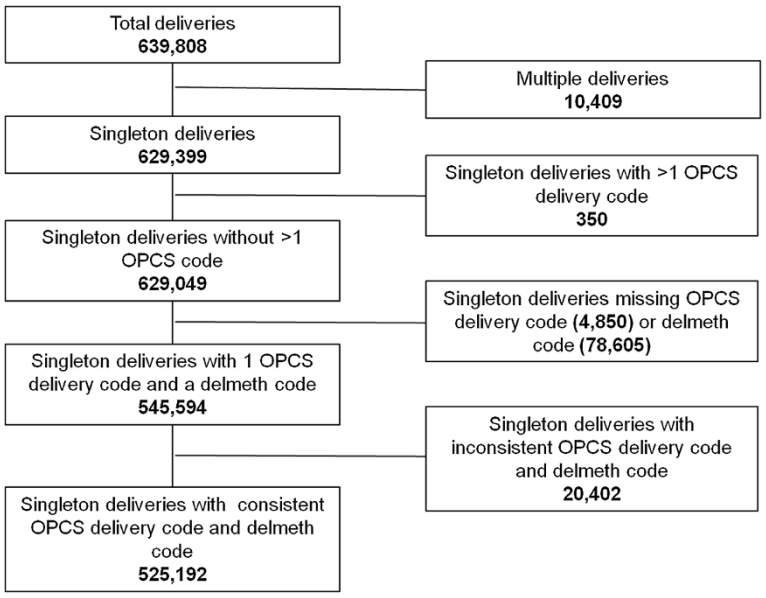

Figure 1 Flow chart.

(76,004/545,594) from procedure codes and 13.7% (74,539/545,594) from maternity tail codes). However, coding inconsistencies had a large relative effect on the proportion of breech vaginal deliveries because it was an uncommon method of delivery. There were nearly twice as many records having this method of delivery in the maternity tail (3,170) compared to the procedures field (1,809) (Table 3).

Among all coding disagreements, 39% were inconsistencies between elective and emergency caesarean section (=[4,131 + 3,890]/20,402), while 19% were inconsistencies between instrumental and non-instrumental vaginal delivery (= [1,573 + 1,481 + 414 + 493]/20,402). A further 9% of inconsistencies were related to the type of instrument used to assist the delivery of the baby (=[1,573 + 1,481 + 414 + 493]/20,402) (see Table 3).

Variation in coding consistency between NHS hospital trusts

Figure 2 shows the variation in coding consistency among the 136 NHS trusts that had more than 500 delivery records containing both procedure and maternity tail codes. Eleven NHS trusts had levels of coding consistency lower than 92%, which was poorer performance than would be expected from random variation alone. The coding inconsistencies in these trusts appeared to be occurring systematically, accounting for 31% of all emergency/elective caesarean section discrepancies, 42% of all forceps/vacuum delivery discrepancies, 28% of all instrumental/non-instrumental delivery discrepancies, and 99% of all breech/vacuum delivery discrepancies.

The 11 NHS trusts with "poor" data quality accounted for 38,100 (7%) of the 545,594 singleton deliveries.

Table 3 Consistency of Method of delivery in English NHS trusts in 2009/10 as defined using OPCS delivery code and the maternity tail delmeth code

	Method of delivery (OPCS)							
Method of Delivery (Delmeth)	**Elective CS**	**Emergency CS**	**Breech vaginal**	**Forceps**	**Vacuum**	**Cephalic vaginal**	**Other**	**Row total**
Elective CS	**47,623**	4,131	15	26	186	139	1	52,121
Emergency CS	3,890	**70,298**	18	17	29	287	0	74,539
Breech vaginal	101	115	**1,547**	63	919	424	1	3,170
Forceps	324	173	5	**28,755**	438	414	0	30,109
Vacuum	13	52	3	1,347	**31,526**	493	0	33,422
Cephalic vaginal	396	904	202	1,573	1,481	**345,723**	37	350,316
Other	125	332	19	727	50	652	**1**	1,906
Total	52,472	76,004	1,809	32,508	34,629	348,132	40	545,594

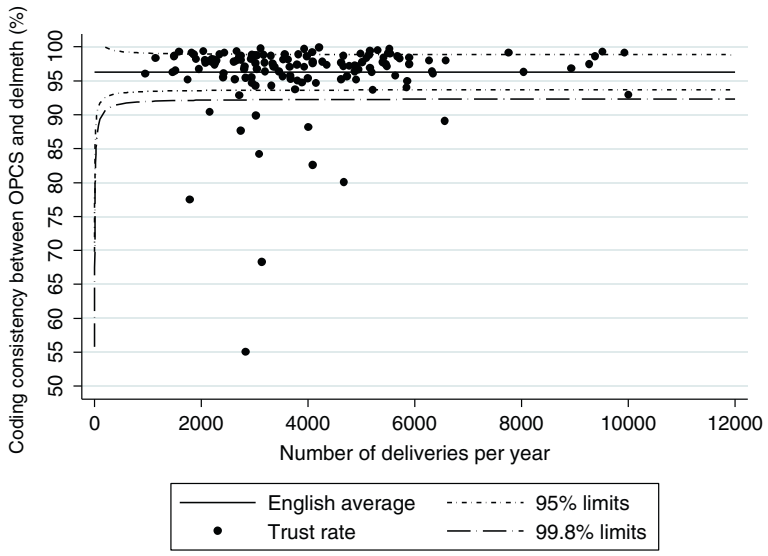

Figure 2 Funnel plot showing consistency between OPCS mode of delivery code and delmeth code for English NHS trusts (2009/10). The English average was calculated by dividing the number of records with consistent mode of delivery recorded in both fields by the total number of records containing information about mode of delivery in both fields.

Removing these trusts from the analysis improved the overall level of coding agreement from 96.3% (kappa = 0.93, $p < 0.001$) to 97.4% (kappa = 0.95, $p < 0.001$).

Impact of rules for handling data inconsistencies on maternity statistics

Table 2 shows the impact of using different analysis rules upon the three selected maternity statistics. At a national level, the different definitions had the smallest impact on the overall rate of third/fourth degree perineal tears amongst instrumental deliveries, with only 0.05% difference between the lowest and highest estimates. For the emergency caesarean section rate, the difference was almost 1%.

The most unstable statistic was the elective caesarean section rate among all women with breech presentation, with the estimated proportion ranging between 46.4% and 52.6% depending on which analysis rule was used. The inconsistencies in the definition of elective caesarean section affected the numerator, while the denominator was affected by the poor consistency in the definition of breech delivery.

Figure 3 shows the difference between the figures derived using two analysis rules at the level of individual NHS trusts. For the majority of NHS trusts, there was little difference between the emergency caesarean section rate and the third/fourth degree perineal tear rate amongst instrumental deliveries. The standard deviation (SD) of the difference was 1.6% and 1.0%, respectively. The spread of differences was larger for the elective caesarean section rate for breech presentation, with the SD of the differences being 5.5%. This reflects its comparatively smaller sample size in relation to the other statistics. Further analysis of these results showed that, for most trusts, the differences arose from changes in hospital sample size due to incomplete maternity tail data rather than inconsistencies of coding (Figure 2). Nonetheless, for each statistic, the different analysis rules produced very different figures for some NHS trusts, and these were typically those with poorer levels of coding consistency.

Discussion and conclusion

This study evaluated the completeness and internal consistency of data on method of delivery within the HES database and how the accuracy of this data could affect different maternity statistics. We found that the procedure fields contained the most complete information on method of delivery, being available in 99.2% of records. They were also more consistently complete across all NHS trusts. The completeness of maternity tail information was considerably lower, and was missing entirely for seven NHS trusts.

When information was available in both sources, there was a high level of agreement between the method of delivery codes overall. Inconsistent coding was a problem in a minority of NHS trusts, with only 11 out of 136 trusts showing divergent coding practices. It was, therefore, not surprising that, at a national level, different rules for handling inconsistent data had a small effect on the derived statistics. Nonetheless, the degree of sensitivity varied across the statistics tested.

The variation in the level of data completeness and coding consistencies across NHS trusts meant that, for all statistics tested, the differences in the estimates produced by the alternative analysis rules were substantial for some

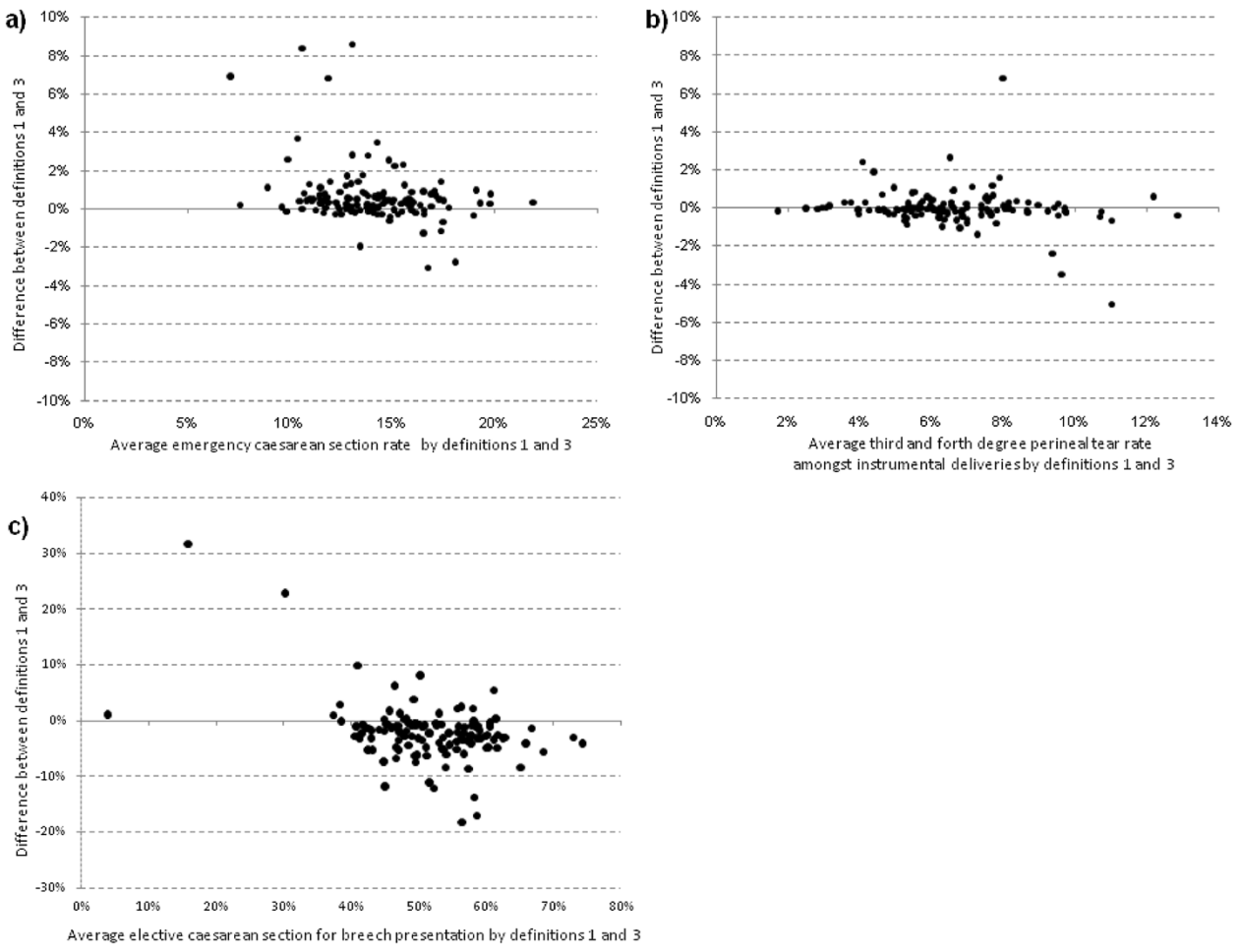

Figure 3 Mean difference plots: Impact of using different method of delivery definitions on trust-level rates of: a) emergency caesarean section; b) third and fourth degree perineal tears amongst instrumental deliveries, and c) elective caesarean section for breech presentation. Definition 1: Use all episodes with an OPCS method of delivery code & base method of delivery definitions on OPCS codes alone; Definition 3: Uses only episodes in which both OPCS and maternity tail codes are present and in agreement; base method of delivery definitions on agreed method of delivery code.

trusts. These results highlight the need for a careful assessment of data quality and for the transparent reporting of how incomplete and inconsistent data are handled when producing maternity statistics, particularly at an organisational level.

This study included all singleton deliveries occurring in English NHS maternity units, providing a very large sample size for analysis and thereby reducing the risk of selection bias. We identified 629,049 singleton deliveries during the study time period, which represents approximately 97% of all hospital deliveries registered in England during 2009/10 by the Office for National Statistics [16]. Previous research shows that women with severe morbidity and prolonged hospitalisation are more likely to have delivery information missing from their records [17]. Although the loss of these women from analyses of mode of delivery is unlikely to make a difference, it would become extremely important if the data are used to assess maternal or perinatal morbidity and mortality.

A limitation of this evaluation is that it only assessed internal consistency. We did not attempt to validate the HES dataset by comparing a sample of records against hospital medical records. We are not aware of any studies that have specifically validated "method of delivery" coding in HES against hospital records, but studies of similar administrative health databases in other countries have reported high levels of agreement (kappa > 0.98, where stated) [18-21].

The seven method of delivery categories used in this study represent only one possible classification. The grouping was dictated by the OPCS procedure and maternity tail codes. A weakness of this classification is the definition of caesarean section as either elective or emergency. The 2004 NICE guideline recommended that the urgency of a

caesarean section be indicated using the Lucas/National Confidential Enquiry into Patient Outcome and Death (NCEPOD) classification and noted that replacing the terms 'emergency' and 'elective' with its four grades of urgency would aid communication between health professionals [22]. Currently, the HES database is unable to capture this classification system.

Data quality is a concern for healthcare providers, managers and policy makers [23]. In England, the Care Quality Commission now mandates an annual audit of data quality within NHS trusts, [24] and a recent systematic review of coding accuracy in all types of routinely collected hospital discharge data found that coding accuracy rates have been improving [25]. Since 2002, the coding of primary diagnosis within HES has improved in accuracy from 73.8 per to 96.0% when compared against case notes [24].

The results of this study add to this work by addressing concerns about the quality of HES maternity data [26]. The high level of consistency in the recording of method of delivery overall supports its use for the construction of national maternity statistics. Coding disagreements were most common for the categories of emergency and elective caesarean section. Nonetheless, overall consistency was excellent between both emergency (kappa = 0.92; $p < 0.001$) and elective (kappa = 0.90; $p < 0.001$) caesarean section procedure and maternity tail codes. This supports a previous conclusion that coding errors were unlikely to account for the large variation in the rates of emergency caesarean section observed between NHS trusts [27].

At an NHS trust level, levels of consistency were high for the majority of organisations, which provides evidence to support the use of HES-based quality indicators for the purpose of comparing the performance of NHS trusts. However, our results illustrate the importance of addressing data quality within NHS trusts with divergent coding practices. The risk of organisations being mistakenly identified as "outliers" on performance indicators due to data errors is well-known. Our results suggest this risk is also increased by the sensitivity of maternity statistics to the analysis rules used to handle inconsistent data.

The study's results also suggest that any publishers of maternity statistics should describe details of how data quality was assessed and incomplete and consistent data were handled in the analysis. In England, the Health and Social Care Information Centre (HSCIC) publishes maternity statistics at Strategic Health Authority, NHS trust and individual unit level annually [3]. This public body is England's central source of health and social care information and the value of its publications on maternity services would be enhanced if they again provided information on the level of agreement between data in the procedure fields and in the maternity tail.

Providing methodological information may be more problematic for commercial companies that supply hospitals with comparative measures of organisational performance given the need to balance transparency with the protection of intellectual property. Nonetheless, companies that provide maternity benchmarking services could be required to meet minimum standards of transparency as part of the conditions of access to administrative health data. Whilst national trends and local over time can be reported as long as the definitions used by these organisations remain the same, the definitions used are still important for interpretation.

Implications

Approaches to validate the use of administrative health data for maternity statistics commonly fall into two categories. They either check the consistency of the administrative health data against medical records [17-20,28] or against another source of maternity data such as national birth registers [29-31]. Such external validation studies can be time consuming, costly and technically challenging, as well as raising ethical and information governance issues related to access and data linkage. We used a particular feature of HES to examine its internal consistency and this is an example of how relationships within administrative health data can be used to identify organisations with divergent coding practices [32]. Whilst external validation should remain the "gold standard", this approach to data quality assessment is simple to perform and has the potential to be developed more widely as a complementary technique.

Abbreviations

HES: Hospital Episode Statistics; ARHQ: Agency for Healthcare Research and Quality; IC: Information Centre; NHS: National Health Service; OPCS: Office of Population Census and Surveys; ICD-10: International Classification of Diseases, 10th Edition.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

DC, JvdM, TM, DR and AT conceived the idea. HK, DC, IG-U and JvdM designed the methodology. HK, IG-U and DC conducted the statistical analysis. HK wrote the manuscript. DC, JvdM, IG-U, TM, DR and AT commented on subsequent drafts and approved the final version. All authors read and approved the final manuscript.

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5. Development and validation of techniques to overcome missing data on obstetric history

In Chapter 4, a novel technique was described for examining the internal consistency of method of delivery coding within the HES database. This work resulted in the development of methods for identifying hospitals with divergent coding practices and improved existing techniques for defining obstetric groups based on the requirements of the specific research question. The study's findings highlight how maternity statistics are sensitive to inconsistencies in data on method of delivery and the choice of definition selected.

In this chapter, the focus remains on thesis objective 2 but attention is turned to another key piece of information for the evaluation of care and outcomes in maternity services: maternal parity. As we will see in later chapters, in studies of the outcomes and processes of maternity care it is important to know whether a woman is having her first baby (is primiparous) or has already had one or more births (is multiparous) because obstetric history strongly influences the need for intrapartum intervention in the current pregnancy. Rates of induction and emergency caesarean section are typically higher among primiparous women, whereas rates of elective caesarean are typically lower. Both primiparity and grand multiparity (typically defined as more than six previous pregnancies) are also risk factors for certain adverse outcomes, including perinatal death.[64]

Despite the importance of information about parity, there are particular concerns about the recording of this variable in HES. In 2009/10, 36 out of 148 NHS trusts were missing this

information in the maternity tail, and in a further 22 the distribution of this variable was implausible, i.e. there were too many or too few primiparous women.

As in Chapter 4, the themes within this chapter relate particularly to the handling of missing or inconsistent information and the definition of obstetric subgroups. This theme is addressed using an alternative approach, which involves deriving information about parity by following up individual patients within HES over many years using the HESID.

The results have been presented in the form of the published paper.

Statement of authorship

This chapter has been written as a published paper:

Cromwell DA, **Knight HE**, Gurol-Urganci I. Parity derived for pregnant women using historical administrative hospital data: accuracy varied among patient groups. J Clin Epidemiol 2014;67(5):578-85.

The authors have certified that:

a. they meet the criteria for authorship in that they have participated in the conception, execution or interpretation of at least that part of the publication in their field of expertise
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Contributor	**Statement of contribution**
H.E. Knight	Contributed to the design of the study; undertook the data preparation and statistical analysis; participated in the drafting of the manuscript and its modification based on reviewer comments
Signature & Date:	H Knight 20.04.18
D.A. Cromwell, I. Gurol-Urganci,	Conceived the research; advised on study design and statistical methods; supervised the research; participated in drafting and editing the manuscript and responding to reviewer comments

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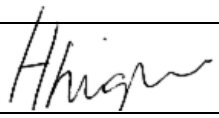
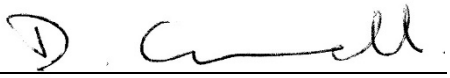
Student Signature:  **Date:** 20.04.18

Supervisor Signature:  **Date:** 20.04.18

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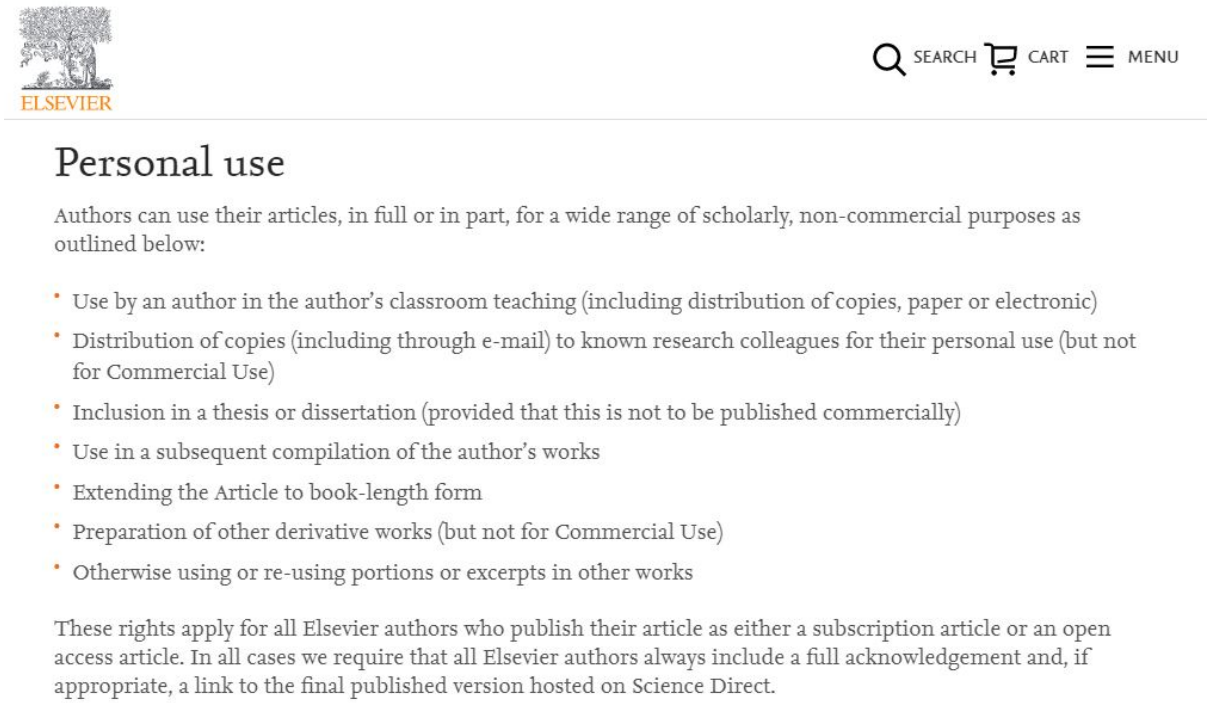

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Parity derived for pregnant women using historical administrative hospital data: Accuracy varied among patient groups

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Abstract

Objectives: Understanding patterns of maternity care requires knowing which women have given birth previously, but this information is typically unavailable in administrative hospital data sets. We assessed how well parity can be derived using linked historical records.

Study Design and Setting: Using Hospital Episode Statistics data, we identified records of women who gave birth between April 2009 and March 2010 in English National Health Service hospitals. The parity coded in these records was compared with an estimate derived from deliveries identified in previous hospital admissions between April 2000 and March 2009.

Results: We identified 358,849 eligible deliveries with complete parity data in the 2009−10 birth records. The historical data classified 168,041 women as multiparous; of whom, 98% were coded as multiparous in their birth record. Among 190,798 women classified as primiparous using historical data, 72% were coded as primiparous in their birth record. The proportion of accurate predictions about primiparous status from historical data varied with age, ranging from 89% for 15−18 year olds to 50% for women aged more than 35 years.

Conclusion: Historical records in administrative hospital data sets give accurate information on multiparous status of women. There is some misclassification of primiparous status, and error rates differ among subgroups of women.

Keywords: Obstetrics; Parity; Hospitals; Administrative data; Missing data; Medical record linkage

1. Introduction

In studies on the patterns and outcomes of maternity care, it is typically necessary to have information on past medical events. In particular, the course of a current pregnancy will be influenced by various aspects of any previous pregnancy such as past obstetric conditions (eg, preeclampsia), the mode of delivery (eg, cesarean section), and an adverse outcome [1−3]. In addition, intrapartum care is strongly influenced by whether a woman is giving birth to her first child (is primiparous) or has already had one or more children (multiparous). For instance, rates of induction and emergency cesarean section are typically higher among primiparous women, whereas rates of elective cesarean are typically lower [4].

Various studies have used administrative hospital data to examine obstetric care in different countries, including the United States [5], Australia [6], and the United Kingdom [1,2,4]. The challenge for these studies is that the records are limited to capturing medical conditions, and, in many countries, information related to previous pregnancies such as parity is typically unavailable. In England, the administrative data set for English National Health Service (NHS) hospitals, known as Hospital Episode Statistics (HES), can capture information about obstetric deliveries in a set of supplementary fields called the maternity tail. However, the maternity tail is currently not completed for a sizable proportion of all deliveries. This led one study to exclude 76 of 146 English NHS trusts because parity was missing from more than 50% of their deliveries in at least 7 of the 9 years analyzed [2].

The HES database contains a unique identifier (the HESID), which is assigned to episodes of care that belong to the same patient. The ability to build a longitudinal profile of a person's inpatient care within NHS hospitals means data on past events for a select patient cohort could be derived from their historical records using a "look-back" technique [7,8]. However, the accuracy of this approach will be influenced by the number of years of data available and how well the HESID allocation algorithm performs. Hospital episodes in HES are linked by an iterative algorithm that uses information about a patient's NHS number, sex, date of birth, postcode, and local provider identifiers [9]. Although linkage should be accurate over short time frames because

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What is new?

Key findings

- Parity of women giving birth can be derived from women's historical records if records are linked with a unique identifier.
- In English National Health Service hospital data, 98% of women with a previous delivery in historical data were coded as multiparous in their birth record. Seventy-two percentage of women with no previous delivery in the historical data were coded as primiparous in their birth record. The proportion of accurate predictions about primiparous status from historical data decreased with age, ranging from 89% for 15−19 year olds to 50% for women aged 35 years or more.

What this adds to what was known?

- Analyzing historical records using a look-back technique can give accurate information on the multiparous status of women. The technique is less accurate for classifying primiparous status, and error rates differ among subgroups of women.

What is the implication and what should change now?

- Studies on obstetric care using administrative hospital data sets can overcome the lack of information on women's parity by using a look-back technique

people are unlikely to move or change their names (such as through marriage), studies on maternity care may be more susceptible to matching errors because pregnancies are typically years apart [10]. In this article, we examine how well the primiparous/multiparous status of pregnant women can be derived from historical linked records. We used the HES records of women with known parity admitted to English NHS obstetric units to assess the agreement between these parity values and the primiparous/multiparous status as derived from the historical HES data. Whether the level of agreement varied among different patient groups was also investigated.

2. Method

2.1. Observed parity cohort

We extracted records from HES of pregnant women who delivered in English NHS trusts (acute hospital organizations) between April 1, 2009 and March 31, 2010. A delivery episode was defined as any record that contained valid information about the mode of delivery in either the maternity tail or the procedure fields (OPCS-4 codes: R17−R25) [11]. This cohort was restricted to women aged between 15 and 45 years. We also omitted the second delivery for the minority of women who had two deliveries in this period.

For women in this cohort, information was collected on their age at delivery, ethnicity, social deprivation, the NHS trust to which they were admitted, and region of residence. Region of residence was defined using the 10 Strategic Health Authorities (SHAs) that existed on April 1, 2006. Deprivation was defined using a five-category indicator that was derived from the English Indices of Deprivation 2009 ranking of the English super output areas [12]. The categories were defined by partitioning the ranks of the 32,480 areas into quintiles and were labeled 1 (least deprived) to 5 (most deprived).

Parity (defined as the number of previous pregnancies resulting in either a live newborn or stillbirth) was extracted from the maternity tail, if available. The completeness and quality of this varied between NHS trusts. We therefore restricted the analysis of agreement to data from NHS trusts with ''good-quality'' parity information in their maternity tail (Table 1). NHS trusts were excluded if (1) more than 80% of their records had either a missing or invalid parity value or (2) the observed ratio of primiparous to multiparous women was outside the expected range of values. This was defined to be 25−55%, a pragmatic interval, which reflected that roughly 40% of women giving birth are primiparous [10].

2.2. Derivation of parity from historical data

The historical data set contained admissions to English NHS trusts between April 1, 2000 and March 31, 2009. As before, delivery episodes were defined as records that contained the mode of delivery in either the maternity tail or the procedure fields (OPCS-4 codes: R17−R25). The number of deliveries in the historical data set was then derived for all women in the observed parity cohort by matching the HESIDs of the various episodes. This matching took into account changes to a person's HESID due to corrections in the algorithm over time.

2.3. Statistical analysis

The agreement between the observed parity and derived parity was investigated among all women and for various patient subgroups: age at delivery, ethnicity, social deprivation, and the region of residence. Agreement of the derived primiparous/multiparous status was first calculated with reference to the observed parity values, which were considered the ''gold standard,'' using two measures: the proportion of women coded as primiparous in the observed parity data who were correctly identified from the historical data (sensitivity) and the proportion of women coded as multiparous who were correctly identified from the historical data (specificity). We also calculated how accurately the look-back

Table 1. Quality of maternity tail and parity information in HES records of women who gave birth between April 2009 and March 2010

Quality of maternity tail and parity data	Number of trusts (%)	Delivery records (%)	Records with maternity tail	% Records with tail
Trusts with limited parity data in maternity tail[a]	39 (26)	149,525 (23)	1,248	1
Trusts with too many primiparous (>55%)	15 (10)	54,241 (9)	47,716	88
Trusts with too few primiparous (<25%)	7 (5)	43,313 (7)	36,939	85
Trusts with expected distribution of parity[b]	87 (59)	389,734 (61)	358,849	92
Total	148	636,813	444,752	70

Abbreviation: HES, Hospital Episode Statistics.

[a] More than 80% of records had missing or invalid data.

[b] Proportion of women who were primiparous at NHS trust was between 25% and 55% among records with a parity value entered.

technique predicted the observed primiparous/multiparous status using measures equivalent to the positive and negative predictive values [13]: the proportion of women with no previous delivery in the historical data who were coded as primiparous in the observed parity data and the proportion of women with a previous delivery in historical data who were coded as multiparous. Overall agreement was summarized using the unweighted kappa (κ) statistic [13]. This statistic ranges from 0 (a level of agreement no greater than would be obtained by chance) to 1 (perfect agreement). Kappa values above 0.80 are generally considered to indicate excellent agreement.

The time between births was calculated for multiparous women who had up to three previous births, all of which had been found in the historical data set (ie, the observed and derived parity values were equal).

Finally, we investigated the variation between NHS trusts in the proportion of women labeled as primiparous in the observed parity data for whom no deliveries were found in the historical data using a funnel plot [14]. The inner and outer control limits were defined to be two and three standard deviations (SDs) above and below the overall average, respectively, and were adjusted to take into account a measure of overdispersion. This was derived using the random-effects method and incorporated 10% winsorization [14].

Differences in proportions between subgroups were tested using the chi-square test, and P values lower than 0.05 were judged to be statistically significant. We have not included 95% confidence intervals for proportions because standard errors were typically less than 0.5% for patient subgroups, and their omission aided the presentation of results. Stata 11 (StataCorp LP, College Station, TX, USA) was used for all statistical calculations.

Table 2. The primiparous and multiparous statuses of women who gave birth between April 2009 and March 2010 by various maternal characteristics at the time of delivery

Characteristic	No. of women (%)	Primiparous, %	Multiparous, %
All women	358,849	39	61
Age group (yr)			
15–19	22,207 (6)	78	22
20–24	71,473 (20)	50	50
25–29	100,995 (28)	40	60
30–34	96,219 (27)	33	67
35 and older	67,955 (19)	23	77
Ethnicity			
White	253,578 (71)	40	60
Afro-Caribbean	18,909 (5)	29	71
Asian	43,842 (12)	31	69
Other	13,748 (4)	41	59
Unknown	28,772 (8)	53	47
Social deprivation			
1 (least deprived)	53,271 (15)	40	60
2	55,621 (15)	42	58
3	64,262 (18)	42	58
4	78,315 (22)	41	59
5 (most deprived)	107,380 (30)	35	65

Figures from observed parity cohort.

3. Results

In 2009–10, a total of 636,813 delivery records were identified within 148 English NHS trusts. Parity had been entered in the maternity tail of 444,752 (70%) of these records. There were 35 NHS trusts that contained no parity information in any of their delivery records and 4 trusts in which parity was missing from more than 80% of records. In another 22 NHS trusts, the proportion of primiparous women was outside the expected range. This left 87 NHS trusts that were judged to have good-quality data and provided data on 358,849 women for analysis (Table 1).

Of the 358,849 women in the final study population, the average age of the women was 28.8 years (SD = 6.0 years). Among these, 140,843 (39.2%) were primiparous. There were 22,207 women whose age at delivery was between 15 and 19 years; of whom, 78% were primiparous (Table 2). The proportion of primiparous women decreased with increasing age and was 23% in women aged 35 years and older. There were also differences among women from different ethnic backgrounds (chi-square test, $P < 0.001$) and from different levels of social deprivation (chi-square test, $P < 0.001$). The proportion of primiparous women in the 10 English regions varied from 37% to 44% (chi-square test, $P < 0.001$). Among multiparous women, the median time between the first and second deliveries was 31 months (interquartile range: 22 to 45 months). The median time between the second and third deliveries was 32 months (interquartile range: 22 to 47 months).

Among women coded as multiparous in the observed parity data, 76% had one or more previous pregnancies found in the 9 years of historical data. The proportion increased

Table 3. Agreement between parity coded in the maternity tail (observed parity cohort) and parity derived from historical data

Parity coded in the maternity tail	No. of women in observed parity cohort	No. of women with at least one delivery in historical data (%)	Distribution of parity derived from historical data, %				
			0	1	2	3	4+
0	140,843	3,424 (2)	**98**	2	0	0	0
1	111,835	79,205 (71)	29	**70**	1	0	0
2	55,753	43,571 (78)	22	41	**37**	0	0
3	26,197	21,361 (82)	18	35	30	**16**	0
4 or more	24,221	20,490 (85)	15	30	28	15	**10**

Historical data covered 9 years from April 2000 to March 2009.

Bold values indicate an exact match between the observed and historical parity figures. If there was perfect agreement, each of these cells to be 100%.

among women with higher observed parity values, but this gradient was only slight (Table 3). The agreement between the exact parity values became worse as the observed parity value increased. When there was disagreement, the derived parity was typically an underestimate of the observed value in the birth record (Table 3). Previous pregnancies were also found for 2% of women coded as primiparous in the observed parity data. This level of agreement was generally consistent across NHS trusts (Fig. 1). A previous pregnancy was found for fewer than 5% of women coded as primiparous in the observed parity data at 75 of the 87 NHS trusts (86%).

The agreement between the observed and derived multiparous statuses improved as the time frame of the historical data lengthened. For time frames of 5-, 7-, and 9-year durations, the proportions of women coded as multiparous for whom a previous pregnancy was found in the historical data were 65%, 72%, and 76%, respectively. The agreement between the observed and derived primiparous statuses was not influenced by the time frame covered by the historical data set, remaining at 98% for the 5-, 7-, and 9-year time-frames.

The agreement between primiparous and multiparous statuses of women varied across the three patient characteristics (Table 4). The agreement was highest among the 20- to 24-year old women, decreasing among the higher age groups. Surprisingly, the historical data contained only 54% of previous deliveries among 15- to 19-year old women coded as multiparous in the observed parity data despite the historical data providing a complete look-back period. The agreement also varied by ethnicity, being noticeably worse for women with an Afro-Caribbean, other, or unknown ethnic background compared with women of white ethnicity. The level of agreement did not differ substantially between the 10 English regions in general. The exception was the London SHA, which had noticeably lower levels of agreement in all age groups (Fig. 2).

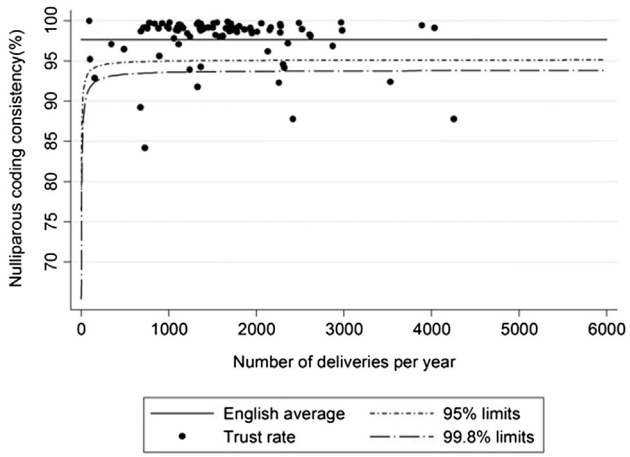

Fig. 1. The funnel plot showing the proportion of women coded as primiparous in the observed parity data (2009–10) who were correctly identified from the historical data by English National Health Service trusts.

Table 5 gives the positive and negative predictive values of the look-back technique. The results demonstrate that the method achieved high levels of accuracy if a woman was labeled as multiparous using historical data, the proportion of accurate predictions being typically 98%. The method was less accurate among women labeled as primiparous, and accuracy was strongly associated with age. The level of inaccuracy was also greater among women of nonwhite ethnicity and in the group of highest social deprivation.

4. Discussion

The use of administrative hospital data to investigate patterns of inpatient maternity care is hampered by the lack of parity information. We used HES data to assess how well a look-back technique could derive parity from historical hospital records for women giving birth in English NHS hospitals. When evaluated using 9 years of historical data, we found that this technique identified 70% of deliveries among women coded as having one previous pregnancy in their birth record. However, agreement became worse for higher parity values. The look-back technique achieved better levels of agreement when the objective was limited to determining whether a woman was primiparous or multiparous. The technique accurately labeled women as multiparous, having an overall predictive value of 98%. It was less able to correctly label women as primiparous, having an overall predictive value of 72% because the historical data could miss past pregnancies. The performance of the technique decreased as the length of the historical time frame became shorter.

The performance of the look-back technique was also found to vary among the various subgroups of women. Its

Table 4. Levels of agreement in parity among different patient groups as coded in the maternity tail (observed parity cohort) and derived from historical data

Characteristic	Primiparous in maternity tail		Multiparous in maternity tail		
	No. of women	% Primiparous in historical data (sensitivity)	No. of women	% Multiparous in historical data (specificity)	κ
All women	140,843	98	218,006	76	0.69
Age group[a] (yr)					
15–19	17,362	99	4,845	54	0.64
20–24	35,399	98	36,074	77	0.75
25–29	40,638	98	60,357	79	0.73
30–34	32,081	97	64,138	76	0.66
35 and older	15,363	96	52,592	72	0.51
Ethnicity[a]					
White	100,841	98	152,737	77	0.71
Afro-Caribbean	5,461	97	13,448	67	0.52
Asian	13,578	97	30,264	79	0.68
Other	5,680	98	8,068	61	0.55
Unknown	15,283	98	13,489	63	0.63
Social deprivation[a]					
1 (least deprived)	21,387	98	31,884	77	0.72
2	23,268	98	32,353	76	0.71
3	26,895	98	37,367	75	0.69
4	31,844	98	46,471	74	0.68
5 (most deprived)	37,449	96	69,931	76	0.66

Historical data covered 9 years from April 2000 to March 2009.

[a] Chi-square test of differences in the proportions between the patient categories, $P < 0.001$.

ability to correctly label women as primiparous was worse among older women. Moreover, it performed less well among women aged 15–19 years compared with women aged 20–24 years, although the 9 years of historical data provided complete look-back periods for both groups. Performance was also lower among women of nonwhite ethnicity compared with those of white ethnicity, for women of highest social deprivation, and for women who were resident within London.

There are various explanations for the poor agreement among these subgroups of women. First, HES does not include information about overseas deliveries for women who used to live abroad. Overall, births to non-UK born mothers accounted for 25.1% of all live births in 2010 [15], and this might be one reason for the lower levels of agreement among women in the nonwhite ethnic groups and among women living in London. However, we have no information about when these women migrated to England.

Second, the performance of the HESID algorithm may be affected by changes to patients' demographic data and data errors. Women may change their surname between pregnancies if they have married, divorced, or remarried in the intervening period. Postcodes may also change because families

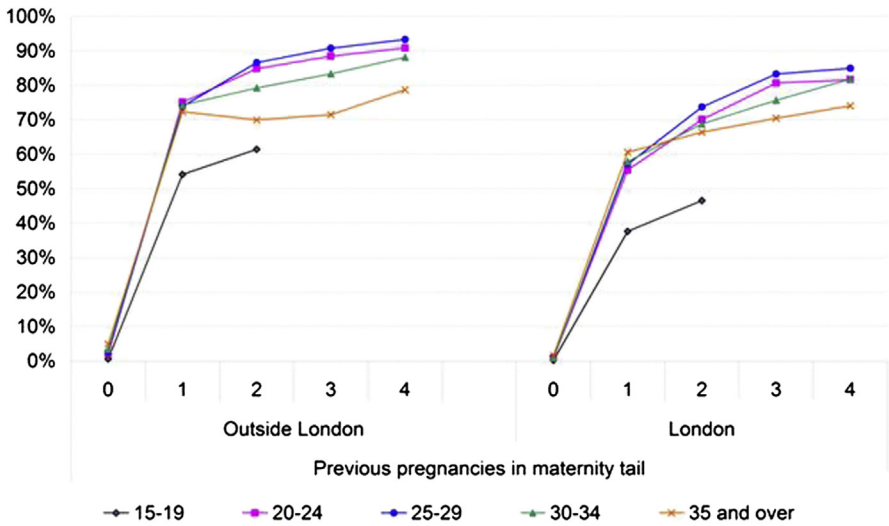

Fig. 2. The proportion of women delivering in 2009–10 for whom a previous pregnancy was found in the historical data set, stratified by the parity coded in the 2009–10 delivery record, age group (years), and region of residence.

Table 5. Performance of the look-back technique at predicting primiparous/multiparous status when calculated using 9 years of historical data (April 2000 to March 2009)

Characteristic	Primiparous in historical data		Multiparous in historical data	
	No. of women	% Primiparous in observed parity cohort	No. of women	% Multiparous in observed parity cohort
All women	190,798	72	168,051	98
Age group[a] (yr)				
15–19	19,482	89	2,725	96
20–24	42,926	81	28,547	97
25–29	52,299	76	48,696	98
30–34	46,437	67	49,782	98
35 and older	29,654	50	38,301	98
Ethnicity[a]				
White	132,843	74	120,735	98
Afro-Caribbean	9,756	54	9,153	98
Asian	19,471	68	24,371	98
Other	8,741	64	5,007	98
Unknown	19,987	75	8,785	97
Social deprivation[a]				
1 (least deprived)	28,157	74	25,114	98
2	30,496	75	25,125	98
3	35,890	73	28,372	98
4	43,156	72	35,159	98
5 (most deprived)	53,099	68	54,281	98

[a] Chi-square test of differences in the proportions between the patient categories, $P < 0.001$.

move house. In addition, some births are registered jointly by parents living at separate addresses, which could have affected the accuracy of postcodes. Although this was a small proportion of all births for women aged more than 25 years, this situation applied to 19% of births to women aged 20–24 years and 35% of births to women aged 15–19 years [16]. This could explain the poor levels of agreement for teenage pregnancies despite the potential for complete follow-up. The lack of agreement may also reflect poor coding of the NHS number, which has not always been at the high level of quality currently achieved [9].

Finally, HES data include neither deliveries in independent hospitals nor home births. Nonetheless, the effect of these omitted deliveries on the results is likely to be small. Home births and deliveries in non-NHS hospitals account for around 3% and 0.5%, respectively, of all deliveries [10].

4.1. Study strengths and limitations

A strength of this study is that it includes multiple NHS trusts spread across all English regions. The observed parity cohort included small (<2,500 deliveries), medium (2,500–4,000), and large (>4,000 deliveries) NHS trusts, and characteristics of the women in the included and excluded NHS trusts were similar. The principal limitation is the possibility of inaccuracies in the coding for the method of delivery. Coding errors could affect the selection of women in the observed parity cohort and the identification of past deliveries. However, the definition of delivery categories in administrative hospital data has been shown to be reliable. For example, studies on the coding of cesarean procedures have reported high levels of agreement ($\kappa > 0.98$, where stated) [5,17,18]. A second limitation is that we assumed the parity information in the maternity tail was correct in NHS trusts with a typical parity distribution. These data would have contained some errors. However, there were only negligible changes to the measures of performance when we repeated the analysis using the 75 NHS trusts that had the most accurate coding of primiparous (as identified in Fig. 2).

4.2. Implications for studies on maternity care using routine hospital data sets

The lack of complete information on parity is a serious handicap for studies on the patterns and outcomes of maternity care. Primiparous women are at greater risk of having a difficult labor and postdelivery complications compared with multiparous women [19]. HES data have the potential to capture parity, but the completeness of the maternity tail means that statistics requiring parity for patient selection, stratification, or risk adjustment can only be derived using this source of data for a sample of all English NHS hospitals.

Our analysis suggests that for studies using administrative hospital data sets with unique patient identifiers, historical data can be used to accurately identify multiparous status for patient records without parity data. It could also be used to determine primiparous/multiparous status of women when this variable acts as a confounder and is required for risk adjustment in a multiple regression. There would be some misclassification due to the incomplete capture of past pregnancies, with errors mostly resulting in multiparous women classified as being primiparous. Assuming the actual ratio of primiparas to multiparas in a study cohort is 40:60, extrapolating our results to a situation in which there was

no information on parity, the look-back technique evaluated here would give a ratio of 54:46. For studies using HES data, there would be the option of determining the primiparous/multiparous status only for the 30% of HES records missing parity in the maternity tail. In this situation, the look-back technique would produce a ratio of 44:56.

4.3. Implications for longitudinal studies based on routine hospital data sets

Several studies have evaluated the benefit of using historical records to improve the measurement of particular risk factors. Preen et al. [7] demonstrated that in regression models, the explanatory power of comorbidity on 1-year mortality was influenced by the length of historical time frame for various types of hospital care. In obstetrics, Chen et al. [8] found higher prevalence of chronic diseases by increasing the length of the historical time frame but reported that this did not improve prognostic models for obstetric hemorrhage. Our study suggests that this look-back technique can be a useful way on improving the completeness and the validity of routine hospital data sets.

Validation studies of routine hospital data sets have tended to examine the accuracy of diagnostic and procedure information, by either assessing agreement with medical records [20,21] or linking them to population registers and assessing the agreement of equivalent data items [8]. This study highlights another important aspect of their construction, namely, the performance of the algorithm that links episodes of care to the same patient. More research on the performance of these algorithms is needed. First, we need to understand why particular patient groups may be at greater risk of not having their episodes of care linked correctly. Second, information is required on how the performance of the algorithm depends on the time between episodes of care.

In conclusion, this study demonstrates that it is possible to classify women giving birth as primiparous or multiparous from historical data when using administrative hospital data sets to examine obstetric care. Historical data can be used to identify the multiparous status of women accurately, but the look-back technique will be prone to errors among women classified as primiparous because of the incomplete capture of all past pregnancies. The utility of the look-back technique will depend on how parity information is to be used in specific studies, but the importance of parity to understand patterns of obstetric care means that in many circumstances, having imperfect data will be better than not having it at all.

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Application of techniques to analyse routine maternity data

Chapters 4 and 5 sought to address thesis objective 2 by demonstrating how the analysis of routinely collected maternity data can be improved through the application of novel techniques for data validation and the handling of missing data.

The third component of the thesis, presented in the following three chapters, comprises a series of case studies that apply these new techniques to research that aims to answer clinically relevant questions in maternity care.

6. Uptake and success of vaginal birth after caesarean section

In this chapter, the novel method to assess the completeness and accuracy of data on method of delivery, described in Chapter 4, is used, together with the 'look-back' technique for deriving parity, described in Chapter 5, to define a subgroup of women giving birth for the second time following a primary caesarean section.

The majority of women with a primary caesarean section, in an otherwise uncomplicated second pregnancy, are candidates for attempting VBAC. However, little was known about how many of these women *attempt* a VBAC because it has not previously been possible to capture this information on a national level. For this reason, it was also not previously possible to accurately calculate rates of *successful* VBAC, among those who attempt a trial of labour.

The methodological contribution made by this study enables rates of attempted and successful VBAC to be calculated for the first time for English NHS hospitals. The analysis also examines the impact of maternal demographic and clinical factors, including the indication for the primary caesarean section, on these outcomes.

The work presented in this chapter also included the development of definitions for important risk factors associated with VBAC attempt and success, in order to investigate the associated demographic and obstetric factors. A multivariate logistic regression model was developed to estimate the crude and adjusted effect of maternal demographic and clinical risk factors, and indication for primary caesarean section, on rates of attempted and successful VBAC.

The funnel plots in this chapter reveal substantial variation over and above the level expected based on the maternal demographic and clinical factors that it was possible to control for in the study. As the study also attempted to limit the impact of differences in data collection and coding practices between trusts, it is likely that much of the systematic variation observed between trusts reflects unmeasured confounding. In particular, there may be differences between trusts in clinical culture or local policy, which influences the way women are counselled regarding VBAC. There may also be differences between populations in maternal preferences for attempting VBAC vs. ERCS. Finally, it was not possible to control for certain maternal risk factors such as height, BMI, smoking, nor for factors that occur during labour and delivery, each of which may influence the likelihood of VBAC. The presence of residual confounding means that the between-trust adjusted variation observed in Figure 2 may represent an overestimate. However, this limitation would not impact on the main findings of the study which relate to the overall national rates of attempted and successful VBAC.

The results have been presented in the form of the published paper. The supplementary material referred to in the paper is available at the end of this chapter.

Statement of authorship

This chapter has been written as a published paper:

Knight HE, Gurol-Urganci I, van der Meulen JH, Mahmood TA, Richmond DH, Dougall A, Cromwell DA. Vaginal birth after caesarean section: a cohort study investigating factors associated with its uptake and success. BJOG 2014;121(2):183-92.

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Contributor	**Statement of contribution**
H.E. Knight	Conceived and conducted the research; designed and implemented the statistical analysis; wrote the first draft of the manuscript; modified the manuscript as suggested by co-authors and reviewers
Signature & Date:	H Knight 20.04.18
D.A. Cromwell, I. Gurol-Urganci, J.H. van der Meulen	Involved in developing the research idea; advised on study design, statistical methods and analysis; supervised the research; assisted in editing the manuscript
T. Mahmood	Involved in developing the research idea; technical input into the clinical aspects of the work; interpreted the results from a clinical perspective; commented on the manuscript
A. Dougall, D. Richmond	Technical input into the clinical aspects of the work; interpreted the results from a clinical perspective; commented on the manuscript

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Thesis Title	To what extent can routinely collected data be used to evaluate the performance and quality of English NHS maternity services?

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Vaginal birth after caesarean section: a cohort study investigating factors associated with its uptake and success

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Objectives To investigate the demographic and obstetric factors associated with the uptake and success rate of vaginal birth after caesarean section (VBAC).

Design Cohort study using data from Hospital Episode Statistics.

Setting English National Health Service.

Population Women whose first birth resulted in a live singleton delivery by caesarean section between 1 April 2004 and 31 March 2011, and who had a second birth before 31 March 2012.

Methods Logistic regression to estimate adjusted odds ratios (OR).

Main outcome measures Attempted and successful VBAC.

Results Among the 143 970 women in the cohort, 75 086 (52.2%) attempted a VBAC for their second birth. Younger women, those of non-white ethnicity and those living in a more deprived area had higher rates of attempted VBAC. Overall, 47 602 women (63.4%) who attempted a VBAC had a successful vaginal birth. Younger women and women of white ethnicity had higher success rates. Black women had a particularly low success rate (OR, 0.54; 95% confidence interval [CI], 0.50–0.57). Women who had an emergency caesarean section in their first birth also had a lower VBAC success rate, particularly those with a history of failed induction of labour (OR, 0.59; 95% CI, 0.53–0.67).

Conclusion In this national cohort, just over one-half of women with a primary caesarean section who were eligible for a trial of labour attempted a VBAC for their second birth. Of these, almost two-thirds successfully achieved a vaginal delivery.

Keywords Administrative data, England, trial of labour, vaginal birth after caesarean.

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Introduction

Women who become pregnant after delivering their first baby by caesarean section often have a decision about how to deliver their second baby. Typically, they will be offered the choice of having an elective repeat caesarean section (ERCS) or attempting a vaginal birth after caesarean section (VBAC). The majority of women with an uncomplicated first caesarean section, in an otherwise uncomplicated pregnancy, are candidates for attempting VBAC.[1,2]

In recent years, there has been a reported decline in the use of VBAC in several countries.[3–6] In the USA, the overall rate of VBAC (i.e. successful VBAC/all women with a previous caesarean section) decreased from 24% in 1996 to 8% in 2010. This downward trend, accompanied by rising rates of primary caesarean section, has been a significant driver of the overall caesarean section rate, which continues to cause widespread public and professional concern.[7–9]

It has been suggested that this decline has been a response to new evidence on the risks associated with VBAC and providers' fear of liability.[10,11] There are no randomised controlled trials comparing planned VBAC with ERCS,[12] although several observational studies examining maternal and neonatal outcomes related to failed trial of labour have identified an increased risk of various complications, including uterine rupture during labour,

complications of emergency caesarean and perinatal morbidity or mortality.[13–15] However, successful VBACs have the lowest overall morbidity rates.[13]

Little is known about how many women currently attempt VBAC. Data from a sample of English general practices reported that the overall VBAC rate fell from 45% in 1991 to 37% in 1999, but were unable to capture the proportion of women attempting VBAC.[5] The probability of a successful VBAC has been estimated at 70–80%,[13,16–20] but various factors are known to increase the risk of failed VBAC (and hence delivery by emergency caesarean), including advanced maternal age, a previous caesarean section for dystocia, maternal obesity, non-white ethnicity and higher birthweight.[21–27]

In this study, we use an administrative database of all deliveries in English National Health Service (NHS) hospitals to describe the rates of attempted and successful VBAC in women having their second child, excluding those who did not have the option to attempt a VBAC for clinical reasons. In addition, we assess which maternal and clinical characteristics are associated with the decision to attempt a VBAC and the probability of success. This includes an examination of the effects of factors from both the first and second pregnancies.

Methods

We used the Hospital Episode Statistics (HES) database to identify births that have taken place in English NHS trusts (acute hospital organisations). The HES database contains patient demographics, clinical information and administrative data for each inpatient episode of care since 1997. A unique identifier (the HESID) links episodes of care related to the same patient, which enables studies to examine events before or after an index episode. Diagnostic information is coded using the *International Classification of Diseases, 10th Revision* (ICD10),[28] and operative procedures are coded using the UK *Office for Population Censuses and Surveys Classification, 4th Revision* (OPCS4).[29] For episodes related to childbirth, supplementary fields (the 'maternity tail') capture parity, birthweight, gestational age, method of delivery and pregnancy outcome. The maternity tail is not compulsory and the level of data completeness varies across NHS trusts. Birthweight and parity are available in 79 and 65% of the delivery episodes, respectively.

Deliveries were defined as records containing information about the mode of delivery in either the OPCS4 codes (R17–R25) or the maternity tail. We included all women aged 15–45 years whose first birth resulted in a live, singleton delivery by caesarean section between 1 April 2004 and 31 March 2011, and who had a second birth by 31 March 2012.

For both the first and second birth, the mode of delivery was defined using information in the OPCS4 codes or, if this was unavailable, by the mode of delivery specified in the maternity tail. We distinguished between vaginal delivery (including instrumental delivery) (OPCS R19–R24), elective caesarean section (R17) and emergency caesarean section (R18; R251). In HES, pre-labour caesarean sections are defined as 'elective' and intrapartum caesarean sections are defined as 'emergency'. Elective caesarean sections were reclassified as emergency caesarean sections if the diagnosis codes indicated that this procedure had been misclassified, for example because there was evidence of labour (Appendix S1, see Supporting information). Onset of labour was defined using the HES maternity tail. If the 'onset of labour' field contained a code for 'caesarean section carried out immediately following the onset of labour, when the decision was made before labour', we coded the caesarean section as 'elective'. Records missing information on the onset of labour were excluded from the analysis.

We identified potential candidates for VBAC by a process of elimination (Figure 1). We excluded women who, for their second birth, had a multiple pregnancy, non-cephalic presentation or placenta praevia or abruption, as these are indications for ERCS. We also excluded women who went into preterm labour or who required an emergency caesarean section prior to the onset of labour, because these situations remove the option of choice about the mode of delivery. Second births of women meeting the eligibility criteria were labelled as attempted VBACs unless the mode of delivery was by elective caesarean section. Successful VBAC was defined as a vaginal delivery following attempted VBAC.

Parity was defined using historical data from the HES database because the maternity tail is incomplete. A woman was defined as primiparous if there was no evidence of a birth prior to the index delivery, using a minimum of 7 years of obstetric history. Recent research suggests that over 90% of women in this population have their second child within 7 years of the first delivery (Gurol-Urganci I, Cromwell D, Mahmood T, van der Meulen J, Templeton A, unpubl obs).

Maternal demographic risk factors were age (15–23, 24–34, 35–45 years), ethnicity (white, Asian, black, other, unknown) and socio-economic deprivation of the mother's area of residence using the Index of Multiple Deprivation (IMD), a measure that combines economic, social and housing indicators. Ethnicity was based on the 2001 UK Census definitions.[30] Deprivation was based on the quintiles of 32 480 areas in England ranked according to IMD score.[31] Obstetric risk factors included the indication for the index caesarean, the type of index caesarean performed (elective, emergency), pre-existing conditions (hypertension, diabetes) and characteristics of the second pregnancy,

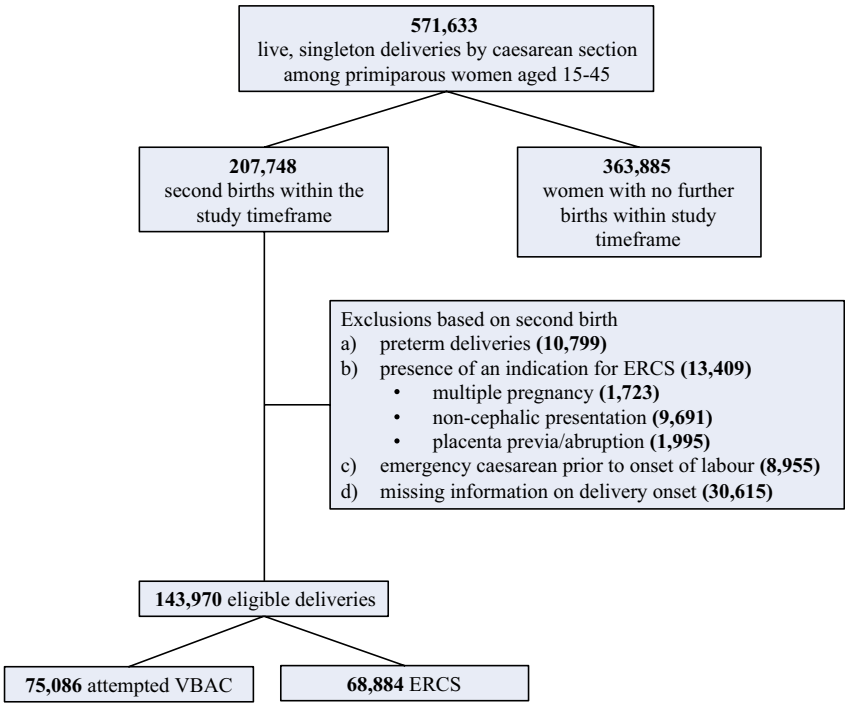

Figure 1. Selection of cohort. ERCS, elective repeat caesarean section; VBAC, vaginal birth after caesarean section.

including gestational diabetes, pre-eclampsia or eclampsia, premature rupture of membranes and birthweight. The year of the first birth was recorded as a linear variable to take into account changes in clinical practice over time. The interval between the first and second birth was calculated from the date of the first birth to the date of the second birth. The coding of all variables used in the analysis is provided in Appendix S2 (see Supporting information).

We used multivariate logistic regression models to estimate the crude and adjusted effect of maternal demographic and clinical risk factors and the indication for primary caesarean section on the rates of attempted and successful VBAC. To account for a lack of independence in the data of women treated in the same trust, the standard errors of the regression model coefficients were calculated using a clustered sandwich estimator. Interactions between ethnicity and the indication for the primary caesarean section were examined, but were not included in the final model because they were not significant.

To examine between-trust variation in the rate of attempted and successful VBAC, predicted rates were calculated by summing the individual probabilities for all women who delivered at the same NHS trust. Risk-adjusted rates were produced for each NHS trust by dividing the trust's unadjusted rate by its predicted rate and multiplying this ratio by the national mean.

Funnel plots were used to examine the variation among NHS trusts in the adjusted rates of attempted and successful VBAC.[32] These plots 'test' whether the rate of an NHS trust differs significantly from the national rate for England, assuming that the trust's rate is only influenced by sampling variation (that is, random errors). The plot contains two funnel limits. Assuming that differences arise from random errors alone, the chance of the trust being within the limits is 95% for the inner funnel and 99.8% for the outer funnel. We measured the amount of variation between NHS trusts above that expected from the sampling variation using a random effects approach.[32] All analyses were performed in STATA version 11 (StataCorp, College Station, TX, USA).

Results

There were 2 298 312 live, singleton births to primiparous women aged 15–45 years between April 2004 and March 2011, 571 633 (24.9%) of which were carried out by caesarean section. Of these, 207 748 (36.3%) women went on to have a second delivery within the study timeframe. Using information from the second delivery record, we excluded women who had a preterm delivery (5.2%), an indication for ERCS (6.5%) or an emergency caesarean prior to the onset of labour (4.3%). We also excluded 14.7% of records that were missing information on the onset of labour (Figure 1).

This left 143 970 women in the cohort who were defined as potential candidates for a VBAC. Of these, 75 086

Table 1. Rate of attempted vaginal birth after caesarean section (VBAC) in 143 970 women according to maternal and obstetric risk factors

	Proportion of women (%)	Rate of attempted VBAC (%)	Crude OR (95% CI)	Adjusted OR (95% CI)	*P*
Maternal age (years)					
<24	11.5	59.8	1.25 (1.19, 1.31)	1.15 (1.10, 1.20)	
24–34	59.6	54.3	1	1	<0.001
>34	29.0	44.7	0.68 (0.65, 0.71)	0.75 (0.71, 0.78)	
Ethnicity					
White	72.4	49.3	1	1	<0.001
Black	7.2	61.7	1.65 (1.48, 1.85)	1.51 (1.36, 1.68)	
Asian	10.9	63.9	1.82 (1.64, 2.01)	1.66 (1.53, 1.82)	
Other	3.3	53.7	1.19 (1.06, 1.34)	1.17 (1.04, 1.31)	
Unknown	6.2	52.6	1.14 (1.03, 1.25)	1.12 (1.02, 1.24)	
Deprivation (quintile)					
1 -Least deprived	20.2	47.2	1	1	<0.001
2	18.4	49.3	1.08 (1.03, 1.14)	1.06 (1.00, 1.11)	
3	18.5	51.0	1.16 (1.09, 1.24)	1.08 (1.01, 1.15)	
4	19.6	53.7	1.29 (1.20, 1.40)	1.11 (1.04, 1.19)	
5 -Most deprived	23.3	58.4	1.57 (1.41, 1.73)	1.20 (1.10, 1.31)	
Year of first birth					
2004	18.1	51.2	1	1	0.154
Increase per year	–	–	1.03 (1.02, 1.04)	1.01 (1.00, 1.03)	
Birth interval					
Less than 3 years	66.4	53.7	1	1	<0.001
3 years or more	33.6	49.1	0.83 (0.81, 0.86)	0.86 (0.83, 0.89)	
Pre-existing conditions					
Diabetes	0.8	25.9	0.32 (0.28, 0.37)	0.31 (0.27, 0.35)	<0.001
Hypertension	0.5	36.0	0.51 (0.43, 0.61)	0.56 (0.47, 0.67)	<0.001
Characteristics of first pregnancy					
Birthweight (g)					
<2500	6.4	63.2	1.50 (1.44, 1.57)	1.27 (1.21, 1.34)	<0.001
2500–4000	61.5	53.3	1	1	
>4000	11.9	39.2	0.56 (0.54, 0.59)	0.58 (0.55, 0.60)	
Unknown	20.2	52.9	0.99 (0.91, 1.07)	1.00 (0.92, 1.08)	
Preterm	5.7	61.5	1.50 (1.43, 1.57)	1.21 (1.14, 1.29)	
Type of primary CS					
Elective	17.2	42.9	1	1	<0.001
Emergency	82.8	54.1	1.57 (1.49, 1.68)	1.53 (1.44, 1.63)	
Characteristics of second pregnancy					
Gestational diabetes	3.6	35.0	0.48 (0.44, 0.53)	0.46 (0.42, 0.51)	<0.001
Birthweight (g)					
<2500	2.1	60.3	1.37 (1.24, 1.51)	1.10 (1.00, 1.22)	
2500–4000	80.4	52.6	1	1	0.097
>4000	12.9	47.9	0.83 (0.79, 0.86)	1.02 (0.98, 1.06)	
Unknown	4.5	51.9	0.97 (0.86, 1.09)	0.94 (0.83, 1.06)	

CI, confidence interval; CS, caesarean section; OR, odds ratio.

(52.2%) women attempted a VBAC. Table 1 describes the rates of attempted VBAC according to maternal and obstetric risk factors. After adjustment for other factors, younger women, those of non-white ethnicity and those who lived in a deprived area had a higher rate of attempted VBAC. Attempted VBAC rates were also higher in women whose first baby had a lower birthweight, and those who had their second baby less than 3 years after the first. The presence of any clinical risk factor (pre-existing diabetes or hypertension, or gestational diabetes) reduced the attempted VBAC rate. The rate of attempted VBAC did not change significantly during the study period.

Of the 75 086 women in the cohort who attempted a VBAC, 47 602 (63.4%) had a successful vaginal delivery.

After adjustment, younger women and women of white ethnicity had a higher success rate. Black women had a particularly low success rate. Women who gave birth more than 3 years after the first baby was born were also less likely to have a successful VBAC. In addition, clinical risk factors, including gestational diabetes and premature rupture of membranes, as well as higher birthweights, decreased the VBAC success rate. There was a slight increase in the rate of successful VBAC during the study period ($P = 0.002$), which was not explained by maternal demographic and clinical risk factors (Table 2).

Women whose first birth was by emergency caesarean section were more likely to attempt a VBAC, but had a lower success rate than women who had a prior elective caesarean section (Tables 1 and 2). Table 3 presents the odds ratios (OR) for attempted and successful VBAC according to the indication for the initial caesarean section. Among women whose first birth was by emergency caesar-

Table 2. Rate of vaginal birth after caesarean section (VBAC) success in 75 086 women who attempted VBAC, according to maternal and obstetric risk factors

	Prevalence of risk factor (%)	Rate of VBAC success (%)	Crude OR (95% CI)	Adjusted OR (95% CI)	*P*
Maternal age (years)					
<24	13.1	69.3	1.28 (1.22, 1.35)	1.23 (1.17, 1.29)	
24–34	62.1	63.8	1	1	<0.001
>34	24.8	59.3	0.83 (0.80, 0.86)	0.79 (0.77, 0.82)	
Ethnicity					
White	68.5	65.5	1	1	<0.001
Black	8.5	50.3	0.53 (0.50, 0.57)	0.54 (0.50, 0.57)	
Asian	13.3	60.6	0.81 (0.75, 0.88)	0.76 (0.71, 0.82)	
Other	3.4	61.4	0.84 (0.76, 0.91)	0.83 (0.76, 0.91)	
Unknown	6.3	65.0	0.98 (0.90, 1.06)	0.97 (0.89, 1.06)	
Deprivation (quintile)					
1 -Least deprived	18.3	64.0	1	1	0.374
2	17.4	64.7	1.03 (0.99, 1.09)	1.02 (0.97, 1.08)	
3	18.1	64.4	1.02 (0.96, 1.08)	1.02 (0.96, 1.08)	
4	20.2	62.4	0.93 (0.86, 1.01)	0.97 (0.90, 1.04)	
5 -Most deprived	26.0	62.3	0.93 (0.84, 1.03)	0.99 (0.91, 1.08)	
Year of first birth					
2004	17.8	62.6	1	1	0.002
Increase per year	-	-	1.02 (1.01, 1.04)	1.02 (1.01, 1.04)	
Birth interval					
Less than 3 years	68.4	64.1	1	1	0.012
3 years or more	31.7	62.0	0.91 (0.88, 0.95)	0.95 (0.91, 0.99)	
Type of CS at first birth					
Elective	14.1	71.7	1	1	<0.001
Emergency	85.9	62.0	0.64 (0.61, 0.68)	0.66 (0.63, 0.69)	
Pre-existing conditions					
Diabetes	0.4	37.7	0.35 (0.28, 0.43)	0.36 (0.29, 0.45)	<0.001
Hypertension	0.4	54.1	0.68 (0.53, 0.88)	0.74 (0.56, 0.98)	0.039
Characteristics of second pregnancy					
Gestational diabetes	2.4	52.1	0.62 (0.56, 0.69)	0.67 (0.61, 0.75)	<0.001
Pre-eclampsia/eclampsia	0.9	45.7	0.48 (0.41, 0.57)	0.49 (0.42, 0.58)	<0.001
Premature rupture of membranes	6.0	51.8	0.6 (0.55, 0.66)	0.62 (0.57, 0.68)	<0.001
Birthweight (g)					
<2500	2.5	66.5	1.05 (0.96, 1.16)	1.08 (0.97, 1.19)	
2500–4000	81.2	65.4	1	1	<0.001
>4000	11.8	48.7	0.50 (0.48, 0.53)	0.50 (0.48, 0.53)	
Unknown	4.5	63.7	0.93 (0.83, 1.04)	0.96 (0.86, 1.06)	

CI, confidence interval; CS, caesarean section; OR, odds ratio.

Table 3. Attempted and successful vaginal birth after caesarean section (VBAC) by indication for primary caesarean section

	Attempted VBAC			Successful VBAC		
	Prevalence of risk factor (%)	Adjusted OR* (95% CI)	*P*	Prevalence of risk factor (%)	Adjusted OR** (95% CI)	*P*
Indication for emergency CS						
Fetal distress	38 652 (32.4)	1	<0.001	21 469 (33.3)	1	<0.001
Prolonged/obstructed labour	32 603 (27.3)	1.10 (1.06, 1.15)		17 681 (27.4)	1.02 (0.97, 1.08)	
Fetal distress and prolonged/obstructed labour	22 009 (18.5)	1.08 (1.02, 1.13)		12 044 (18.7)	0.90 (0.85, 0.95)	
Failed induction of labour	6082 (5.1)	0.51 (0.47, 0.55)		2216 (3.4)	0.59 (0.53, 0.67)	
Other reasons	19 876 (16.7)	1.02 (0.96, 1.08)		11 065 (17.2)	1.29 (1.22, 1.36)	
Total	119 222 (100)			64 475 (100)		
Indication for elective CS						
Placenta praevia/abruption	1236 (5.0)	0.84 (0.74, 0.95)	<0.001	694 (6.5)	0.88 (0.76, 1.03)	<0.001
Non-cephalic delivery	12 647 (51.1)	1		7757 (73.1)	1	
Other reasons	10 865 (43.9)	0.15 (0.14, 0.17)		2160 (20.4)	0.47 (0.42, 0.53)	
Total	24 748 (100)			10 611 (100)		

CI, confidence interval; CS, caesarean section; OR, odds ratio.
*Adjusted for the following risk factors: maternal age at second birth, ethnicity, deprivation quintile, year of first birth, birth interval, pre-existing diabetes, pre-existing hypertension, birthweight (index and second pregnancy), preterm delivery (index pregnancy), gestational diabetes and clustering at the trust level.
**Adjusted for the following risk factors: maternal age at second birth, ethnicity, deprivation quintile, year of first birth, birth interval, pre-existing diabetes, pre-existing hypertension, gestational diabetes, pre-eclampsia, premature rupture of membranes, birthweight (second pregnancy) and clustering at the trust level.

ean section, those with a history of failed induction of labour were the least likely group both to attempt and to succeed with a VBAC ($P < 0.001$). Among women whose first birth was by elective caesarean section, those with an indication other than non-cephalic presentation or placenta praevia were least likely to attempt and to succeed with a VBAC ($P < 0.001$).

There was variation in the rate of attempted and successful VBAC between NHS trusts, which was independent of maternal demographic and clinical risk factors (Figure 2). The funnel plots showed greater between-trust variation in adjusted rates of attempted VBAC than successful VBAC. The interquartile range of the adjusted rate of attempted VBAC across 140 NHS trusts was 47.1–58.6%, although there was almost a threefold variation across trusts (33.2–93.6%). The interquartile range of the adjusted rate of successful VBAC was 60.4–65.9%, although there was almost a twofold variation across all trusts (47.6–84.5%).

Discussion

Main findings

Our findings suggest that just over one-half of women with a primary caesarean section who are eligible for a trial of labour attempt a VBAC for their second birth. Of those who attempt a VBAC, almost two-thirds of women successfully achieve a vaginal delivery.

We found evidence of variation in the uptake and success of VBAC according to maternal demographic and clinical characteristics. Younger women and women with low-risk pregnancies were more likely to attempt a VBAC and had higher rates of successful VBAC, independent of other risk factors. Socially deprived women and women of non-white ethnicity also had higher rates of attempted VBAC. However, non-white women had considerably lower rates of successful VBAC.

Attempt and success rates also varied according to the indication for the primary caesarean section. Women with a history of emergency caesarean section were more likely to attempt and to fail a VBAC than women who had an elective caesarean for their first birth. Women with a history of failed induction of labour were amongst the least likely both to attempt and to succeed with a VBAC. Attempted and successful VBAC rates varied significantly between English NHS trusts.

Strengths and limitations

This is the first national cohort study to describe rates of attempted and successful VBAC among a well-defined cohort of women, rather than reporting overall VBAC rates. The exclusion of women who are not candidates for VBAC represents an important development as it provides a more appropriate denominator for the estimation of VBAC rates.

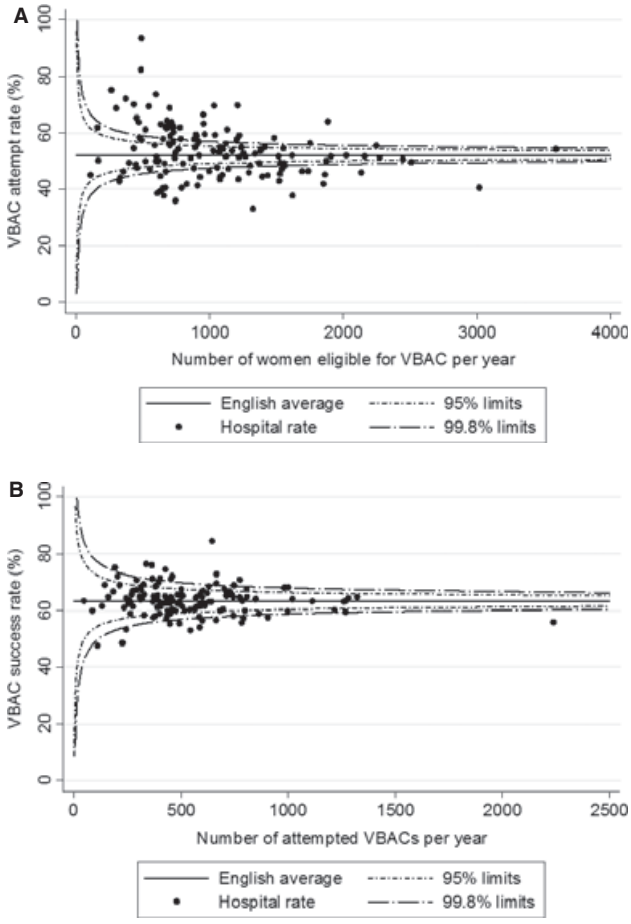

Figure 2. Funnel plots showing rates of attempted vaginal birth after caesarean section (VBAC) **A** and successful VBAC **B** among women who had a primary caesarean section in English NHS trusts between 2004 and 2011, adjusted for maternal characteristics and clinical risk factors.

This is the largest cohort study to date to analyse the association between primary caesarean section and subsequent mode of delivery. The cohort included over 75 000 women who attempted a VBAC over an 8-year period. The database includes all deliveries occurring in English NHS maternity units (96% of all deliveries in England),[33] thereby minimising the risk of selection bias. Case ascertainment is expected to be extremely high as women who have a primary caesarean section are not eligible for home delivery for their second birth. The availability of data since 1997 allowed for an analysis of obstetric histories and patterns of care over time. Finally, HES data capture multiple procedures and diagnoses on individual patients, and so provide a rich description of patient case mix, which supports the definition of an appropriate cohort and risk adjustment.

A limitation of this study is that our adjusted results may be affected by residual confounding because we were unable to control for maternal height,[34] body mass index (BMI)[35] and tobacco use,[35] which may affect the likelihood of attempted and/or successful VBAC. However, we observed large differences in the rate of attempted and successful VBAC among women from different ethnic and socioeconomic backgrounds, and it is unlikely that any confounding caused by the absence of these risk factors from the model could account for these disparities. For example, Asian women living in England have the lowest prevalence of BMI over 30[36] and smoking,[37] and yet have a significantly higher rate of failed VBAC than white women. Our use of only five ethnic categories may have biased our findings. However, this bias would most likely have caused women with similar genetic make-ups to be considered in different groups, reducing the impact of ethnicity on the VBAC rate observed in our study.

A weakness of administrative datasets is that the coding of the diagnoses and procedures is potentially inaccurate. However, the definition of method of delivery categories has been shown to be reliable in studies from other countries with routine hospital data.[38–40] This issue has also been examined using the HES database, with high levels of internal consistency reported for the method of delivery ($\kappa = 0.93$; $P < 0.001$).[41]

Finally, the method employed to define parity using a 'lookback' approach[42,43] may have resulted in some multiparous women whose first birth was not recorded in HES being incorrectly labelled as primiparous.[44] However, sensitivity analyses using the parity information in the HES maternity tail – which is available in only two-thirds of episodes – yield comparable results.

Interpretation

In this population, we did not observe the decline in attempted VBAC rates that has been reported in other developed countries.[3–6] The rate of attempted VBAC during the timeframe of this study (52.2%) is considerably higher than that in the USA, where it was estimated recently that 20% of women choose this option,[3,45] but slightly lower than in several European countries, where rates of up to 70% have been reported.[46–51] These differences in national rates are likely to arise from a combination of factors, including the type of healthcare system, patient preferences and the extent to which national clinical guidelines recommend VBAC. The current VBAC guidelines produced by the American College of Obstetricians and Gynecologists mandate that an obstetrician and anaesthesiologist be 'immediately available' during a trial of labour and restrict the availability of VBAC in community and rural hospitals.[2] A recent qualitative study from the USA suggests that fear of litigation is a further reason why providers are highly selective in choosing candidates for VBAC.[11]

We found a higher rate of attempted VBAC among women living in socially deprived areas and in women of non-white ethnicity. This may reflect different patient preferences,[52–54] but may also indicate problems with a lack of access to ERCS among these groups. A recent study from the USA observed that black women are more likely than white women to attempt VBAC (OR, 1.26; 95% confidence interval [CI], 1.04–1.52).[24] Two studies have also reported that women with low socioeconomic status are less likely to decline trial of labour after caesarean.[55,56]

The overall VBAC success rate during the study timeframe (63.4%) was slightly lower than that found in other studies, which suggest rates of over 70%.[13,20,57] However, these studies were carried out using data from 1985 to 2002, and in populations with different maternal risk profiles and rates of attempted VBAC.[3] For example, all three studies included women with a prior vaginal delivery, which is the single best predictor of a successful VBAC.[1] The lower VBAC success rate in this study could also be a result of clinicians adopting a more cautious approach to the management of women who attempt a VBAC, for example through greater willingness to resort to emergency caesarean if progress in labour is slow. Most clinicians also now avoid using labour-stimulating agents for women attempting VBAC,[10] as there is growing evidence that these can increase the risk of uterine rupture.[58]

Several studies from other countries confirm our finding that women of black ethnicity are less likely to have a successful VBAC compared with white women, with ORs of between 0.63 and 0.87 reported in the literature.[22–24] Physiological explanations for this finding have been postulated, although the evidence for these remains unclear. Interestingly, despite the lower success rate, the overall VBAC rates for women of white and black ethnicity in our study were similar (32 and 31%, respectively), and lower than that of Asian women (39%).

A number of smaller studies have found associations between the indication for initial caesarean section and the likelihood of successful VBAC, but none of these have been conducted on a national basis.[59–61] Our findings confirm the results of these earlier studies and lend support to the hypothesis that women with a history of labour induction are more at risk of failed VBAC than women without such a history.

There are now at least two validated prediction models for successful VBAC, reporting high levels of predictive accuracy.[21,34,62–64] The models produce a similar pattern of risk factors to that in our study with respect to maternal age and indication for caesarean section. However, the model by Smith et al.[34] does not include ethnicity, which we found to be an important risk factor. The ability to accurately predict VBAC success could be improved by the inclusion of additional risk factors and by having the ability to take into account changes during pregnancy and as labour progresses.[65]

Conclusions

The choice of whether to attempt a trial of labour after delivering a first child by caesarean section is a decision that affects over 50 000 women a year in England and many hundreds of thousands more around the world. In our population, we found that, among such women, just over one-half attempt to give birth vaginally. Of women who attempt a VBAC, almost two-thirds successfully achieve a vaginal delivery. Women of non-white ethnicity are more likely both to attempt and to fail a VBAC, independent of other risk factors. Women who deliver their first baby by emergency caesarean section also have lower VBAC success rates, particularly if the indication for the initial emergency caesarean is failed induction of labour. This information could be used to improve candidate selection for VBAC.

Disclosure of interests

None.

Contribution to authorship

HEK, IGU and TAM conceived the study. HEK, IGU, JHvdM and DAC contributed to its design and conducted the analyses. HEK wrote the paper, and IGU, DAC, JHvdM, TAM, DHR and AD commented on the drafts. All authors approved the final version for publication.

Details of ethics approval

The study is exempt from UK National Research Ethics Service (NRES) approval because it involved the analysis of an existing dataset of anonymised data for service evaluation. Approval for the use of HES data was obtained as part of the standard Hospitals Episode Statistics approval process.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Conditions suggesting delivery by emergency caesarean section.

Appendix S2. Coding of variables in the analysis. ■

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Appendix S1. Conditions suggesting delivery by emergency caesarean section

Diagnosis	ICD-10 code
Eclampsia	O15.0-9
Maternal care for unstable lie	O32.0
Maternal care for (suspected) central nervous system malformation in fetus	O35.0
Maternal care for (suspected) chromosomal abnormality in fetus	O35.1
Maternal care for intrauterine death	O36.4
Premature rupture of membranes, onset of labour within 24 hours	O42.0
Premature separation of placenta with coagulation defect	O45.0
Other premature separation of placenta	O45.8-9
Other antepartum haemorrhage	O46.8-9
Labour and delivery complicated by fetal stress [distress]	O68

Appendix S2. Coding of variables in the analysis

Diagnosis	ICD-10 Code
Failed induction of labour	O61
Fetal distress	O68; O690
Gestational diabetes	O244; O249
Placenta praevia / abruption	O44-5
Preeclampsia / eclampsia	O14-5
Pre-existing hypertension	O10-11; I10
Pre-existing diabetes	O240-3; E10-11
Premature rupture of membranes	O48
Prolonged / obstructed labour	O63; O620-2; O64-5

Stillbirths were defined as delivery episodes with a maternity tail code for stillbirth (birthstat 2-4;9). If this field was missing in the maternity tail, ICD-10 codes for stillbirth were used (Z371; Z373-4; Z376-7).

Multiple deliveries were defined as delivery episodes with an ICD-code for a multiple birth (Z37.2–7) OR strong evidence of a multiple birth in the maternity tail (>1 valid date of birth [dobbaby], birthweight [birweit] , birth order [birord] AND >1 in the number of babies [numbaby] field).

Preterm deliveries <37 weeks were defined as delivery episodes with an ICD-10 code for preterm delivery (O60).

Non-cephalic deliveries were defined as delivery episodes with an OPCS code for breech delivery (R19-20) OR a maternity tail code for breech delivery (delmeth_1 5 or 6) OR an ICD code for breech delivery (O801; O830-1) OR an ICD code for maternal care for malpresentation (O320-2; O641)

Onset of labour was defined using the labour and delivery onset (delonset 2) field in the maternity tail. This was used in conjunction with the mode of delivery to identify emergency caesarean sections prior to the onset of labour.

Birthweight was defined using the maternity tail code (birweit) and re-coded into the following categorical variables: <2500g; 2500-4000g, >4000g; missing.

7. Routine induction of labour at 39 weeks in nulliparous women aged 35 or over

The previous results paper examined a clinical issue that has become increasingly topical in many high-income countries given the rising rates of primary caesarean section. In this chapter, attention is turned to another common obstetric intervention, induction of labour, and another highly topical issue: the clinical implications of the increasing number of women giving birth for the first time aged 35 years and over.

A recent randomised controlled trial (RCT) addressed the effect of routine induction of labour at 39 weeks in nulliparous women aged 35 and above,[65] a group known to be at higher risk of stillbirth.[64 66] The key finding of this RCT was that this intervention was not associated with an increased risk of the common adverse maternal and infant outcomes. However, the trial was unable to address the effect of the intervention on the outcome which motivates routine early delivery in that population, namely, stillbirth. Moreover, an NICHD study which is in progress is also underpowered to determine the effect of this intervention on stillbirth.[67]

This chapter sought to use the HES dataset to address this question in a sufficiently large sample of women aged 35 year and over, to allow the association between induction of labour and stillbirth to be examined. Several previous observational studies have compared outcomes of women with induced labour with those of women who labour spontaneously.[68 69] However, the appropriate comparison group should be women who are expectantly managed.[70] A key challenge for this study was therefore to define an appropriate

comparison group using observational data in which gestational age was only available in completed weeks and not in days.

Other methodological themes addressed include the application of methods for handling missing gestational age and onset of labour data; defining the relevant risk factors and outcomes; utilising data linkage to examine both maternal and neonatal outcomes, and adjusting for differences in obstetric case mix between groups.

The results have been presented in the form of the published paper. The supplementary material referred to in the paper is available at the end of this chapter.

Statement of authorship

This chapter has been written as a published paper:

Knight HE, Cromwell DA, Gurol-Urganci I, Harron K, van der Meulen JH, Smith GC. Perinatal mortality associated with induction of labour versus expectant management in nulliparous women aged 35 years or over: An English national cohort study. Plos Medicine 2017;14(11):e1002425.

The authors have certified that:

a. they meet the criteria for authorship in that they have participated in the conception, execution or interpretation of at least that part of the publication in their field of expertise
b. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
c. there are no other authors of the publication according to these criteria;
d. potential conflicts of interest have been disclosed to granting bodies, the editor or publisher of journals or other publications and the head of responsible academic unit;
e. they agree to the use of the publication in the student's thesis and its publication on the LSHTM Research Online database consistent with any limitations set by publisher requirements.

Contributor	**Statement of contribution**
H.E. Knight	Conceived and conducted the research; designed and implemented the statistical analysis; wrote the first draft of the manuscript; modified the manuscript as suggested by co-authors and reviewers
Signature & Date:	H Knight 20.04.18
G.C. Smith	Conceived the research; advised on study design, statistical methods and analysis; technical input into the clinical aspects of the work; assisted in editing the manuscript
D.A. Cromwell, I. Gurol-Urganci, J.H. van der Meulen	Involved in developing the research idea; advised on study design, statistical methods and analysis; supervised the research; assisted in editing the manuscript
K. Harron	Assisted in the preparation and linkage of the data; advised on statistical methods; commented on the manuscript

Principal Supervisor Confirmation:
I have sighted email or other correspondence for all co-authors confirming their authorship.

Signature & Date:

D Cromwell 20th April 2018

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PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Hannah Knight
Principal Supervisor	David Cromwell
Thesis Title	To what extent can routinely collected data be used to evaluate the performance and quality of English NHS maternity services?

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	PLOS Medicine		
When was the work published?	14 November 2017		
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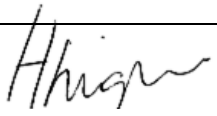
For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	see page 97

Student Signature:  **Date:** 20.04.18

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RESEARCH ARTICLE

Perinatal mortality associated with induction of labour versus expectant management in nulliparous women aged 35 years or over: An English national cohort study

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Data Availability Statement: The data governance arrangements for the study do not allow us to redistribute HES data to other parties. Researchers interested in accessing HES data can apply for access through NHS Digital's Data Access Request Service (DARS) https://dataaccessrequest.hscic.gov.uk/. This study made use of pseudonymised HES extracts of women who gave birth between April 2009 and March 2014.

Abstract

Background

A recent randomised controlled trial (RCT) demonstrated that induction of labour at 39 weeks of gestational age has no short-term adverse effect on the mother or infant among nulliparous women aged ≥35 years. However, the trial was underpowered to address the effect of routine induction of labour on the risk of perinatal death. We aimed to determine the association between induction of labour at ≥39 weeks and the risk of perinatal mortality among nulliparous women aged ≥35 years.

Methods and findings

We used English Hospital Episode Statistics (HES) data collected between April 2009 and March 2014 to compare perinatal mortality between induction of labour at 39, 40, and 41 weeks of gestation and expectant management (continuation of pregnancy to either spontaneous labour, induction of labour, or caesarean section at a later gestation). Analysis was by multivariable Poisson regression with adjustment for maternal characteristics and pregnancy-related conditions. Among the cohort of 77,327 nulliparous women aged 35 to 50 years delivering a singleton infant, 33.1% had labour induced: these women tended to be older and more likely to have medical complications of pregnancy, and the infants were more likely to be small for gestational age.

Induction of labour at 40 weeks (compared with expectant management) was associated with a lower risk of in-hospital perinatal death (0.08% versus 0.26%; adjusted risk ratio [adjRR] 0.33; 95% CI 0.13–0.80, $P = 0.015$) and meconium aspiration syndrome (0.44% versus 0.86%; adjRR 0.52; 95% CI 0.35–0.78, $P = 0.002$). Induction at 40 weeks was also associated with a slightly increased risk of instrumental vaginal delivery (adjRR 1.06; 95% CI 1.01–1.11, $P = 0.020$) and emergency caesarean section (adjRR 1.05; 95% CI 1.01–

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Competing interests: We have read the journal's policy and the authors of this manuscript have the following competing interests: GCS is a member of the Editorial Board of *PLOS Medicine*. GCS receives/has received research support from GE (supply of 2 diagnostic ultrasound systems), from Roche (supply of equipment and reagents for biomarker studies, value £596,142), and from GSK (£199,413 for in vitro studies on human myometrium). GCS has been paid to attend advisory boards by GSK (preterm birth) and Roche (preeclampsia biomarkers). GCS has acted as a paid consultant to GSK (preterm birth). GCS has received support to attend a scientific meeting from Chiesi. GCS is a named inventor in a patent submitted by GSK for a novel application of an existing GSK compound for the prevention of preterm birth (PCT/EP2014/062602). GCS is a member of a GSK Data Safety Monitoring Committee for a trial of RSV vaccination in pregnancy and infancy.

Abbreviations: adjRR, adjusted risk ratio; HES, Hospital Episode Statistics; NHS, National Health Service; NNT, number needed to treat; RCT, randomised controlled trial.

1.09, $P = 0.019$). The number needed to treat (NNT) analysis indicated that 562 (95% CI 366–1,210) inductions of labour at 40 weeks would be required to prevent 1 perinatal death. Limitations of the study include the reliance on observational data in which gestational age is recorded in weeks rather than days. There is also the potential for unmeasured confounders and under-recording of induction of labour or perinatal death in the dataset.

Conclusions

Bringing forward the routine offer of induction of labour from the current recommendation of 41–42 weeks to 40 weeks of gestation in nulliparous women aged ≥35 years may reduce overall rates of perinatal death.

Author summary

Why was this study done?

- National guidelines recommend that induction of labour is carried out between 41 and 42 weeks of gestation to prevent the risks associated with prolonged pregnancy. However, women having their first baby at age 35 years or over are at increased risk of pregnancy complications, including perinatal death.
- A recent randomised controlled trial demonstrated that induction of labour at 39 weeks of gestation has no short-term adverse effect on the mother or infant among nulliparous women aged 35 years or older. However, the trial was underpowered to address the effect of routine induction of labour on the risk of perinatal death.
- The present study aims to answer the question 'Does routine induction of labour at or after 39 weeks of gestation reduce the risk of perinatal mortality in first-time mothers aged 35 years or older, compared with expectant management?'

What did the researchers do and find?

- In this national cohort study of 77,327 first-time mothers aged 35 or older, induction of labour at 40 weeks of gestation was associated with a 66% lower risk of perinatal death (0.08% versus 0.26%) than expectant management.
- Perinatal death is a rare outcome even in this group and 562 inductions of labour at 40 weeks would be required to prevent 1 perinatal death.

What do these findings mean?

- Bringing forward the routine offer of induction of labour from the current recommendation of 41–42 weeks to 40 weeks of gestation in this group of women may reduce overall rates of perinatal death.

Introduction

Across industrialised nations, the proportion of births to women aged ≥35 years is rising [1,2]. In England and Wales, births to women aged ≥35 years have increased from 6% of all births in 1975 to 21% in 2015 [3]. There has also been an increase in the number of babies born to first-time mothers aged ≥35 years, which in 2015 accounted for 14% of all first-time births and 5.4% of all births in England and Wales [4].

Older women are at increased risk of pregnancy complications, including gestational diabetes, placenta praevia, and postpartum haemorrhage [5,6], and experience higher rates of intervention during labour and delivery [5,7]. After controlling for comorbidities, the risk of antepartum stillbirth at term is higher among women aged ≥35 years than among younger women [8] and is higher still for nulliparous women aged ≥35 years [9]. Observational data indicate that induction of labour at or before term may be beneficial because the risk of perinatal death is at its lowest for births between 38 and 39 weeks of gestation [9]. However, current United Kingdom guidelines recommend that induction for prolonged gestation is offered to women between 41 to 42 weeks of gestation, when the risk of stillbirth is 2 to 3 per 1,000 deliveries [10].

A recent randomised controlled trial (RCT) has shown that among nulliparous women aged ≥35 years, elective induction of labour at 39 weeks of gestation had no significant effect on the rate of caesarean section and no adverse short-term effects on maternal or neonatal outcomes compared with expectant management [11], but the trial was underpowered to examine the effect of induction of labour on the risk of perinatal death. Well-conducted observational studies have found that induction of labour at term is associated with decreased perinatal mortality in the general pregnant population [12]; however, none has been sufficiently powered to examine the impact on this specific age group known to be at increased risk. We employed a large English routine dataset to determine the association between induction of labour at ≥39 weeks and the risk of perinatal death among nulliparous women aged ≥35 years.

Methods

We designed our methods to test the hypothesis that induction of labour at 39, 40, and 41 weeks reduced the risk of perinatal mortality among nulliparous women aged ≥35 years compared with expectant management (continuation of pregnancy to either spontaneous labour, induction of labour, or caesarean section at a later gestation).

Details of ethics approval

The study is exempt from UK National Research Ethics Service (NRES) approval because it involved the analysis of an existing dataset of anonymised data for service evaluation. Hospital Episode Statistics (HES) data were made available by NHS Digital (Copyright 2015, re-used with the permission of NHS Digital. All rights reserved.) Approvals for the use of anonymised HES data were obtained as part of the standard NHS Digital data access process.

Data source

We used the HES database to identify births in English National Health Service (NHS) hospitals. The HES database contains patient demographics, diagnostic and procedure information, and administrative data for each inpatient episode of care since 1997 [13]. A unique identifier enables studies to combine episodes of care that belong to the same patient.

In the HES database, for episodes related to childbirth, supplementary fields (the 'maternity tail') capture details including parity, birthweight, gestational age, onset of delivery, method of

delivery, and birth outcome. Mothers' delivery episodes were defined as records containing information about the mode of delivery in either the OPCS4 codes (R17–R25) or the maternity tail.

Diagnostic information is coded using the *International Classification of Diseases*, *10th Revision* (ICD10) [14], and operative procedures are coded using the UK *Office for Population Censuses and Surveys Classification*, *4th Revision* (OPCS4) [15]. The level of data completeness has improved over time [16,17] but varies across NHS hospitals: in 2014, data on onset of labour and gestational age were available in 85% and 82% of all delivery episodes, respectively [18].

Study population

We included all nulliparous women aged 35 to 50 years delivering at 39 weeks of gestation or beyond, between April 2009 and March 2014. We excluded multiple births; women with pre-existing comorbidities (hypertension, diabetes, and cardiac or lung disease); births complicated by fetal malpresentation, abdominal pregnancy, and placenta praevia; and pregnancies resulting in perinatal deaths due to congenital abnormality. We excluded records that were missing birth status, delivery onset, or gestational age. We also performed data quality assessments at the individual hospital level and excluded hospitals with suspected poor-quality data for these key data items (S1 Appendix, Text A). The characteristics of women excluded on the basis of these assessments were compared with those of the study cohort. Limiting birth cohorts in this way to include only hospitals with high completeness of recording has been demonstrated to be a valid way of constructing cohorts from routine hospital data [16,17]. The mothers' delivery records were linked to the hospital records of their babies using probabilistic linkage [19] to obtain data on perinatal outcomes using the babies' birth records (e.g., for in-hospital perinatal death) and any subsequent hospital inpatient or A&E records (e.g., emergency neonatal readmission within 28 days). Induction of labour was defined as either surgical induction by amniotomy; medical induction, including the administration of agents either orally, intravenously, or intravaginally; or a combination of surgical and medical induction.

Definitions of the induction and expectant management groups

For an observational study to appropriately examine the outcomes of induction of labour at different gestational ages, it is important to compare outcomes of women who have an induction of labour at a particular week of gestation (week n) with women who are expectantly managed, i.e., go on to deliver at a later gestation by any mode of onset, and not with women who labour spontaneously at the same gestation. There are 2 possible ways to define the expectant management group using observational data in which gestational age is recorded in weeks (see Stock et al. [12] for discussion):

1. women delivering at weeks $>n$
2. women delivering at weeks $\geq n$

For the primary analysis, we adopted the first approach, including women delivering at weeks $>n$ following spontaneous or induced labour or prelabour caesarean. The robustness of this approach was then tested using a secondary analysis that used the alternative definition.

For each week of gestation examined, we excluded women if their labour was induced following an antepartum intrauterine death or prelabour rupture of membranes because, in both conditions, if labour does not begin spontaneously within 24 hours, the standard management is induction of labour [10]. However, we did not exclude women with these complications from the expectant management group if the event occurred after the week of gestation of induction in the induction group (at weeks $>n$). This followed a similar approach used in

previous studies [12] and is supported by evidence that delays in the delivery of antepartum stillbirths or PROM are uncommon in UK hospitals [20]. Intrapartum stillbirths in all weeks $\geq n$ were included in both groups.

Outcomes

We examined the following neonatal outcomes: stillbirth, in-hospital perinatal death, birth injury, shoulder dystocia, hypoxia in labour, meconium aspiration syndrome, neonatal seizures, and emergency readmission to hospital within 28 days of birth. In-hospital perinatal death was defined as stillbirth or in-hospital neonatal death within 7 days of birth. We also recorded the following maternal outcomes: emergency caesarean section, instrumental delivery, third or fourth degree perineal tear, and emergency readmission to hospital within 28 days of delivery. To calculate readmission rates, births that occurred in the last 28 days of the study period were excluded. Details of the definitions used are given in S1 Appendix, Table A.

Statistical analysis

All analyses were prespecified as described in the Methods section, with the exceptions of the exclusion of women with preexisting comorbidities and the use of Poisson rather than logistic regression. These modifications were made prior to the commencement of any statistical analyses; the rationale for each change is provided in S1 Appendix, Text B. We did not publish or pre-register a plan for this analysis.

We used proportions to summarise the distribution of pregnancy characteristics of induced and non-induced women and the chi-squared test for comparisons of variables between the groups. For each week of gestation, univariable and multivariable Poisson regression with robust standard errors was used to estimate the crude and adjusted effects of induction of labour compared with expectant management on each maternal and perinatal outcome. We chose not to use logistic regression because odds ratios overestimate the risk ratio for common outcomes [21]. The confounding variables included in all models were maternal age (years); ethnicity (white, Asian, black, other, or unknown); year of birth; baby's sex (male or female); birthweight percentile according to UK 1990 fetal growth charts (<10th, 10th–90th, or >90th) [22]; and socioeconomic quintile according to the a Index of Multiple Deprivation (IMD) score, a measure that combines economic, social, and housing indicators [23]. The year of the birth was recorded as a linear variable to take into account changes in clinical practice over time. Estimates were adjusted for pregnancy-related conditions (pregnancy-induced hypertension, preeclampsia, or oedema; gestational diabetes; and fluid abnormalities) when these were found to have significant coefficients. No formal tests of interaction were done, and no adjustments were made for multiple comparisons. For both our primary and secondary analyses, we estimated the number of inductions of labour needed to prevent 1 perinatal death: number needed to treat (NNT) = 1/([induction of labour event risk]−[expectant management event risk]). All statistical tests were 2-sided, and the level of significance was set at $P < 0.05$. All analyses were performed in STATA version 14.1 (StataCorp, College Station, TX, United States).

Results

There were 77,327 women aged 35–50 years who met the inclusion criteria and gave birth in hospitals that passed the data quality assessments for key data items (Fig 1). Of these women, 25,583 (33.1%) were induced and 51,744 (66.9%) were not. Induction of labour rates among this group of women increased each year during the time period from 30.2% in 2009–2010 to 35.7% in the 2013–2014 cohort. Medical induction of labour was the principal method of

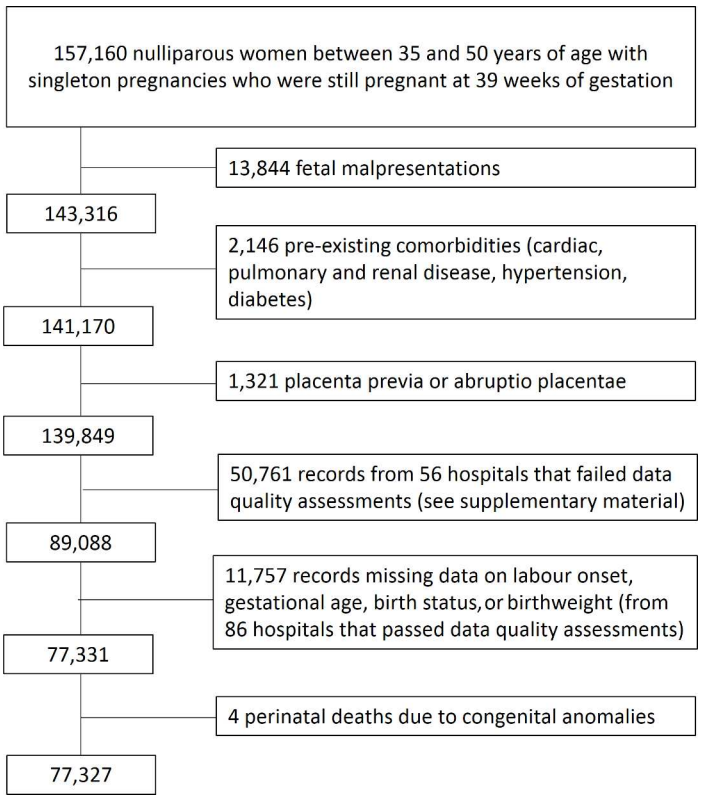

Fig 1. Cohort selection flow chart.

https://doi.org/10.1371/journal.pmed.1002425.g001

induction throughout the time period (57.7% of inductions), with surgical and combined methods used less frequently (19.7% and 19.4% of inductions, respectively).

There were 50,761 eligible women who gave birth in hospitals that failed the data quality assessments for key data items required in the analysis, and these women were therefore not included in the study. The women included in the study shared similar characteristics to the excluded women who gave birth in hospitals with poor data quality (S1 Appendix, Table B). Hospitals that failed the data quality assessments were missing data on gestational age, birth status, and onset of labour in 40%, 25%, and 24% of records, respectively, compared with 11%, 10%, and 11% of records in hospitals that passed these assessments.

Women who had labour induced were more likely to be over 40 years old, of white ethnicity, and to deliver infants in less than the 10th centile for birthweight (Table 1). They were also more likely to have acquired complications of pregnancy. Fig 2 describes the composition of the cohorts used for the primary and secondary analyses.

Perinatal mortality

Labour induction from 40 weeks onwards was associated with a significantly reduced rate of both in-hospital perinatal death and stillbirth when compared with expectant management (Fig 3).

In the primary analysis, the adjusted risk ratio (adjRR) for in-hospital perinatal death associated with induction compared with expectant management was 0.33 (95% CI 0.13–0.80) at 40 weeks and 0.24 (95% CI 0.09–0.65) at 41 weeks (Table 2). However, there was no difference

Table 1. Pregnancy characteristics of 77,327 women according to induction of labour.

Characteristic	Group	Not induced (*n* = 51,744) *n* (%)	Induced (*n* = 25,583) *n* (%)	Total *n* (%)
Maternal age (years)	35–39	43,691 (84.4)	19,880 (77.7)	63,571 (82.2)
	40–50	8,053 (15.5)	5,703 (22.3)	13,756 (17.8)
Maternal ethnicity*	White	37,507 (80.1)	19,341 (82.7)	56,848 (81.0)
	Asian	3,352 (7.2)	1,453 (6.2)	4,805 (6.8)
	Black	2,655 (5.7)	1,224 (5.2)	3,879 (5.5)
	Other	3,319 (7.1)	1,357 (5.8)	4,676 (6.7)
Maternal SES quintile	SES 1 (least deprived)	11,350 (21.9)	5,565 (21.8)	16,915 (21.9)
	SES 2	10,861 (21.0)	5,444 (21.3)	16,305 (21.1)
	SES 3	10,470 (20.2)	5,190 (20.3)	15,660 (20.3)
	SES 4	11,225 (21.7)	5,492 (21.5)	16,717 (21.6)
	SES 5 (most deprived)	7,836 (15.1)	3,890 (15.2)	11,726 (15.2)
Year of birth	2009	11,897 (23.0)	5,147 (20.1)	17,044 (22.0)
	2010	10,732 (20.7)	5,001 (19.6)	15,733 (20.4)
	2011	10,756 (20.8)	5,348 (20.9)	16,104 (20.8)
	2012	9,545 (18.5)	5,193 (20.3)	14,738 (19.1)
	2013	8,814 (17.0)	4,894 (19.1)	13,708 (17.8)
Birthweight centile	10–90th	43,538 (84.1)	21,164 (82.7)	64,702 (83.7)
	<10th	4,545 (8.8)	2,597 (10.2)	7,142 (9.2)
	>90th	3,661 (7.1)	1,822 (7.1)	5,483 (7.1)
Sex of baby	Male	21,311 (50.9)	13,245 (51.8)	39,556 (51.2)
Pregnancy complications	Preeclampsia	2,493 (4.8)	3,319 (13.0)	5,812 (7.5)
	Gestational diabetes	875 (1.7)	1,440 (5.6)	2,315 (3.0)
	Abnormal fluid volume	240 (0.5)	417 (1.6)	657 (0.9)

* Ethnicity was unknown in 7,119 (9.2%) of records. A missing category was included in the regression models.

Abbreviations: SES, socioeconomic status.

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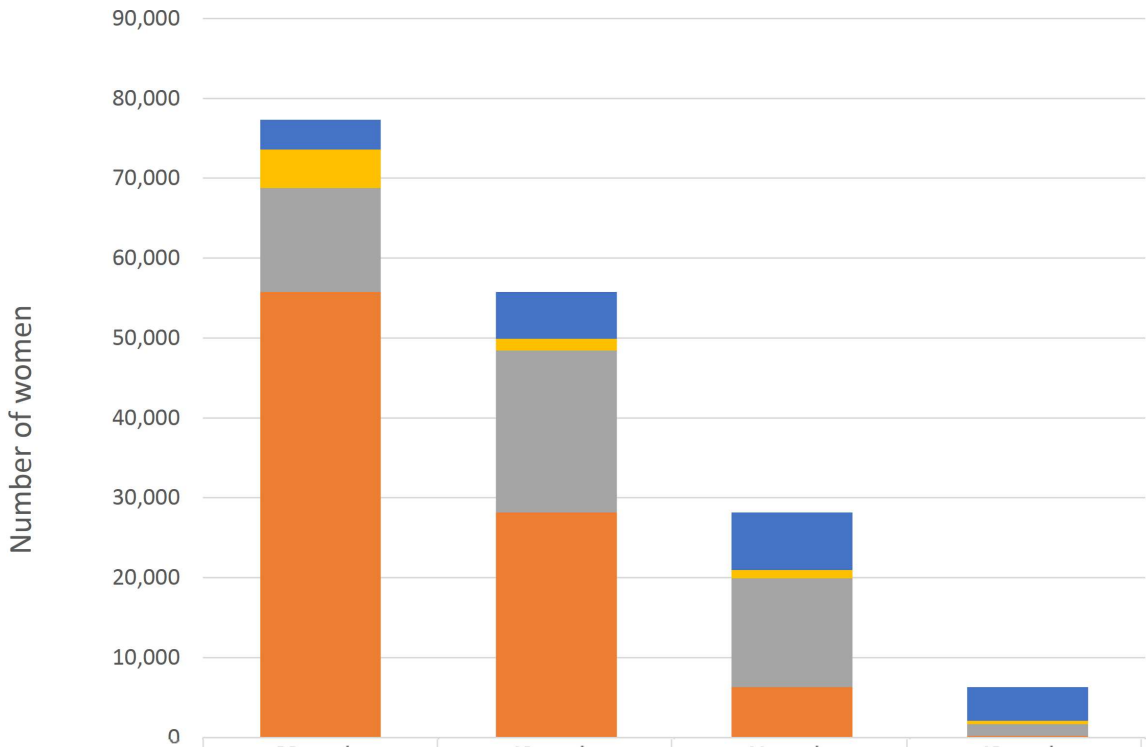
in the estimated adjRR for in-hospital perinatal death associated with induction at 39 weeks (0.37; 95% CI 0.12–1.15). Similar magnitudes of effect were observed for stillbirth, with an adjRR of 0.25 (95% CI 0.09–0.79) at 40 weeks and 0.18 (95% CI 0.05–0.65) at 41 weeks. The results of the secondary analysis were also consistent with those in the primary analysis for both outcomes (Fig 3 and S1 Appendix, Table C). The unadjusted risk ratios did not materially differ from the risk ratios adjusted for maternal characteristics (Table 2 and S1 Appendix, Table C).

The NNT analysis indicated that 562 (95% CI 366–1,210) and 658 (95% CI 421–1,506) inductions of labour at 40 weeks would be required to prevent 1 perinatal death, for the primary and secondary analysis, respectively.

Perinatal morbidity

In the primary analysis, labour induction from 39 weeks onwards was associated with a significantly reduced rate of meconium aspiration syndrome, when compared with expectant management (Fig 3). Induction at 39 weeks was also significantly associated with reduced rates of hypoxia in labour (adjRR 0.74; 95% CI 0.65–0.85). However, this association was not significant at later weeks of gestation. Labour induction at 40 weeks was associated with higher rates of neonatal readmission to hospital within 28 days of birth (adjRR 1.30; 95% CI 1.03–1.50). Induction at 41 weeks was associated with reduced rates of birth injury (adjRR 0.47; 95%



	39 weeks	40 weeks	41 weeks	42 weeks
Start week n pregnant	77,327	55,785	28,190	6,276
Induction during week n	3,715	5,908	7,254	4,211
Prelabour CS during week n	4,836	1,459	1,029	429
Spontaneous onset of labour during week n	12,991	20,228	13,631	1,417
Still pregnant at end of week n	55,785	28,190	6,276	219

Fig 2. Composition of cohort by week of gestation. For each week of gestation (column), the primary analysis compares women who were induced at week *n* (blue column segment) with women who were expectantly managed, defined as those who delivered at weeks >*n* (orange column segment). The secondary analysis compares women who were induced at week *n* (blue column segment) with those who were expectantly managed according to the alternative definition, i.e., delivered at weeks ≥*n* (orange, grey, and yellow column segments). Abbreviation: CS, caesarean section.

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CI 0.29–0.78) and neonatal seizures (adjRR 0.50; 95% CI 0.26–0.99). No differences were found in the rates of shoulder dystocia in association with induction. Similar observations were seen in the secondary analysis, although the association with neonatal seizures was not replicated in secondary analysis (adjRR 0.67, 95% CI 0.38–1.16), and the association with higher neonatal readmission was seen at 39 as well as 40 weeks (Fig 3 and S1 Appendix, Table C).

Maternal outcomes

In the primary analysis, no differences in the rates of emergency caesarean section or instrumental delivery were found in association with induction at 39 weeks when compared with expectant management (Fig 3). Induction at 40 weeks was associated with a slightly increased risk of instrumental vaginal delivery (adjRR 1.06; 95% CI 1.01–1.11) and emergency caesarean delivery (adjRR 1.05; 95% CI 1.01–1.09). Induction at 41 weeks was associated with a slightly reduced risk of emergency caesarean section (adjRR 0.94; 95% CI 0.90–0.97) compared with expectant management. No differences were found in the rates of severe perineal tears in association with induction. Induction at 39 weeks was associated with higher risk of maternal

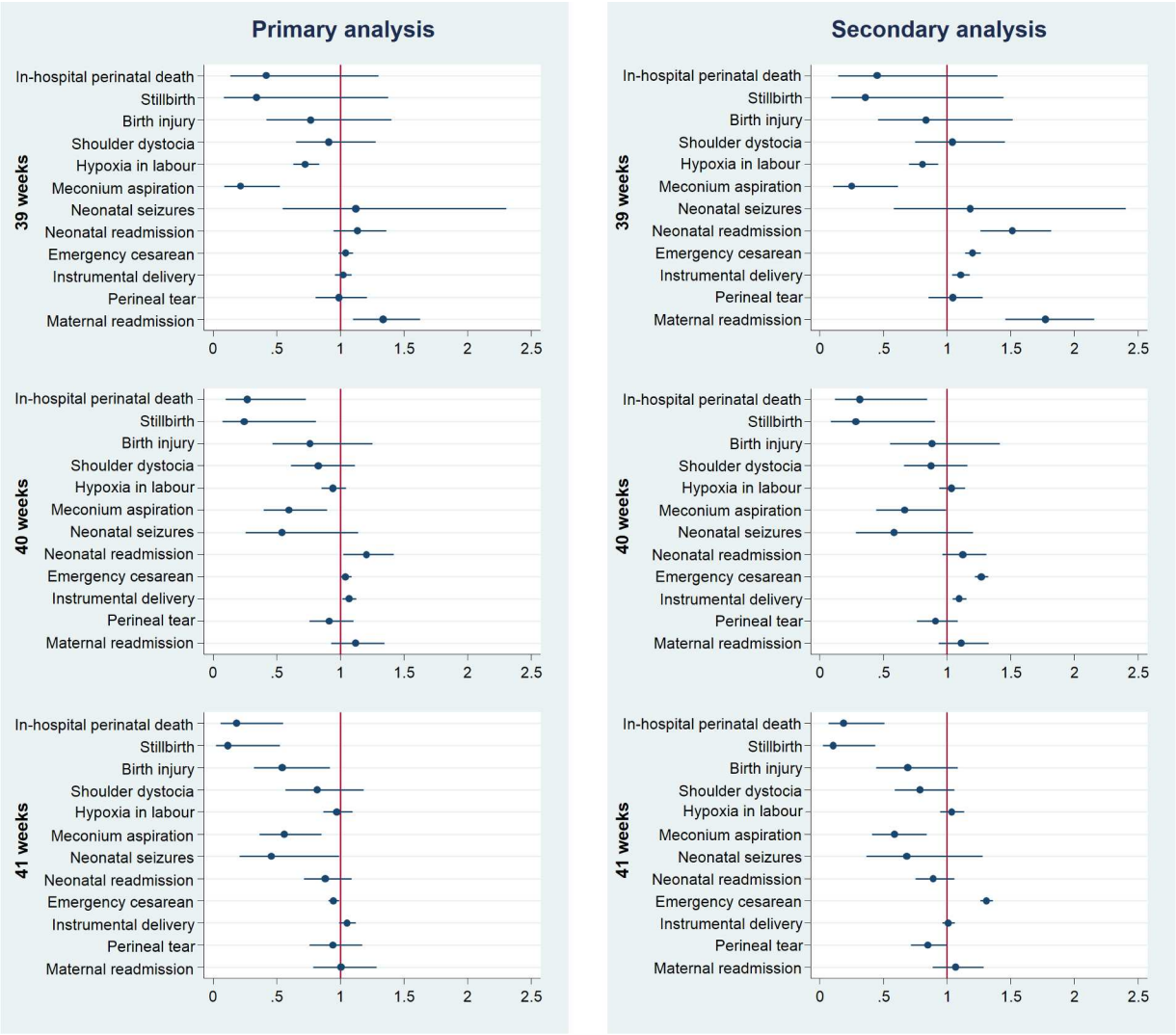

Fig 3. Perinatal outcomes after induction of labour compared with expectant management by week of gestation of induction of labour. Outcomes have been adjusted for potential confounders. Full details and results of all models are presented in Table 2 and S1 Appendix, Table C. The horizontal axis represents adjusted relative risk, with a relative risk <1 favouring induction of labour.

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readmission within 28 days of delivery (adjRR 1.38; 95% CI 1.13–1.60). In the secondary analysis, induction from 39 weeks onwards was associated with a 20%–30% increased rate of emergency caesarean section when compared with expectant management and a 10% increased rate of instrumental delivery at 39 and 40 weeks (S1 Appendix, Table C).

Discussion

The key finding of the present study is that induction of labour at 40 weeks of gestation was associated with a third of the risk of perinatal death compared with expectant management in a national cohort of nulliparous women aged ≥35 years. At this stage in pregnancy, the risk of perinatal death with expectant management was 26 per 10,000 pregnancies, whereas the risk among women induced at 40 weeks was 8 per 10,000 pregnancies. If these associations are causal, these data indicate that 562 (95% CI 366–1,210) inductions of labour would be required

Table 2. Perinatal outcomes after induction of labour compared with expectant management (primary analysis).

Outcome	Week of gestation induction was performed	Induction group	Expectant management group (delivery beyond week of induction)	Univariate analysis		Multivariable analysis	
		n (%)	*n* (%)	RR	95% CI	adjRR	95% CI
In-hospital perinatal death	39	3 (0.08)	123 (0.22)	0.36	(0.12 to 1.15)	0.37	(0.12 to 1.15)
	40	5 (0.08)	74 (0.26)	0.32	(0.13 to 0.80)*	0.33	(0.13 to 0.80)*
	41	5 (0.07)	19 (0.30)	0.25	(0.10 to 0.62)**	0.24	(0.09 to 0.65)**
Stillbirth	39	2 (0.05)	99 (0.18)	0.30	(0.07 to 1.23)	0.31	(0.08 to 1.26)
	40	3 (0.05)	61 (0.22)	0.23	(0.07 to 0.75)*	0.25	(0.08 to 0.79)*
	41	3 (0.04)	15 (0.24)	0.18	(0.06 to 0.58)**	0.18	(0.05 to 0.65)**
Birth injury	39	15 (0.40)	249 (0.45)	0.90	(0.54 to 1.52)	0.87	(0.52 to 1.46)
	40	28 (0.47)	137 (0.49)	0.98	(0.65 to 1.46)	0.96	(0.63 to 1.46)
	41	24 (0.33)	41 (0.65)	0.63	(0.41 to 0.97)*	0.47	(0.29 to 0.78)**
Shoulder dystocia	39	42 (1.13)	602 (1.08)	1.05	(0.77 to 1.43)	0.87	(0.64 to 1.19)
	40	66 (1.12)	308 (1.09)	1.02	(0.78 to 1.33)	0.85	(0.65 to 1.11)
	41	64 (0.88)	75 (1.20)	0.76	(0.58 to 1.00)	0.68	(0.49 to 0.94)*
Hypoxia in labour[a]	39	219 (5.90)	4,310 (7.73)	0.76	(0.67 to 0.87)***	0.74	(0.65 to 0.85)***
	40	492 (8.33)	2,367 (8.40)	0.99	(0.90 to 1.09)	0.98	(0.89 to 1.08)
	41	645 (8.89)	560 (8.92)	1.08	(0.99 to 1.17)	1.02	(0.91 to 1.13)
Meconium aspiration syndrome	39	6 (0.16)	414 (0.74)	0.22	(0.10 to 0.49)***	0.22	(0.10 to 0.49)***
	40	26 (0.44)	242 (0.86)	0.51	(0.34 to 0.77)**	0.52	(0.35 to 0.78)**
	41	41 (0.57)	62 (0.99)	0.67	(0.48 to 0.93)*	0.57	(0.39 to 0.83)**
Seizures[a]	39	12 (0.32)	143 (0.26)	1.26	(0.70 to 2.27)	1.14	(0.62 to 2.10)
	40	12 (0.20)	78 (0.28)	0.73	(0.40 to 1.35)	0.67	(0.36 to 1.24)
	41	15 (0.21)	23 (0.37)	0.74	(0.43 to 1.29)	0.50	(0.26 to 0.99)*
Neonatal readmission within 28 days of birth[a]	39	119 (3.20)	1,534 (2.75)	1.16	(0.97 to 1.30)	1.16	(0.96 to 1.30)
	40	192 (3.25)	709 (2.52)	1.29	(1.04 to 1.50)**	1.30	(1.03 to 1.50)**
	41	176 (2.43)	160 (2.55)	0.90	(0.76 to 1.00)	0.95	(0.76 to 1.10)
Emergency caesarean section[a,b,c]	39	1,301 (35.02)	15,992 (28.67)	1.22	(1.17 to 1.28)***	1.04	(0.99 to 1.09)
	40	2,312 (38.94)	9,409 (33.38)	1.17	(1.13 to 1.22)***	1.05	(1.01 to 1.09)*
	41	2,994 (41.27)	2,636 (42.00)	1.26	(1.23 to 1.31)***	0.94	(0.90 to 0.97)**
Instrumental delivery[a,b,c]	39	994 (26.76)	15,414 (27.63)	0.97	(0.92 to 1.02)	1.04	(0.98 to 1.10)
	40	1,647 (27.88)	7,894 (28.00)	1.00	(0.95 to 1.04)	1.06	(1.01 to 1.11)*
	41	2,024 (27.90)	1,699 (27.07)	1.00	(0.96 to 1.04)	1.06	(1.00 to 1.12)
3rd or 4th degree tears[a]	39	121 (3.26)	1,945 (3.49)	0.93	(0.78 to 1.12)	0.97	(0.81 to 1.17)
	40	183 (3.10)	973 (3.45)	0.90	(0.77 to 1.05)	0.93	(0.79 to 1.10)
	41	216 (2.98)	208 (3.31)	0.85	(0.74 to 0.98)	0.91	(0.75 to 1.10)
Maternal readmission within 28 days of giving birth[a]	39	114 (3.07)	1,120 (2.01)	1.52	(1.26 to 1.80)***	1.38	(1.13 to 1.60)**
	40	146 (2.47)	543 (1.93)	1.28	(1.07 to 1.50)**	1.16	(0.96 to 1.30)
	41	156 (2.15)	118 (1.88)	1.08	(0.91 to 1.00)	1.06	(0.83 to 1.30)

* $P < 0.05$

** $P < 0.01$

*** $P < 0.001$. Estimates were adjusted for pregnancy-related conditions when these were found to have significant coefficient: [a]preeclampsia/pregnancy-induced hypertension/edema in pregnancy

[b]gestational diabetes

[c]abnormal fluid volume (oligohydramnios or polyhydramnios).

Abbreviations: adjRR, adjusted risk ratio; RR, risk ratio (unadjusted).

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to prevent each perinatal death. Induction of labour was also associated with a significantly reduced risk of meconium aspiration syndrome.

A recent RCT has demonstrated no short-term adverse effect on the mother or infant of routine induction of labour at 39 weeks for women of advanced maternal age, and an associated economic evaluation has suggested that such a policy was associated with lower healthcare costs, principally through reduced rates of maternal readmission [24]. These findings could be taken together with those of the present study and used to support a policy of actively offering all women aged ≥35 years in their first pregnancy to have labour induced around their due date.

However, it could be argued that, because the data in this study are observational, the findings may be due to bias. We do not feel that this is a plausible explanation. First, the women being induced had higher proportions of risk factors, such as very advanced age and acquired complications of pregnancy. Second, we were able to adjust for these and other confounding factors in our statistical models, and this was without material effect. Third, while the risk adjustment models did not include all potential confounders, if there was an imbalance in their distribution across the 2 groups, it is likely that the confounders would be more prevalent in the induction group. Fourth, other well-conducted observational studies using other datasets have found similar effects on perinatal mortality, albeit not in this specific maternal age group [12].

The major cause of perinatal death at term is antepartum stillbirth. It is biologically plausible that stopping pregnancy at week 40 prevents the possibility of an antepartum stillbirth at 41 weeks. It may be argued that induction of labour in this context should only be widely recommended when these results are confirmed by an RCT, but the rarity of the outcome means a trial would be difficult. A sample size calculation based on the observed rates of perinatal death and effect size in the present study indicates that around 15,000 women would be required for a trial with 90% power to detect similarly large effects at 40 weeks of gestation. A well-funded multicentre RCT managed to recruit just over 600 such women [11], which is 4% of the required sample size.

In our primary analysis, we observed a 5% increase in the rate of emergency caesarean section and a 6% increase in the rate of operative vaginal delivery in the induction group. Although the 35/39 trial demonstrated no statistically significant association between induction and these outcomes, the point estimates for the effects in the present study are within the 95% CIs reported in the RCT [11]. Given the higher-risk nature of the women being induced, the adverse associations with induction of labour may be due to unmeasured confounders, as discussed above. These issues may be resolved by a larger-scale RCT of routine induction of labour in 6,000 nulliparous women aged ≥35 years, which is currently in progress [25]. However, that study will not be powered to detect a reduction in the risk of perinatal death, on the basis of the sample size calculation above.

The present study had a number of methodological strengths. The cohort is large and was drawn from an unselected population-based database which records the necessary data items for the appropriate comparison groups to be defined for this study. The use of a novel technique to link mothers' and babies' hospital records [19] enabled an examination of both maternal and perinatal outcomes, including morbidity as well as mortality. We were also able to follow up newborns after hospital discharge to examine emergency hospital readmission rates. A disadvantage of hospital administrative birth data is varying data quality between hospitals, which led to the records from some hospitals being excluded from this study. However, this approach has been demonstrated by others to be a valid way of constructing birth cohorts [16], and validation studies have found that the data are nationally representative for key variables, including sex, gestation, birth weight, maternal age, stillbirth, and multiple birth [19].

Despite the large sample size in the present study, it could be argued that because the number of observed perinatal deaths in the induced group is very small, under-recording of labour

induction in the dataset could have a major impact on the results. However, since HES is used to guide the reimbursement of maternity care expenses and labour induction is recognised within the national pricing framework [26], we would expect hospitals not to overlook this procedure when coding. To reduce the risks associated with under- and over-coding of induction, we also excluded hospitals that appeared to have divergent coding practices from the analysis (S1 Appendix, Table A).

As with other studies using routine data to examine this issue, we addressed the limitation of gestational age being recorded in weeks rather than in days by testing the robustness of our primary definition of the expectant management group using a secondary analysis that used the alternative definition [12]. Nevertheless, we were not able to control for some important possible confounders, such as maternal obesity, nor to examine some important outcomes, such as postpartum haemorrhage. It is also possible that a small number of antepartum stillbirths were inappropriately included in the expectant management group in the case of delay between death and delivery following induction. Inclusion of these women in the expectant management group would overestimate the risk of perinatal death rate in this group. However, this bias is more likely to affect the results of our secondary analysis, and we found that the magnitude of effect was similar in both analyses.

In summary, our results suggest that among women aged ≥35 years, induction of labour at term is associated with a lower rate of perinatal mortality and morbidity. Hence, bringing forward the routine offer of induction of labour from the current recommendation of 41–42 weeks to 40 weeks of gestation in this group may reduce overall rates of perinatal death. It is, however, important to note the potential for downsides to a policy which would significantly increase the use of labour induction, and further studies should examine the impact of such a policy on resource utilisation and patient satisfaction.

Supporting information

S1 STROBE Checklist.
(DOCX)

S1 Appendix. Includes Text A. Hospital-level data quality assessments; Text B. Analysis history; Table A. Definition; Table B. Comparison of included and excluded deliveries; and Table C. Perinatal outcomes after induction of labour compared with expectant management (secondary analysis).
(DOCX)

Author Contributions

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Writing – review & editing: Hannah E. Knight, David A. Cromwell, Ipek Gurol-Urganci, Katie Harron, Jan H. van der Meulen, Gordon C. S. Smith.

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S1 Appendix.

Hannah E Knight, David A Cromwell, Ipek Gurol-Urganci, Katie Harron, Jan H van der Meulen, Gordon CS Smith.

Contents

Text A. Hospital-level data quality assessments

Hospitals were excluded from the analysis if they failed one or more of the following assessments:

Birth status

- More than 30% of birth records were missing the birth status field

  and/or

- The total stillbirth rate was less than 1 per 1,000 or more the 10 per 1,000. These cut-offs were set based on the trust-level stillbirth rates reported in the 2014 MBRRACE perinatal mortality report.[1]

  and/or

- More than 20% of stillbirths had 'unknown timing'

Onset of labor and delivery

- More than 30% of birth records were missing the onset of labor field

  and/or

- The total induction of labor rate was less than 10% or more than 40%

Gestational age

- More than 30% of birth records were missing the gestational age field

  and/or

- The proportion of all births that took place between 39 and 42 completed weeks of gestation was less than 60% or more than 90**%**

[1] Manktelow BN, Smith LK, Seaton SE, et al. MBRRACE-UK Perinatal Mortality Surveillance Report, UK Perinatal Deaths for Births from January to December 2014. Leicester: The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester; 2016.

Table A. Definitions

Category	Variable	Codes used
Induction	**Delivery onset**	Delivery onset (delonset) 3-5
Co-morbidities	**Gestational diabetes**	ICD-10: O24.X
	Fluid abnormality	ICD-10: O40.X; O41.1
	Pre-eclampsia	ICD-10: O12.X-O16.X
Outcomes	**Emergency (intrapartum) cesarean section**	OPCS: R18.X; R25.1. Birth episodes with delivery onset (delonset) coded as 2 'no labour – caesarean section' were classified as prelabour caesarean sections.
	Instrumental delivery	OPCS: R21.X-R22.X
	3rd/4th degree perineal tear	ICD-10: O70.2-3
	Maternal/neonatal readmission	Babies/mothers readmitted with the following admission method codes: 21, 22, 23, 24, 28, 2A, 2B, 2D, 31, 32, 82, 83 within 28 days of the birth episode. The discharge date from the readmission must be at least one day after the readmission date. Planned transfers are identified as follows: the admission date of the second spell is within plus/minus one day of the discharge date. Either the first spell has a discharge destination of 51 or 52, or the second spell has an admission source of 51 or 52, or the second spell has an admission method of 81. Deaths within the delivery spell are identified using discharge method 4 (Died) or 5 (Baby was stillborn) and excluded from the denominator
	Stillbirth	Value suggesting stillborn in birth status (2, 3, 4) or discharge fields (5),
	In-hospital perinatal death	Value suggesting stillborn in birth status (2, 3, 4) or discharge fields (5), or discharged within 7 days with discharge method (4) or discharge destination (79) suggesting death, or attended A&E within 7 days of birth and was either brought in dead (70) or died in the department (10)
	Birth injury	ICD-10: P10.X-11.X; P13.X-14.X
	Shoulder dystocia	ICD-10: O66.0; P03.1; S14.3; P14.X
	Hypoxia in labor	ICD-10: P20.1
	Seizures	ICD-10: P90.X; R56.X
	Meconium aspiration	ICD-10: P24.0
Exclusion criteria	**Prelabour caesarean section**	OPCS: R19 or delivery onset (delonset) 2 (no labour – caesarean section)
	PROM	ICD-10: O42.X
	Placenta previa	ICD-10: O44.X-45.X
	Breech/malposition	ICD-10: O32.1; O64.1; O32.0; O32.2; O80.1; ICD-10: O83.0-1; O83.3; O36.7; O64.0; O64.2-5; O64.8-9 OPCS: R19.X-20.X Delmeth: 5-6
	Cardiac condition	ICD-10: I00.X-I02.X; I05.X-I09.X; I2.X; I31.X; I4.X; I51.X-52.X; I6.X-7.X
	Pre-existing hypertension	ICD-10: O10.X-O11.X; I1.X
	Pulmonary condition	ICD-10: JXX.X (except J45.X); I26.X-I28.X

Table B. Comparison of included and excluded deliveries

Characteristic	Group	Eligible women in hospitals with good quality data n (%)	Eligible women in hospitals with bad quality data
Maternal age	Age 35-39	63,571 (82.2)	41,197 (81.2)
	Age 40-50	13,756 (17.8)	9,564 (18.8)
Maternal ethnicity	White ethnicity	56,848 (81.0)	35,390 (79.8)
	Asian ethnicity	4,805 (6.8)	3,433 (7.7)
	Black ethnicity	3,879 (5.5)	2,741 (6.2)
	Other ethnicity	4,676 (6.7)	2,803 (6.3)
Maternal socioeconomic status quintile	SES 1 (least deprived)	16,915 (21.9)	12,006 (23.7)
	SES 2	16,305 (21.1)	10,811 (21.3)
	SES 3	15,660 (20.3)	10,882 (21.4)
	SES 4	16,717 (21.6)	9,659 (19.0)
	SES 5 (most deprived)	11,726 (15.2)	7,403 (14.6)
Year of birth	2009	17,044 (22.0)	10,336 (20.4)
	2010	15,733 (20.4)	10,811 (21.3)
	2011	16,104 (20.8)	10,444 (20.6)
	2012	14,738 (19.1)	10,047 (19.8)
	2013	13,708 (17.8)	9,123 (18.0)
Birthweight centile	BW 10-90th centile	64,702 (83.7)	32,840 (64.7)
	BW <10th centile	7,142 (9.2)	3,849 (7.6)
	BW >90th centile	5,483 (7.1)	3,123 (6.2)
Sex of baby	Male sex	39,556 (51.2)	25,984 (51.2)
Pregnancy complications	Preeclampsia	5,812 (7.5)	4,165 (8.2)
	Gestational diabetes	2,315 (3.0)	2,379 (4.7)
	Abnormal fluid volume	657 (0.9)	553 (1.1)

Percentage of records missing key data items, according to results of data quality assessments

Data item	Good quality hospitals (%)	Bad quality hospitals (%)
Gestational age	10.8	40.3
Method of onset of labour	10.5	24.1
Birth status	9.8	25.2

Table C. Perinatal outcomes after induction of labor compared with expectant management (secondary analysis)

Neonatal Outcome	Week of gestation induction was performed	Induction group	Expectant management group (delivery at or beyond week of induction)	Univariate analysis		Multivariable analysis	
		n (%)	n (%)	RR	95% CI	RR	95% CI
In-hospital perinatal death	39	3 (0.08)	159 (0.22)	0.37	(0.12 to 1.17)	0.38	(0.12 to 1.17)
	40	5 (0.08)	118 (0.24)	0.36	(0.15 to 0.88)*	0.36	(0.15 to 0.87)*
	41	5 (0.07)	69 (0.33)	0.21	(0.08 to 0.52)**	0.22	(0.09 to 0.54)**
Stillbirth	39	2 (0.05)	128 (0.11)	0.31	(0.08 to 1.25)	0.31	(0.08 to 1.25)
	40	3 (0.05)	96 (0.19)	0.26	(0.08 to 0.83)*	0.27	(0.08 to 0.84)*
	41	3 (0.04)	58 (0.28)	0.15	(0.05 to 0.48)**	0.16	(0.05 to 0.50)**
Birth injury	39	15 (0.40)	302 (0.41)	0.98	(0.59 to 1.65)	0.95	(0.57 to 1.59)
	40	28 (0.47)	221 (0.44)	1.07	(0.72 to 1.58)	1.06	(0.71 to 1.58)
	41	24 (0.33)	113 (0.54)	0.61	(0.39 to 0.95)*	0.60	(0.39 to 0.93)*
Shoulder dystocia	39	42 (1.13)	732 (0.99)	1.14	(0.83 to 1.55)	0.99	(0.73 to 1.36)
	40	66 (1.12)	536 (1.07)	1.04	(0.81 to 1.34)	0.89	(0.68 to 1.15)
	41	64 (0.88)	244 (1.17)	0.76	(0.58 to 1.00)*	0.70	(0.53 to 0.92)*
Hypoxia in labor [a]	39	219 (5.90)	5,062 (6.88)	0.86	(0.75 to 0.98)*	0.83	(0.73 to 0.94)**
	40	492 (8.33)	3,818 (7.65)	1.09	(0.99 to 1.19)	1.07	(0.97 to 1.17)
	41	645 (8.89)	1,722 (8.23)	1.08	(0.99 to 1.18)	1.09	(1.00 to 1.19)
Meconium aspiration	39	6 (0.16)	471 (0.64)	0.25	(0.11 to 0.56)**	0.26	(0.11 to 0.57)**
	40	26 (0.44)	388 (0.78)	0.57	(0.38 to 0.84)	0.56	(0.37 to 0.83)**
	41	41 (0.57)	201 (0.96)	0.59	(0.42 to 0.82)**	0.59	(0.42 to 0.82)**
Seizures [a]	39	12 (0.32)	172 (0.23)	1.38	(0.77 to 2.48)	1.21	(0.66 to 2.22)
	40	12 (0.20)	131 (0.26)	0.77	(0.43 to 1.40)	0.70	(0.38 to 1.26)
	41	15 (0.21)	63 (0.30)	0.69	(0.39 to 1.21)	0.67	(0.38 to 1.16)
Neonatal readmission within 28 days of birth [a]	39	119 (3.20)	1,534 (2.08)	1.54	(1.28 to 1.85) ***	1.54	(1.28 to 1.86)***
	40	192 (3.25)	1,342 (2.69)	1.21	(1.04 to 1.40) *	1.20	(1.03 to 1.40)*

	41	176	(2.43)	533	(2.55)	0.95	(0.81 to 1.13)	0.95	(0.80 to 1.12)
Emergency cesarean section [a,b,c]	39	1,391	(35.02)	18,527	(25.17)	1.39	(1.33 to 1.46)***	1.19	(1.14 to 1.25)***
	40	2,312	(39.13)	13,680	(27.43)	1.43	(1.38 to 1.48)***	1.26	(1.22 to 1.31)***
	41	2,994	(41.27)	6,415	(30.64)	1.35	(1.30 to 1.39)***	1.28	(1.24 to 1.33)***
Instrumental delivery [a,b,c]	39	994	(26.76)	18,811	(25.55)	1.05	(0.99 to 1.11)	1.12	(1.06 to 1.19)**
	40	1,647	(27.88)	13,767	(27.60)	1.01	(0.97 to 1.05)	1.08	(1.03 to 1.13)***
	41	2,024	(27.90)	5,870	(28.04)	1.00	(0.95 to 1.04)	1.02	(0.97 to 1.06)
3rd/4th degree tears [a]	39	121	(3.26)	2,439	(3.31)	0.98	(0.82 to 1.18)	1.04	(0.87 to 1.24)
	40	183	(3.10)	1,762	(3.553)	0.88	(0.75 to 1.02)	0.94	(0.80 to 1.09)
	41	216	(2.98)	757	(3.62)	0.82	(0.71 to 0.96)*	0.83	(0.71 to 0.96)*
Maternal readmission within 28 days of giving birth [a]	39	114	(3.07)	1,120	(1.52)	2.02	(1.67 to 2.44)***	1.82	(1.49 to 2.23)***
	40	146	(2.47)	974	(1.95)	1.27	(1.07 to 1.50)**	1.15	(0.96 to 1.37)
	41	156	(2.15))	387	(1.85))	1.16	(0.97 to 1.40)	1.11	(0.92 to 1.34)

*p<0.05 ** p<0.01 *** p<0.001. Estimates were adjusted for pregnancy-related conditions when these were found to have significant coefficients. These are labelled in the table: a) pre-eclampsia/pregnancy-induced hypertension/edema in pregnancy; b) gestational diabetes; c) abnormal fluid volume (oligohydramnios or polyhydramnios).

Text B. Analysis history for the observational study described in: Perinatal mortality associated with induction of labour versus expectant management in nulliparous women aged 35 years or over: a national cohort study. Knight HE, Cromwell DA, Gurol-Urganci I, Harron K, van der Meulen JH, Smith GCS. PLOS Medicine.

We did not publish or pre-register a protocol for this secondary analysis of data from Hospital Episode Statistics (HES). We followed a clear analysis plan, as described in the methods section. Further details on the analysis history are described below:

1. The study was motivated by the question "does induction of labour at >=39 weeks reduce the risk of perinatal mortality among nulliparous women aged ≥35 compared with expectant management?" which addressed some of the limitations of previously published studies on this topic.

2. The inclusion/exclusion criteria for the study were established at the outset of the study. As described in the manuscript, we extracted the records of nulliparous women aged between 35 and 50 years who had a singleton birth from the database, excluding deliveries before 39+0 weeks of gestation. We also excluded women who had a caesarean section prior to labour. We originally intended to include women with pre-existing comorbidities in the cohort and to adjust for these potential confounders in the analysis. However, once the cohort was constructed the number of women in it with existing comorbidities (type 1 diabetes, hypertensive disorders or cardiac, renal or lung disease) was very small (less than 500). Upon discussion we therefore decided to exclude these women form the cohort as national guidance recommends they are delivered before 39 weeks of gestation. This modification was made prior to the commencement of any statistical analyses

3. The statistical approach was determined at the outset of the study. The only revision made was to switch to using Poisson regression rather than logistic regression as originally planned because our analysis contains several common outcomes (see Knol et al., 2012). This modification was made prior to the commencement of any statistical analyses. As described in the manuscript, we conducted sensitivity analyses using an alternative definition of expectant management first used by Stock et al. (2012) to interrogate the robustness of our findings.

4. We did not make any changes to the analysis following feedback from the PLOS Medicine editors or reviewers, with the exception of examining and reporting the particular methods of induction of labour (medical; surgical and combined) used for the women in our cohort.

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page number
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Introduction para 1-3
Objectives	3	State specific objectives, including any prespecified hypotheses	Introduction para 3
Methods			
Study design	4	Present key elements of study design early in the paper	Methods para 1
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods para 3-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Methods para 6
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Methods para 7-10. Table A
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Methods para 3-5. Text A. Table A
Bias	9	Describe any efforts to address potential sources of bias	Methods para 7-8
Study size	10	Explain how the study size was arrived at	Methods para 6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Methods para 11
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Methods para 10-11
		(*b*) Describe any methods used to examine subgroups and interactions	Methods para 7 and 10-11
		(*c*) Explain how missing data were addressed	Methods para 6
		(*d*) If applicable, explain how loss to follow-up was addressed	N/A
		(*e*) Describe any sensitivity analyses	Methods para 7-8
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for	Results para 1. Figures 1 and 2

		eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	Results para 1; Figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Results para 3; Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Table 1
		(c) Summarise follow-up time (eg, average and total amount)	Figure 2
Outcome data	15*	Report numbers of outcome events or summary measures over time	Figure 2; Table 2
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Table 2
		(*b*) Report category boundaries when continuous variables were categorized	Table 1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Results para 7-10; Table C
Discussion			
Key results	18	Summarise key results with reference to study objectives	Discussion para 1 and 9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Discussion para 3-8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Discussion para 1-9
Generalisability	21	Discuss the generalisability (external validity) of the study results	Discussion para 1-9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Supplied

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

8. Does consultant presence on the labour ward at the time of birth influence perinatal outcomes?

The previous two chapters have applied novel techniques for analysing routinely collected maternity data to answering questions of a primarily clinical nature. This chapter addresses another highly topical issue in maternity care – this time, one that is related to health policy and structures of care. Specifically, this chapter examines the impact of labour ward staffing on perinatal outcomes using a linked HES and MIS dataset, combined with information collected from hospital staff rotas.

The question of when obstetric consultants should be physically present on the labour ward is one that has been topical in maternity policy for at least a decade.[71] In 2015, further attention was shone on this issue by the publication of research that some commentators claimed revealed a 'weekend effect', responsible for an estimated 11,000 excess deaths in the NHS each year.[72 73] These publications, combined with the Secretary of State's commitment to extend access to NHS services - both GP and hospital - during evenings and weekends, reignited the 24/7 debate within maternity care.

The key challenge for this study was to develop a methodology to appropriately define the exposure variable required to stratify the cohort into births occurring 'in-hours' and 'out-of-hours'. Previous studies on this topic have categorised births based on the time of birth alone, however this does not reflect the nuance that organisations may have different policies in place regarding when consultants are on site. The methodological development was therefore to link the MIS dataset (which contained information on date and time of birth

as well as certain perinatal outcomes) to HES (which enables additional perinatal outcomes to be measured), and to further link this dataset to the results of a survey of hospitals which asked what times of the day and week consultants were scheduled to be physically present on the labour ward.

Epidemiologists are sometimes required to make adjustments for multiple testing in reporting their results, which reduce the apparent significance of effects and thus reduce statistical power. Several methods for adjusting for multiple comparisons were considered in this analysis (Holm; Bonferroni). The decision was made not to apply these techniques as using standard odds ratios with 95% confidence intervals did not identify significant associations between consultant presence and any of the outcomes. Applying a multiple comparison technique would have made the results more conservative.

The results have been presented in the form of the published paper. The supplementary material referred to in the paper is available at the end of this chapter.

Statement of authorship

This chapter has been written as a published paper:

Knight HE, van der Meulen JH, Gurol-Urganci I, Smith GC, Kiran A, Thornton S, Richmond D, Cameron A, Cromwell DA. Birth "out-of-hours": an evaluation of obstetric practice and outcome according to the presence of senior obstetricians on the labour ward. Plos Medicine 2016;13(4):e1002000.

The authors have certified that:

a. they meet the criteria for authorship in that they have participated in the conception, execution or interpretation of at least that part of the publication in their field of expertise
b. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
c. there are no other authors of the publication according to these criteria;
d. potential conflicts of interest have been disclosed to granting bodies, the editor or publisher of journals or other publications and the head of responsible academic unit;
e. they agree to the use of the publication in the student's thesis and its publication on the LSHTM Research Online database consistent with any limitations set by publisher requirements.

Contributor	**Statement of contribution**
H.E. Knight	Conceived and conducted the research; designed and implemented the statistical analysis; wrote the first draft of the manuscript; modified the manuscript as suggested by co-authors and reviewers
Signature & Date:	H Knight 20.04.18
G.C. Smith	Conceived the research; advised on study design, statistical methods and analysis; provided technical input into the clinical aspects of the work; interpreted the results from a clinical perspective; commented on the manuscript
D.A. Cromwell, I. Gurol-Urganci, J.H. van der Meulen	Conceived the research; advised on study design, statistical methods and analysis; supervised the research; assisted in editing the manuscript
S. Thornton, D. Richmond, A. Cameron	Provided technical input into the clinical aspects of the work; interpreted the results from a clinical and policy perspective; commented on the manuscript
A Kiran	Advised on statistical methods; commented on the manuscript

Principal Supervisor Confirmation:
I have sighted email or other correspondence for all co-authors confirming their authorship.

Signature & Date:

20th April 2018

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Hannah Knight
Principal Supervisor	David Cromwell
Thesis Title	To what extent can routinely collected data be used to evaluate the performance and quality of English NHS maternity services?

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	PLOS Medicine		
When was the work published?	19 April 2016		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

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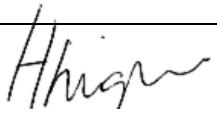
SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	
Please list the paper's authors in the intended authorship order:	
Stage of publication	

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	see page 124

Student Signature:  **Date:** 20.04.18

Supervisor Signature:  **Date:** 20.04.18

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RESEARCH ARTICLE

Birth "Out-of-Hours": An Evaluation of Obstetric Practice and Outcome According to the Presence of Senior Obstetricians on the Labour Ward

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Data Availability Statement: The data used in this paper combines and harmonises data obtained from individual hospital maternity units. The data governance arrangements for the project do not allow us to re-distribute the patient data to other parties without written permission from the Caldicott guardians of the participating trusts (listed in the Acknowledgements section). Researchers interested in accessing the data should contact the RCOG's Caldicott guardian once they have obtained these permissions.

Abstract

Background

Concerns have been raised that a lack of senior obstetricians ("consultants") on the labour ward outside normal hours may lead to worse outcomes among babies born during periods of reduced cover.

Methods and Findings

We carried out a multicentre cohort study using data from 19 obstetric units in the United Kingdom between 1 April 2012 and 31 March 2013 to examine whether rates of obstetric intervention and outcome change "out-of-hours," i.e., when consultants are not providing dedicated, on-site labour ward cover.

At the 19 hospitals, obstetric rotas ranged from 51 to 106 h of on-site labour ward cover per week. There were 87,501 singleton live births during the year, and 55.8% occurred out-of-hours. Women who delivered out-of-hours had slightly lower rates of intrapartum caesarean section (CS) (12.7% versus 13.4%, adjusted odds ratio [OR] 0.94; 95% confidence interval [CI] 0.90 to 0.98) and instrumental delivery (15.6% versus 17.0%, adj. OR 0.92; 95% CI 0.89 to 0.96) than women who delivered at times of on-site labour ward cover. There was some evidence that the severe perineal tear rate was reduced in out-of-hours vaginal deliveries (3.3% versus 3.6%, adj. OR 0.92; 95% CI 0.85 to 1.00). There was no evidence of a statistically significant difference between out-of-hours and "in-hours" deliveries in the rate of babies with a low Apgar score at 5 min (1.33% versus 1.25%, adjusted OR 1.07; 95% CI 0.95 to 1.21) or low cord pH (0.94% versus 0.82%; adjusted OR 1.12; 95% CI 0.96 to 1.31). Key study limitations include the potential for bias by indication, the reliance upon an organisational measure of consultant presence, and a non-random sample of maternity units.

Funding: The author(s) received no specific funding for this work.

Competing Interests: We have read the journal's policy and the authors of this manuscript have the following competing interests: GCS is a member of the Editorial Board of *PLOS Medicine*.

Abbreviations: BMI, body mass index; CI, confidence interval; CS, caesarean section; MIS, maternity information systems; NHS, National Health Service; OR, odds ratio; PPH, postpartum haemorrhage; RCOG, Royal College of Obstetricians and Gynaecologists.

Conclusions

There was no difference in the rate of maternal and neonatal morbidity according to the presence of consultants on the labour ward, with the possible exception of a reduced rate of severe perineal tears in out-of-hours vaginal deliveries. Fewer women had operative deliveries out-of-hours.

Taken together, the available evidence provides some reassurance that the current organisation of maternity care in the UK allows for good planning and risk management. However there is a need for more robust evidence on the quality of care afforded by different models of labour ward staffing.

Introduction

The new United Kingdom government has made a commitment to extend access to National Health Service (NHS) services during evenings and weekends [1]. The policy focuses attention on the quality of care delivered out of normal hours and the concerns that have been raised by recent studies examining the outcomes of hospital services [2,3].

Maternity care is a prime example of when a 24-h hospital service is required–women may begin labour at any time of day, and intrapartum emergencies may develop rapidly and without warning, often in previously uncomplicated pregnancies. In recent years, several large population-based studies have produced evidence to suggest that perinatal outcomes are slightly worse among babies born outside normal office hours [4,5]. In particular, Pasupathy et al. analysed Scottish data on 1 million liveborn, term, cephalic, singleton births between 1985 and 2004 and reported a neonatal mortality rate (excluding deaths due to congenital abnormalities) of 0.42 per 1,000 between 09:00 and 17:00 on Monday to Friday and a rate of 0.56 per 1,000 outside of this time [4].

Pasupathy et al. postulated that their findings could be related to variation in staffing at different times of day [4]. The impact of different models of labour ward staffing on perinatal outcomes has been part of a continuing debate about the delivery of maternity care in several countries, with investigations into poor-quality care and adverse events regularly highlighting concerns about inadequate staffing levels [6,7]. One aspect of this debate has been on the lack of senior obstetricians ("consultants") on the labour ward outside normal hours and the potential benefits of 24-h-per-day consultant cover for both quality of care and the training and supervision of junior doctors [7–11]. In the UK, the Royal College of Obstetricians and Gynaecologists (RCOG) supports a 24-h-per-day, consultant obstetrician-led service but recognises that its implementation poses many challenges in terms of job plans, remuneration, and labour ward facilities [11]. Currently, the number of hours and pattern of consultant presence over the week varies widely among UK maternity units [12]. Clinical standards first published by the RCOG in 2007, and reiterated again in 2011 [13], recommend a minimum of two consultant-led ward rounds (i.e., with the consultant physically present) on Saturdays, Sundays, and bank holidays, and one during the evening [11].

Few studies have examined the extent to which variation in consultant presence on the labour ward contributes to maternal and neonatal outcomes. Woods et al. found no association between consultant presence and mode of delivery or low Apgar score at 1 and 5 min, but the study was limited to 20,187 deliveries in a single UK obstetric unit [14]. Likewise, Ahmed et al. found no objective evidence of the benefits of introducing resident 24/7 consultant cover on patient care in a single tertiary maternity unit [15].

In this study, we investigated whether obstetric practice and outcome varied according to the presence of obstetric consultants on the labour ward using a large clinical dataset of deliveries at 19 UK obstetric units during 2012–13. The study evaluated the relationship between consultant presence and three neonatal outcomes: Apgar score < 7 at 5 min; umbilical cord pH less than 7.1, and admission to neonatal care. In addition, we examined the relationship between consultant presence and operative deliveries (instrumental or intrapartum CS) and severe maternal outcomes (third or fourth degree perineal tear and severe postpartum haemorrhage [PPH]. To our knowledge, this is the first large, multicentre study to provide detailed analysis of obstetric practice and outcome according to the presence of obstetric consultants on the labour ward.

Methods

Ethical Approval

Section 251 approval was granted by the Health Research Authority Confidentiality Advisory Group to process patient identifiable information without consent for the purposes of service evaluation. (CAG 2-06(a)/2013).

Data Source

We used data extracted from the electronic maternity information systems (MIS) of 19 obstetric units across the UK that participated in the RCOG MIS Pilot Project. This project aimed to assess the feasibility of creating a national dataset using electronic patient records. The units were selected following a national call for participation from the RCOG. Ninety units responded positively and 25 were shortlisted on the basis of their size, geographic location, and type of MIS. HEK conducted follow-up telephone calls with the clinical director and data midwife at each unit to determine their ability to supply the required data item and their willingness to participate in the pilot. Following these telephone calls, 19 of the 25 hospitals confirmed that they were able to participate. Each hospital supplied a retrospective 12-mo extract of patient-level MIS data in accordance with a pre-defined specification (S1 Text). The extracts were pooled to create a single database comprising 112,458 infants born between 1 April 2012 and 31 March 2013, representing approximately 15% of the total number of births in the UK during this period.

The participating hospitals ranged in size from 1,800 to 9,800 deliveries per year. Two were large specialist women's hospitals, 15 were teaching/university hospitals, and two were district general hospitals. Fifteen of the hospitals were located in England, one in Scotland, one in Wales, and two in Northern Ireland. All had an obstetric unit able to provide the full spectrum of obstetric care.

Study Population

The records of women who had a singleton birth were extracted from the database, excluding deliveries before 28 completed weeks of gestation. We also excluded women who had a CS prior to the onset of labour because these are predominantly planned in advance and performed during normal working hours, carrying a low risk of neonatal death [16,17]. Hence, inclusion of such cases could lead to an over-estimate of the relative risk of adverse perinatal outcomes for "out-of-hours" deliveries. We could not assess the impact of consultant presence on perinatal mortality due to the rarity of the outcome and the size of the cohort. Moreover, we were not able to distinguish between antepartum and intrapartum stillbirths in the dataset. Antepartum deaths account for six in seven stillbirths [18] and in most cases occur some days

prior to the delivery of the baby. The cohort was therefore restricted to livebirths (Fig 1). We did not exclude women with other co-morbidities or complicating risk factors.

The dataset included information on various maternal characteristics, including age, ethnicity, body mass index (BMI), and smoking status at booking. Obstetric risk factors included baby's birthweight, gestational age at delivery, parity, previous CS, fetal presentation, baby's sex, induction of labour, and mode of delivery.

"Consultant presence at time of birth" was defined as a binary variable by combining data on the time of birth with data from the consultant rotas for the period 2012–13 at each participating hospital. The rotas were obtained from the clinical directors of each maternity unit.

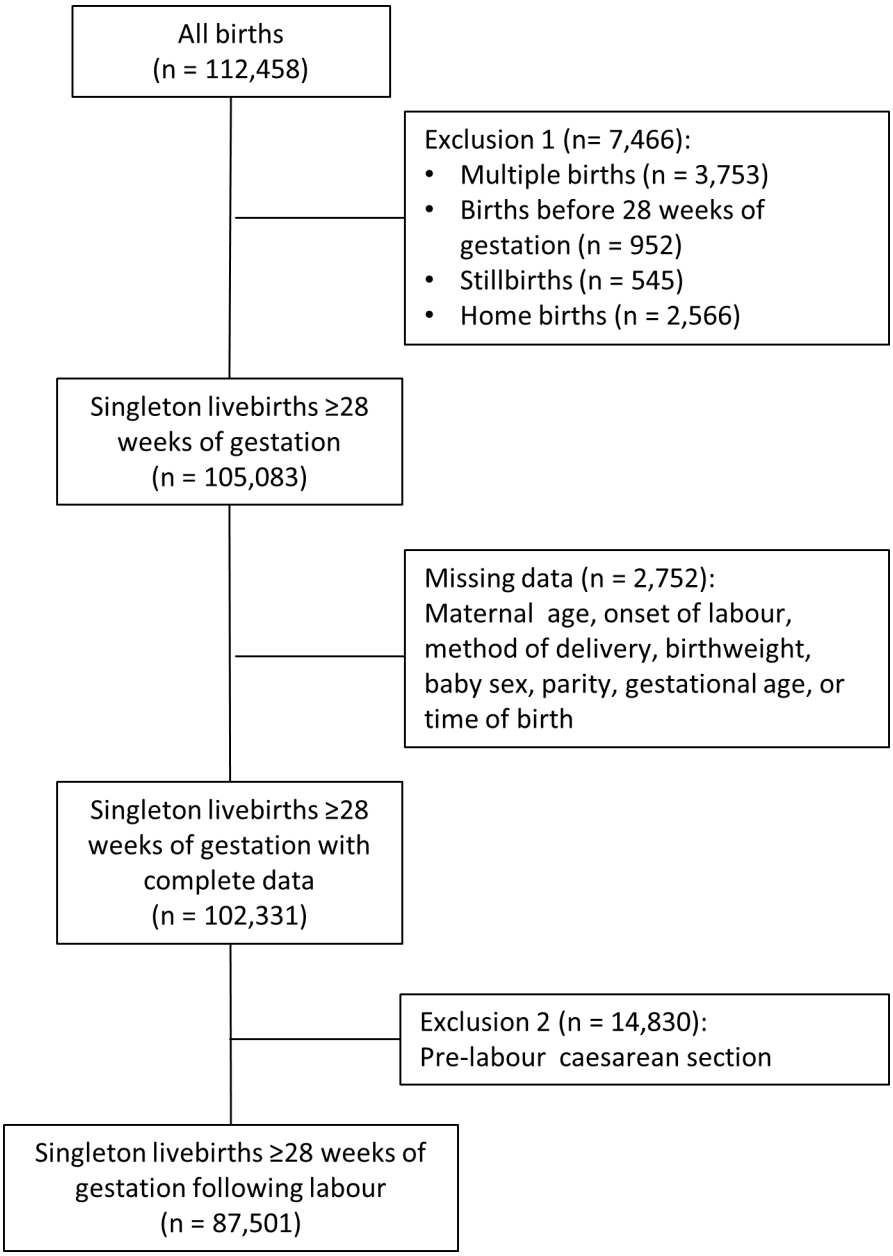

Fig 1. Selection of the cohort.

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Consultant presence refers to dedicated on-site labour ward cover, without other commitments such as antenatal or gynaecology clinics or theatre lists. For each day of the week, the time (in hours and minutes) that scheduled consultant presence on the labour ward began and ended was compared to the date and time of birth to define whether a delivery occurred within of a period of consultant presence ("in-hours") or outside it ("out-of-hours"). The pattern of consultant presence across the week among the 19 hospitals is summarised in S1 Fig.

Outcomes

Outcomes were selected to reflect different aspects of perinatal morbidity. Neonatal outcomes were measured using Apgar score < 7 at 5 min, umbilical cord pH < 7.1, and admission to neonatal care. Maternal outcomes were described by third or fourth degree perineal tear and PPH $>$ 1,500ml, and the rates of intrapartum CS and instrumental delivery were used as indicators of obstetric activity. All hospitals collected Apgar score. Information on perineal tears, cord pH < 7.1, admission to neonatal care, and PPH was supplied by 18, 17, 16, and 15 hospitals, respectively.

Statistical Analyses

We did not publish or pre-register a plan for this analysis. The analysis plan is described below, with any deviations noted in S2 Text.

We used proportions and medians to summarise the distribution of patient characteristics and the chi-square test and Kruskall-Wallis test for comparisons of dichotomous and continuous variables, respectively.

Multilevel multivariable logistic regression was used to estimate the crude and adjusted effects of consultant presence on the various outcomes, with the hospital of delivery modelled as a random-intercept. The potential confounding variables controlled for in all models were: maternal age (years), ethnicity (white, Asian, black, other, unknown), BMI (kg/m^2), smoking status (smoker, non-smoker/ex-smoker, unknown), parity (0, $\geq$1), previous CS (yes, no), gestational age (completed weeks), fetal presentation (cephalic, non-cephalic), baby's sex (male, female) and birthweight (g). For the continuous variables (maternal age, gestational age, and birthweight), quadratic terms were included in the models because there is clinical evidence that the relationship between these risk factors and the outcomes of interest is non-linear. Parity and previous CS were combined into one variable as these are not independent variables.

The completeness of data for the explanatory variables was generally good. No records were missing time of birth. Parity, mode of delivery, onset of labour, gestational age, birthweight, baby's sex, and birth status were more than 99% complete. Patients missing one or more of these variables were dropped from the cohort (Fig 1). Ethnicity, BMI, and smoking status were missing in more than 1% of records, and we assigned missing values to a category of "unknown." Apgar score was over 95% complete for all hospitals.

A sensitivity analyses limited to births at term ($\geq$37 wk of gestation) was conducted to explore the possible risk of confounding due to preterm birth. Prematurity typically accounts for a significant proportion of adverse neonatal outcomes, and the inclusion of preterm deliveries could mask any out-of-hours effect observed among term deliveries. For example, a 30-wk infant will be admitted to neonatal care irrespective of the time of delivery or the care provided.

All statistical tests were two-sided and the level of significance was set at $p < 0.05$. All analyses were performed in Stata version 13 (StataCorp, College Station, TX, United States).

Results

There were 112,458 deliveries in the sample between April 2012 and March 2013 (Fig 1). Restricting the cohort to singleton livebirths of at least 28 completed weeks of gestation excluded 7,466 records (6.6%), and dropping records with missing data in key explanatory variables removed a further 2,752 (2.4%). There was diurnal variation in the number of deliveries, with the majority of pre-labour CSs occurring between 9 A.M. and 7 P.M. (Fig 2). Included in the analysis were 87,501 deliveries following labour. Operative deliveries (intrapartum caesarean sections and instrumental deliveries) appeared to be evenly distributed throughout the day, with no evidence of a "spike" at the beginning and end of consultant shifts (Fig 2).

Consultant presence on the labour ward in the participating hospitals ranged from 51 h to 106 h per week. On weekdays, consultant presence generally began at 8:00 A.M. or 8:30 A.M. There was considerable variation among hospitals in the extent to which consultant presence extended into the evening, and in some units, consultants were rostered for a 24-h period on certain days (see S1 Fig). During weekends, consultant presence was typically only in the morning. The number of deliveries that occurred when a consultant was not rostered, i.e., out-of-hours, was 48,827 (55.8%).

Women who delivered out-of-hours shared similar demographic characteristics to women who delivered in-hours, with some small differences in maternal ethnicity, parity, and smoking status between the groups (Table 1). During in-hours, the rate of intrapartum CS and instrumental delivery were 13.4% and 17.0%, respectively, and 2.4% of women had a severe PPH and 3.6% experienced a severe perineal tear.

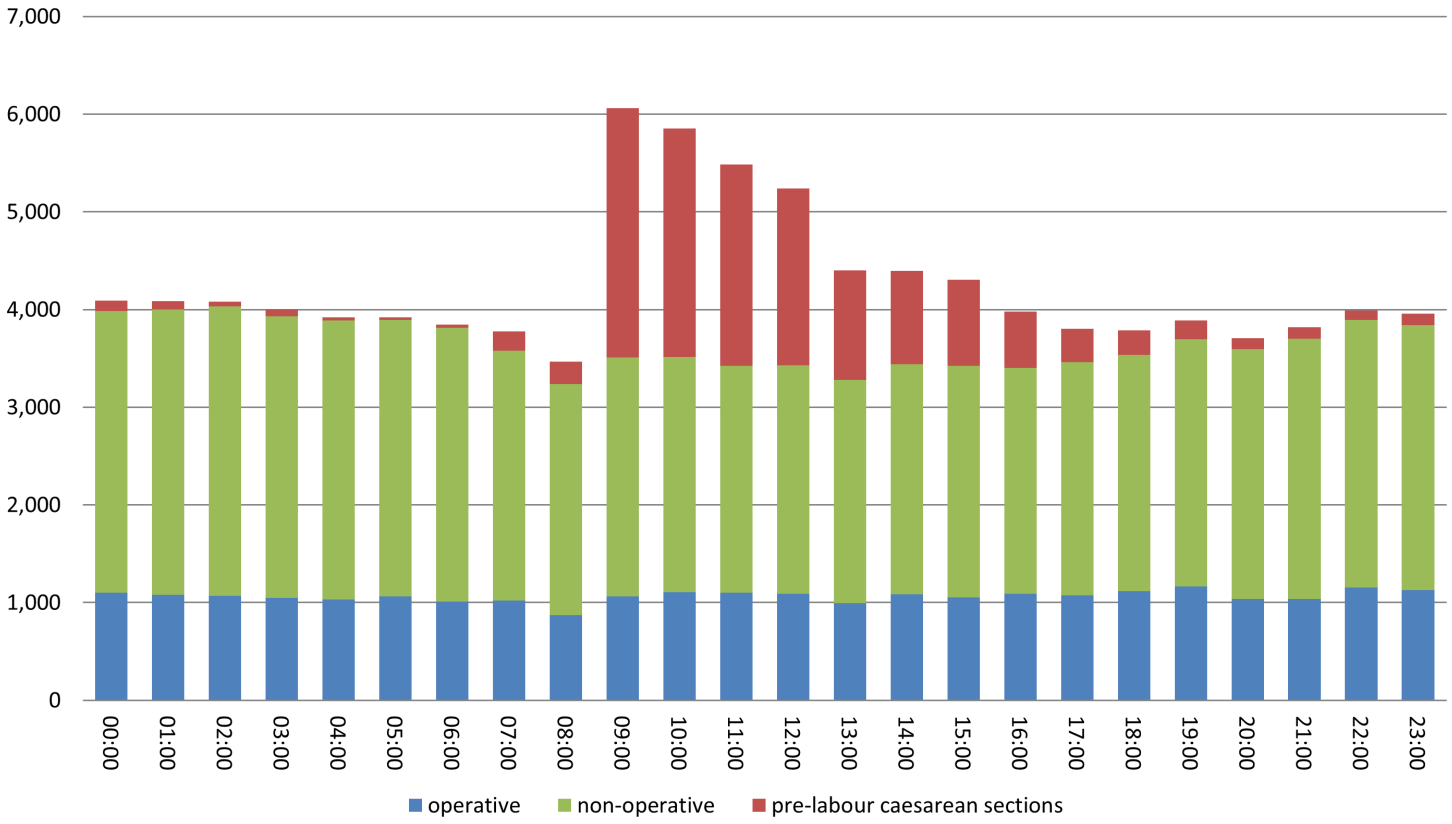

Fig 2. Number of births, by hour and mode of birth.

doi:10.1371/journal.pmed.1002000.g002

Table 1. Characteristics of the cohort, comparing in-hours with out-of-hours.

Characteristic	In-hours		Out-of-hours		*p*-Value
	N	Value	N	Value	
Median (IQR) maternal age (years)	38,674	30.0 (25.7–34.0)	48,827	30.1 (25.8–34.0)	0.267
Ethnicity (%)					<0.001
White	23,585	74.33	29,248	78.75	
Black	2,338	7.37	2,320	6.25	
Asian	3,438	10.83	3,199	8.61	
Other	2,370	7.47	2,375	6.39	
Missing†	6,942	-	11,685	-	
BMI (%)					0.084
<25	17,865	55.68	22,114	54.89	
25–30	9,082	28.29	11,519	28.61	
>30	5,143	16.03	6,647	16.50	
Missing†	6,583	-	8,548	-	
Smoking status at booking (%)					<0.001
Non-smoker	28,544	86.49	38,021	85.40	
Smoker	4,459	13.51	6,500	14.60	
Missing†	5,671	-	4,305	-	
Parity (%)					<0.001
Primiparous	19,552	50.56	23,168	47.45	
Multiparous, no previous CS	12,814	33.13	15,516	31.78	
Multiparous, previous CS	1,646	4.26	2,076	4.25	
Multiparous, unknown	4,661	12.05	8,067	16.52	
Median (IQR) weeks gestation	38,674	40 (39–41)	48,827	40 (39–41)	0.185
Median (IQR) birthweight (g)	38,674	3,400 (3,070–3,740)	48,827	3,400 (3,068–3,730)	0.225
Fetal presentation (%)					0.546
Cephalic	38,128	98.59	48,115	98.54	
Non-cephalic	545	1.41	712	1.46	

† Missing values are not included in the calculation of proportions.

doi:10.1371/journal.pmed.1002000.t001

After adjustment for maternal and obstetric risk factors, women who delivered out-of-hours were slightly less likely to have an intrapartum CS (OR 0.94; 95% CI 0.90 to 0.98) or an instrumental delivery (OR 0.92; 95% CI 0.89 to 0.96) than women who delivered in-hours (Table 2). There was no evidence of an overall difference in the incidence of severe PPH by consultant presence. There was weak evidence for a lower overall risk of perineal tears (OR 0.92; 95% CI 0.85 to 1.00).

During in-hours, overall rates of Apgar score < 7 at 5 min, cord pH < 7.1 and admission to neonatal care were 1.25%, 0.82%, and 6.73%, respectively. We found no statistical association between the neonatal outcomes and consultant presence. There was no evidence of a difference in the rates of neonates with Apgar score < 7 at 5 min (OR 1.06; 95% CI 0.93 to 1.20), cord pH < 7.1 (OR 1.12; 95% CI 0.96 to 1.31) or admission to neonatal care (OR 0.99; 95% CI 0.93 to 1.06), after adjustment for maternal demographic and obstetric characteristics.

The restriction of the cohort to term deliveries (37 wk or later) in the sensitivity analysis did not alter the pattern of results observed in the cohort of all deliveries for neonatal outcomes, maternal outcomes, or obstetric interventions (Table 3).

Table 2. Crude and adjusted odds ratios for adverse perinatal outcomes, comparing in-hours and out-of-hours.

Overall cohort								
Outcome measures	**In-hours**		**Out-of-hours**		**CrudeOR**	**Adjusted OR (95% CI)**		***p*-Value**
	N	**Rate (%)**	**N**	**Rate (%)**				
Onset of labour/Mode of delivery								
Intrapartum CS	38,674	13.43	48,827	12.72	0.92	0.93	(0.89 to 0.98)	0.003**
Instrumental delivery	38,674	16.97	48,827	15.61	0.91	0.92	(0.89 to 0.96)	<0.001***
Maternal outcomes								
Severe perineal tear (among vaginal deliveries)	30,788	3.58	39,967	3.27	0.90	0.92	(0.85 to 1.00)	0.054
Severe PPH (>1500ml)	30,858	2.38	36,094	2.31	1.01	1.03	(0.93 to 1.14)	0.589
Neonatal outcomes								
Apgar score < 7 at 5 min	38,384	1.25	47,206	1.33	1.06	1.06	(0.93 to 1.20)	0.374
Cord pH < 7.1	33,887	0.82	42,615	0.94	1.13	1.12	(0.96 to 1.31)	0.158
Admission to neonatal care	33,004	6.73	41,415	5.93	1.00	0.99	(0.93 to 1.06)	0.854

doi:10.1371/journal.pmed.1002000.t002

Discussion

This study analysed data from 19 UK obstetric units to investigate whether measures of neonatal and maternity morbidity varied during times when obstetric consultants were or were not present on the labour ward. Among women with singleton deliveries following labour, over half (55.8%) of all births occurred out-of-hours when consultants were not present on the labour ward. The birth rate peaked between 22:00 and 05:00.

Overall, we found no difference in the adjusted rates of morbidity among neonates born according to consultant presence on the three measures used in the study: Apgar score < 7 at 5 min, umbilical cord pH < 7.1, and admission to neonatal care. On the two measures of maternal morbidity, we found weak evidence that the adjusted rate of perineal tears was 10% lower during out-of-hours periods compared with in-hours, but there was no difference in adjusted rates of severePPH.

Table 3. Crude and adjusted odds ratios for adverse perinatal outcomes among term deliveries, comparing in-hours and out-of-hours.

Term deliveries (≥37 wk)								
Outcome measures	**In-hours**		**Out-of-hours**		**Crude OR**	**Adjusted OR (95% CI)**		***p*-Value**
	N	**Rate (%)**	**N**	**Rate (%)**				
Onset of labour/Mode of delivery								
Intrapartum CS	36,826	13.12	46,541	12.41	0.92	0.94	(0.90 to 0.98)	0.005**
Instrumental delivery	36,826	17.19	46,541	15.83	0.91	0.92	(0.89 to 0.96)	<0.001***
Maternal outcomes								
Severe perineal tear (among vaginal deliveries)	29,423	3.66	38,220	3.36	0.90	0.92	(0.85 to 1.01)	0.072
Severe PPH (>1500ml)	29,383	2.40	34,419	2.35	1.02	1.04	(0.94 to 1.16)	0.451
Neonatal outcomes								
Apgar score < 7 at 5 min	36,602	1.13	45,063	1.16	1.03	1.03	(0.90 to 1.18)	0.650
Cord pH < 7.1	32,267	0.80	40,629	0.92	1.12	1.12	(0.95 to 1.32)	0.164
Admission to neonatal care	31,399	4.97	39,460	4.24	0.98	0.98	(0.91 to 1.05)	0.555

*$p < 0.05$
**$p < 0.01$
***$p < 0.001$

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We also found that women who deliver out-of-hours were slightly less likely to have an obstetric intervention than women who delivered in-hours. One possible explanation for this finding is that in the absence of an urgent need for delivery, operative deliveries at the end of a night shift will tend to be deferred until the new team comes on, with consultant cover. There could be similar arguments made that at the end of a shift, teams may bring forward operative deliveries, not wanting to leave difficult deliveries until later.

The sensitivity analysis produced results that were broadly consistent with the results derived from the overall cohort. The restriction of the analysis to term infants had no material effect on the crude rates and the adjusted odds ratios.

There has been a broad consensus among medical professionals and policy makers that the duration of periods without consultant presence on the labour ward should decrease [6,11]. The policy stems from a series of studies that highlighted worse outcomes for babies born outside the normal weekdays. In particular, studies from other countries have reported an increase in asphyxia-related deaths among babies born at night [4,19–21]. In addition, figures from the UK National Patient Safety Agency showed that incidents of severe fetal compromise occurred more frequently between 8 P.M. and 4 A.M. [11].

Comparison with Other Studies

Given the background of confidential enquiry reports highlighting that many cases of poor neonatal or maternal outcomes are linked to the failure to recognise and act on problems arising in labour [22–24], it might be expected that our study would show differences in outcomes during periods of time with and without consultant presence. Previous studies examining whether perinatal mortality and morbidity rates vary according to time of birth and have produced inconsistent findings. Some studies reported no difference [25–31], whereas others reported increased risks of mortality for births during the weekend [4,32–36], and/or the night [4,19–21,37,38]. A recent study reported some evidence of a "weekend effect" in perinatal mortality in England [36], although it was criticised for failing to exclude antepartum stillbirths from the outcome measure, leading to "unjustified extrapolations of what the results mean in terms of avoidable harm" [39].

That these differences are not apparent in this study may be due to various factors. Our study is smaller than those that are based on national data or use cohorts spanning several years and is therefore less likely to detect statistically significant differences in outcomes. Our study is also unique in that it uses a more nuanced exposure variable, which is likely to be a more accurate proxy of senior input than time of birth alone. As far as we are aware, no other multicentre studies have examined the extent to which variation in consultant presence on the labour ward is associated with maternal and neonatal outcomes.

Second, the results from several previous studies describe patterns of care among births that occurred during the 1980s and 1990s [4,19–21]. There have been considerable changes in the obstetric evidence base, diagnostic technology, and clinical governance since that time, which have improved the safety of NHS maternity services.

Third, since the mid-2000s, it has been recommended that UK obstetric units with over 2,500 deliveries annually have at least 40 h of consultant presence per week, and that larger units with over 5,000 annual deliveries have at least 60 h of consultant presence [11]. In their 2008 report, the Healthcare Commission reported that only 68% of English NHS trusts met the recommended standard. They also reported that roughly one in five midwives and one in four doctors thought more consultant obstetrician presence was needed on their labour ward [6]. The latest RCOG Workforce Census reported that by 2013, the mean number of hours of consultant presence on the labour ward in UK obstetric units had increased to 63.5 [12]. The 19

obstetric units that participated in this study had a mean of 75 h of consultant presence per week, which may be greater than in previous studies.

Finally, it is now expected that a consultant obstetrician should be available within 30 min outside the hours of consultant presence, and any risks associated with on-call cover may have changed [40].

Methodological Considerations

A strength of this study is that it is based on a large, multicentre dataset of over 87,000 deliveries that occurred in 2012–13. It therefore provides a description of recent practice in the UK across a range of obstetric units. We excluded planned CS deliveries, as these carry a low risk of neonatal mortality and are predominantly carried out during "office hours." Their inclusion could have led to an overestimate the risks of out-of-hours deliveries.

The study was also focused on severe morbidity, which has been suggested as a better indicator of the quality of intrapartum care in high-income countries than mortality [41], both for mothers [42–44] and neonates [45]. Mortality is now a rare complication of childbirth in high-income countries, and perinatal mortality rates in the UK are at their lowest recorded levels, at 6.0 per 1,000 live births [18]. Moreover, national data suggests that 86% of stillbirths involve death of the baby prior to the onset of labour, and the majority of neonatal deaths are due to anomalies and preterm birth, with intrapartum complications being an uncommon cause [18]. Low Apgar score has been shown to be strongly associated with the risk of neonatal and infant death ascribed to intrapartum hypoxia [46]. Cord pH < 7.1 is also an objective measure of fetal acidosis.

A weakness of observational studies is the potential for "bias by indication." We minimised this risk by excluding multiple and very preterm infants with a high probability of an adverse outcome and, in that way, including a relatively homogenous group of deliveries. Furthermore, we also carried out a sensitivity analysis confined to term deliveries $\geq$37 wk. Finally, we risk-adjusted outcomes according to relevant maternal and obstetric risk factors.

Another limitation of the study was that we only had access to consultant rotas for each of the hospitals, which allowed us to calculate a hospital-specific out-of-hours classification of routine consultant presence. Consequently, the results are likely to be an underestimate of the effect of delivering out-of-hours compared to a study that would have information about consultant presence for each delivery. Serious complications arise for a minority of women and babies, and to detect the potentially small differences in outcomes that occur in childbirth, it might be necessary to have data on consultant presence at an individual-patient level. Other aspects of the organisation and delivery of maternity care, such as the availability and grade of other staff such as midwives, trainees, and healthcare assistants; patient triage protocols; or deviations from the rotas due to staff absence or vacancies may be important but were not investigated in this study. Some neonatal outcomes may also be related to non-obstetric medical staffing, such as availability of senior paediatricians. A related issue is that we only studied the association between selected outcomes and consultant presence at the time of birth. It is important to note that outcomes may also be influenced by whether or not a consultant is present earlier during labour, when crucial decisions are being made.

Finally, the hospitals in our study may not capture the full variation in obstetric care and outcomes in UK hospitals. The hospitals cover all of the geographic regions of the UK and include three district general hospitals with fewer than 5,000 deliveries per year. Nonetheless, most participating units were teaching or university hospitals with more than 5,000 deliveries per year, and all were selected from a list of hospitals who were able to provide electronic MIS data.

Taken together, the available evidence provides some reassurance that the organisation of maternity care in the UK allows for good planning and risk management. This suggests that politically driven efforts to target resources at increasing senior obstetricians attendance out-of-hours may not, in fact, lead to improved clinical outcomes for women and babies. However, there is a need for more robust national evidence on the quality of care delivered at all times of the week by maternity units employing different models of labour ward staffing. Ideally, studies should also consider longer-term outcomes, including cerebral palsy and school attainment.

Supporting Information

S1 STROBE Checklist. STROBE Checklist.
(DOC)

S1 Fig. Routine consultant presence on the labour ward according to hospital rotas.
(TIF)

S1 Text. RCOG MIS Pilot Project data specification for participating units.
(PDF)

S2 Text. Analysis history for the observational study described in this paper.
(DOCX)

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*These trusts contributed data for more than one hospital.

Author Contributions

Conceived and designed the experiments: HEK DAC IGU JHvdM GCS. Performed the experiments: HEK. Analyzed the data: HEK DAC JHvdM. Wrote the first draft of the manuscript: HEK DAC JHvdM. Contributed to the writing of the manuscript: HEK DAC JHvdM IGU GCS AK ST DR AC. Agree with the manuscript's results and conclusions: HEK DAC JHvdM IGU GCS AK ST DR AC. All authors have read, and confirm that they meet, ICMJE criteria for authorship.

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Editors' Summary

Background

In an ideal world, expert medical care would be available for anyone who needs it 24 hours a day, 7 days a week. But in the real world, a lower level of medical cover is often available in the evening and at weekends, a situation that potentially puts lives at risk. In the United Kingdom, for example, the National Health Service (NHS) does not currently provide consultant-level care or full laboratory and imaging services in the evenings and at weekends (in the UK, a consultant is a senior, hospital-based doctor who provides care in a medical or surgical specialty). Consequently, patients admitted out of normal hours have to wait to see a consultant and to have tests and scans done. Citing studies that suggest that people admitted to hospital at the weekend are more likely to die than those admitted on weekdays, the UK government recently made a pledge to improve access to consultants and other NHS services during evenings and weekends.

Why Was This Study Done?

Maternity care is a specialty in which a 24-hour hospital service is clearly required. Women can go into labor at any time of the day, and intrapartum emergencies (emergencies that arise during labor) can develop rapidly and without warning in previously uncomplicated pregnancies. Concerns have been raised that a lack of senior obstetricians (consultants who look after women during pregnancy, childbirth, and the postpartum period immediately after childbirth) on labor wards outside normal working hours may lead to worse outcomes among babies born during periods of reduced cover. However, few studies have examined the extent to which variation in consultant presence on labor wards affects maternal and neonatal (newborn) outcomes. In this multicenter cohort study, the researchers use data from UK obstetric units to evaluate the relationship between the presence of obstetric consultants on labor wards and the rates of obstetric interventions (surgical delivery by cesarean section and "instrumental" delivery using forceps or a vacuum) and of several maternal and neonatal outcomes.

What Did the Researchers Do and Find?

For their study, the researchers used electronic patient data collected over a 12-month period by 19 obstetric units and administrative data on obstetric rotas at the participating hospitals, which were mainly teaching hospitals. On-site labor ward cover by consultants ranged from 51 to 106 hours per week at the participating hospitals, where there were 87,501 singleton live births over the study period, 55.8% of which occurred "out-of-hours." Women who delivered out-of-hours had slightly lower rates of intrapartum cesarean section (operations initiated after labor had started; 12.7% versus 13.4%) and of instrumental delivery (15.6% versus 17.0%) than women who delivered when there was on-site labor ward cover ("in-hours"). Moreover, whereas 3.6% of women who had an in-hours vaginal delivery had a severe perineal tear (damage to the soft tissue between the vagina and the anus), only 3.3% of women who delivered out-of-hours had a tear. Finally, there was no difference between out-of-hours and in-hours deliveries in the rate of babies with a low Apgar score 5 minutes after birth (a measure of newborn health) or a low cord pH (a measure of oxygen deprivation during birth) or in the rate of mothers with severe postpartum bleeding.

What Do These Findings Mean?

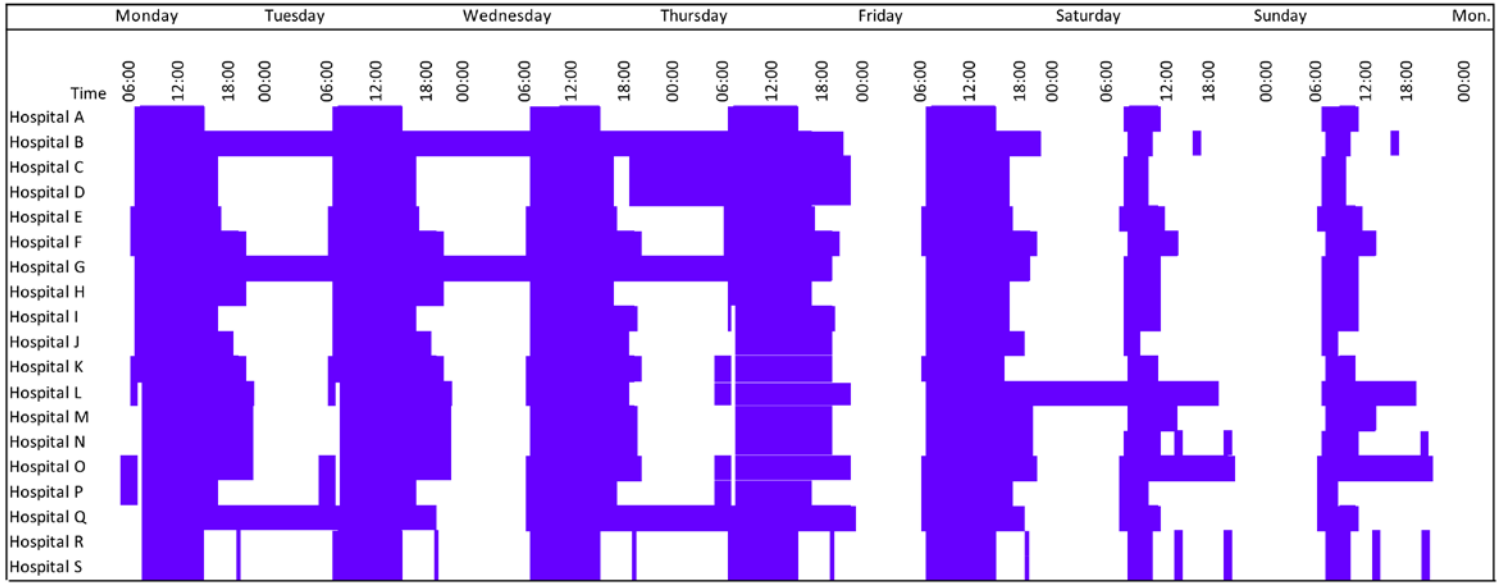
These findings show no association between maternal and neonatal outcomes and the presence of consultants on the labor ward, with the exception of weak evidence for a reduced likelihood of severe perineal tears following out-of-hours delivery. However, women who deliver out-of-hours may be less likely to have an obstetric intervention than women who deliver in-hours, possibly because obstetric teams will usually try to undertake operative deliveries during in-hours shifts. The accuracy of these findings may be limited by the use of administrative records to determine when consultants were present on labor wards and by the potential for "bias by indication." That is, obstetric teams may have tried to ensure that women with a greater risk of a poor outcome delivered in-hours rather than out-of-hours. Nevertheless, these findings suggest that the current organization of maternity care in the UK allows for good planning and risk management. Thus, although further robust evidence on the quality of care delivered at all times of the week by UK maternity units is needed, politically driven efforts to increase senior obstetrician attendance "out-of-hours" may not lead to improved clinical outcomes for women and babies.

Additional Information

This list of resources contains links that can be accessed when viewing the PDF on a device or via the online version of the article at http://dx.doi.org/10.1371/journal.pmed.1002000.

- This study is further discussed in a *PLOS Medicine* Perspective by Jenny Myers and Edward Johnstone
- Information from the UK Department of Health on research into the weekend effect on hospital mortality and the UK government's plans to provide NHS 7-day services by 2020 is available; a news article from the BBC discusses an ongoing controversy about how the UK government has used a recent research study to back its case for more 7-day NHS care
- The UK National Health Service website provides information on current out-of-hours NHS services, labor and childbirth (including a video about giving birth in hospital), cesarean section, assisted delivery (including a video), and perineal tears
- The UK Royal College of Obstetricians and Gynaecologists provides patient information leaflets on all aspects of pregnancy and childbirth
- MedlinePlus provides links to sources of other information on childbirth

S1. Figure. Pattern of consultant presence across the week among the 19 hospitals, according to rotas



STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Manuscript page/s
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	P2, line 7
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	P2, lines 6-22
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	P4-5, lines 31-63
Objectives	3	State specific objectives, including any prespecified hypotheses	P5, lines 64-72
Methods			
Study design	4	Present key elements of study design early in the paper	P2, 7-22 and P6-9, lines 79-156
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	P6, lines 79-94
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	P6-7, lines 96-106 N/A
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	P7-8, lines 108-141
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	P7-8, lines 108-152
Bias	9	Describe any efforts to address potential sources of bias	P6-7, lines 96-106 and P8-9, lines 148-154
Study size	10	Explain how the study size was arrived at	N/A. Population-based dataset containing all deliveries in 19 units
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	P8, lines 129-149

Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	P8-9, lines 129-156
		(*b*) Describe any methods used to examine subgroups and interactions	S2 Text
		(*c*) Explain how missing data were addressed	P8, lines 144-149
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	P8-9, lines 150-154;

Continued on next page

Results			**Manuscript page/s**
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	P9, lines 157-162; Figure 1
		(b) Give reasons for non-participation at each stage	P9, lines 158-160; Figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	P9-10, lines 173-177; Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Table 1
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	Table 2
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	N/A
		Cross-sectional study—Report numbers of outcome events or summary measures	N/A
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	P9-11, lines 173-188; Table 2
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	P11, lines 189-191; Table 2
Discussion			
Key results	18	Summarise key results with reference to study objectives	P13, lines 192-212
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	P15-17, lines 255-293
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	P17, lines 294-301
Generalisability	21	Discuss the generalisability (external validity) of the study results	P17, lines 290-294
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	N/A

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

S1 Text. Analysis history for the observational study described in: Knight HE, van der Meulen JH, Gurol-Urganci I, Smith GCS, Kiran A, Thornton S, Richmond D, Cameron A, Cromwell DA. Birth 'out-of-hours': an evaluation of obstetric practice and outcome according to the presence of senior obstetricians on the labour ward. PLOS Medicine.

We did not publish or pre-register a protocol for this secondary analysis of data from maternity unit information systems (MIS). We followed a clear analysis plan, as described in the methods section. Further details on the analysis history are described below:

1. The study was motivated by the question “what is the variation in obstetric practice and outcome according to the presence of obstetric consultants on the labour ward?” which addressed some of the limitations of previously published studies on this topic.

2. The inclusion/exclusion criteria for the study were established at the outset of the study. As described in the manuscript, we extracted the records of women who had a singleton birth from the database, excluding deliveries before 28 completed weeks of gestation. We also excluded women who had a caesarean section prior to labour. We originally intended to include stillbirths in the cohort because we planned to examine intrapartum stillbirth as one of the neonatal outcomes in our analysis. However, as explained in the Methods, the data collected from the MIS databases did not enable us to differentiate between antepartum and intrapartum stillbirth. Antepartum deaths account for 6 in 7 stillbirths [18] and in most cases occur some days prior to the delivery of the baby. The cohort was therefore restricted to livebirths.

3. The statistical approach was determined at the outset and was not changed. As described in the manuscript, we conducted sensitivity analyses to interrogate the robustness of our findings. The sensitivity analyses were limited to births at term (≥37 weeks of gestation) in order to explore the possible risk of confounding due to preterm birth. Prematurity typically accounts for a significant proportion of adverse neonatal outcomes and the inclusion of preterm deliveries could have masked any ‘out-of-hours’ effect observed among term deliveries. For example, a 30-week infant will be admitted to neonatal care irrespective of the time of delivery or the care provided.

   We also conducted an exploratory subgroup analysis to test for potential bias by indication. The analysis used four mutually exclusive subgroups of deliveries based on type of labour onset (spontaneous or not) and mode of delivery (operative delivery or not). These subgroups were selected because they may give an insight into specific processes of care and were defined a priori. As described in the paper by Gijsen et al [5], induction of labour and caesarean section can influence the time of birth of a high-risk pregnancy. We chose not to report the findings of this analysis in the manuscript because the pattern of results from the subgroup analysis was consistent with the overall findings.

4. Following feedback from the statistical reviewer, we made a minor amendment to the way that some variables were included in the multivariable logistic regression models. For continuous variables, quadratic terms were added to the models because there is clinical evidence that the relationship between these risk factors and the outcomes of interest is non-linear. This amendment has had no significant impact on the results.

9. Construction and validation of a composite adverse neonatal outcome measure

The final case study presented in this section addresses thesis objective 4: to evaluate the feasibility of constructing a composite indicator for severe adverse neonatal outcome using routine hospital administrative data.

This objective builds upon the previous three studies which sought to apply the novel methodological techniques developed in objective 2 to research aimed at answering topical questions in maternity care. The studies presented in the Chapters 7 and 8 examined not only maternal outcomes, but used linked mother-baby data to examine the association between the exposures of interest (induction of labour and consultant presence, respectively) and selected neonatal outcomes. However, in high-income countries, adverse neonatal outcomes, such as mortality or low Apgar score, are relatively rare occurrences. In this context, a composite adverse neonatal outcome indicator, derivable using routinely collected data, would be beneficial for use in research and service evaluation to overcome issues of low statistical power.

Such a composite indicator has been developed and validated in Australia using routinely collected hospital administrative data.[40] It was constructed using the Australian-modified version of ICD-10 diagnosis and procedure codes, and was found to describe rates of adverse events that were comparable to research studies. However, the coding accuracy of neonatal outcomes in HES has not been validated and no such composite indicator has been developed for England.

Some commentators have questioned the accuracy with which hospital administrative data captures individual neonatal morbidities,74 with particular concern about under-reporting.

However, a composite indicator that includes both procedures and diagnoses may be less susceptible to the possible of under-ascertainment of individual morbid events because a) severely ill neonates may have several different diagnoses and require multiple procedures, b) procedures are more reliably reported than diagnoses and c) the more severe the condition, the more likely it is to be reported.[38] A composite indicator that includes any morbid event therefore increases the chance of identifying babies with major morbidity.

As the Australian NAOI indicator was derived using the ICD-10 classification, it has the potential to be applied to the population of newborns in other countries. This chapter therefore seeks to translate the Australian composite indicator and assess its feasibility and validity as an outcome indicator, using English administrative hospital data. It covers themes including the assessment of data quality, the definition of outcomes and subpopulations of interest in linked routine datasets and adjustment for confounding factors.

The study attempts to limit the impact of differences in key maternal and neonatal characteristics using a logistic regression model containing basic maternal and neonatal characteristics. However, the fact that the adjusted funnel plot reveals systematic variation between NHS trusts suggests that unmeasured confounding and/or unrecognised issues in data collection and coding practice between trusts may remain. The adjusted results may therefore overestimate the amount of variation between trusts in the proportion of babies identified as having an adverse outcome. If this is the case, the composite will not be reliable if used to distinguish between 'well' and 'poor' performing hospitals. Consequently, the chapter concludes that it is premature to draw conclusions from these results about whether differences in the E-NAOI reflect differences in the quality of obstetric care provided in individual trusts.

Statement of authorship

This chapter has been written as a manuscript and has been submitted for peer-reviewed publication. It was under review at the time this thesis was submitted. The supplementary material referred to in the paper is available at the end of this chapter.

Knight HE*, Oddie SJ, Harron K, Aughey HK, van der Meulen JH, Gurol-Urganci I, Cromwell DA. Establishing a composite Neonatal Adverse Outcome Indicator (E-NAOI) using English hospital administrative data (under review)

The authors have certified that:

a. they meet the criteria for authorship in that they have participated in the conception, execution or interpretation of at least that part of the publication in their field of expertise
b. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
c. there are no other authors of the publication according to these criteria;
d. potential conflicts of interest have been disclosed to granting bodies, the editor or publisher of journals or other publications and the head of responsible academic unit;
e. they agree to the use of the publication in the student's thesis and its publication on the LSHTM Research Online database consistent with any limitations set by publisher requirements.

Contributor	**Statement of contribution**
H.E. Knight	Conceived and conducted the research; designed and implemented the statistical analysis; wrote the first draft of the manuscript; modified the manuscript as suggested by co-authors and reviewers
Signature & Date:	H Knight 20.04.18
S. Oddie, H.K. Aughey	Provided technical input into the clinical aspects of the work; interpreted the results from a clinical perspective; commented on the manuscript
D.A. Cromwell, I. Gurol-Urganci, J.H. van der Meulen	Involved in developing the research idea; advised on study design, statistical methods and analysis; supervised the research; assisted in editing the manuscript
K. Harron	Assisted in the preparation and linkage of the data; advised on statistical methods; commented on the manuscript

Principal Supervisor Confirmation:
I have sighted email or other correspondence for all co-authors confirming their authorship.

Signature & Date:

20th April 2018

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Hannah Knight
Principal Supervisor	David Cromwell
Thesis Title	To what extent can routinely collected data be used to evaluate the performance and quality of English NHS maternity services?

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?			
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*		Was the work subject to academic peer review?	

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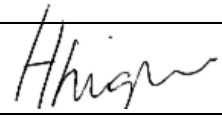
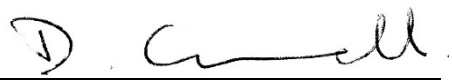
SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Archives of Disease in CHildhood Fetal and Neonatal Edition
Please list the paper's authors in the intended authorship order:	Knight HE, Oddie SJ, Harron K, Aughey HK, van der Meulen JH, Gurol-Urganci I, Cromwell DA.
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	see page 149

Student Signature:  **Date:** 20.04.18

Supervisor Signature:  **Date:** 20.04.18

Establishing a composite Neonatal Adverse Outcome Indicator (E-NAOI) using English hospital administrative data

Knight HE*, Oddie SJ, Harron K, Aughey HK, van der Meulen JH, Gurol-Urganci I, Cromwell DA.

Word count: 2,741

***Corresponding author (hknight@rcog.org.uk 02077726472)**

Abstract

Objective

We adapted a composite neonatal adverse outcome indicator (NAOI), originally derived in Australia, and assessed its feasibility and validity as an outcome indicator in English administrative hospital data.

Design

We used Hospital Episode Statistics (HES) data containing information on 484,007 infants born in the English National Health Service (NHS) between 1 April 2014 and 31 March 2015. The Australian NAOI was mapped to diagnoses and procedure codes used within HES, and modified to reflect data quality and neonatal health concerns in England. To investigate the concurrent validity of the English NAOI (E-NAOI), rates of NAOI components were compared with population-based studies. To investigate the predictive validity of the E-NAOI, readmission rates or death in the first year of life were calculated for infants with and without E-NAOI components. To examine usefulness as an outcome indicator, funnel plots were used to examine the variation among 135 NHS trusts in the incidence of E-NAOI events.

Results

The E-NAOI included 23 components (16 diagnoses and 7 procedures). Among liveborn infants, 5.4% had at least one E-NAOI component recorded before discharge. Among newborns discharged alive, the E-NAOI was associated with a significantly higher risk of death (0.81% v 0.05%; $p<0.001$) and overnight hospital readmission (15.7% v 7.1%; $p<0.001$) in the first year of life. The proportion of neonates identified by the E-NAOI varied from 2% to 11% between trusts.

Conclusions

A composite NAOI can be derived from English hospital administrative data. This E-NAOI demonstrates good concurrent and predictive validity. It is a cost-effective way to monitor neonatal outcomes.

What is already known on this topic?

- In high income countries, severe neonatal morbidity has been suggested as a more relevant outcome than perinatal mortality for monitoring the safety of obstetric care and gauging demand for neonatal specialist services.
- A composite neonatal adverse outcome indicator derived from routine hospital data offers several potential advantages over bespoke data collection on individual morbidities.
- These issues motivated the development of a composite neonatal adverse outcome indicator (the NAOI) using routinely collected Australian hospital administrative data. It is unknown whether this indicator can be used in other countries.

What this study adds

- This study translated the Australian NAOI for use with routinely collected English hospital data, making modifications required to address potential data quality issues as well as current neonatal health concerns in England.
- The resulting English version of the NAOI (the E-NAOI) demonstrated good concurrent validity as a population measure of severe neonatal adverse outcome, and was predictive of death and hospital admission in the first year of life.
- The E-NAOI is a cost-effective way of monitoring the incidence of adverse neonatal outcomes across hospitals. Our results suggest the approach could be applied in other countries with similar routine hospital administrative datasets.

Introduction

Access to information on adverse neonatal outcomes is important for various purposes including monitoring the safety of obstetric care, gauging demand for neonatal specialist services, and providing contextual material for the design of research studies or public health interventions.

The Apgar score is one method for assessing the condition of the newborn infant immediately after birth, and a low Apgar score at 5 minutes has been shown to be associated with both short and long-term morbidity.[1] However, the Apgar score does not directly record severe morbidity, and some commentators have expressed concerns that the score is not weighted to reflect the relative importance of some of the components.[2]

At a national level, it is possible to monitor population-rates of neonatal mortality[3] and individual morbidities, such as seizures or intraventricular haemorrhage (IVH). However, these events are too rare to be used at a local level to monitor quality of care and detect significant changes over time as the signal to noise ratio is too low.[4] Within randomised controlled trials and observational studies,[5-7] it has proven possible to describe rates of adverse outcomes by creating a composite neonatal outcome indicator.

These issues motivated Lain et al. to develop a composite neonatal adverse outcome indicator (the NAOI) using routinely collected Australian hospital administrative data.[8] The development of the indicator followed an iterative process including a literature review, calculation of the incidence of each component and association with hospital readmission, and expert consensus. It was constructed using the Australian-modified version of ICD-10 diagnosis and procedure codes, and was found to describe rates of adverse events that

were comparable to research studies. It also had the advantage of being relatively low cost compared to conducting primary data collection.[9]

As the Australian NAOI was derived using the ICD-10 classification, it has the potential to be applied to the population of newborns in other countries. We evaluated the feasibility of translating the Australian NAOI for use with routinely collected English hospital neonatal data. The study determined what modifications to the NAOI were required to address potential data quality issues as well as known neonatal health concerns in England. Finally, we examined the validity of the resulting English-version NAOI (E-NAOI) in terms of it producing (1) expected rates of adverse events and (2) expected associations with death and hospital admission in the first year of life.

Methods

Data sources

The study used the Hospital Episode Statistics (HES) database to identify births in English National Health Service (NHS) trusts (acute hospital organisations) and inpatient episodes up to a year after birth. The HES database contains patient demographics, diagnostic and procedure information, and administrative data for each inpatient episode of care.[10] Diagnostic information is coded using the *International Classification of Diseases*, *10th Revision* (ICD-10) [11] and operative procedures are coded using the UK *Office for Population Censuses and Surveys Classification*, *4th Revision* (OPCS4).[12] A unique identifier enables the episodes of care that belong to the same patient to be combined.

The HES database contains supplementary fields (the 'baby tail') for episodes related to the birth of a baby, which enable the capture of details such as birthweight and gestational age. Babies' birth episodes were identified by the presence of ICD-10 codes Z37-Z38, HRG codes N01-N05 (neonates) or HES fields relating to episode type, method of admission, age at start of episode and level of neonatal care. The level of data completeness within the 'baby tail' varies across NHS trusts, but, in 2015, data on gestational age and birthweight were available in 90% of all birth episodes.[13]

Study population

We included all liveborn infants from 24 to 43 weeks of gestation born between 1 April 2014 and 31 March 2015. This time period was chosen to allow follow-up for one year after birth in the HES database. We excluded NHS trusts with less than 500 births during the time period (11 of 148 organisations). We also removed records that were missing gestational

age or birthweight (64,084 of 601,713 records), or that had an implausible birthweight for gestational age, defined as above the 99.999th or below the 0.0001th centile (470 of 537,629 records). Finally, we performed data quality assessments at the individual trust level and excluded trusts with suspected poor-quality data for key data items (Text S1). This reduced the dataset to 484,007 liveborn infants.

To obtain data on maternal demographic characteristics, the babies' records were linked to the hospital delivery records of their mothers using probabilistic linkage which took advantage of the fact that information in the baby record was repeated in the maternal record (e.g. birthweight, gestational age). This method is described elsewhere.[14] The baby records were further linked to the Office for National Statistics (ONS) death register to allow an assessment of infant mortality after hospital discharge.

Translation of Australian NAOI

The Australian NAOI contained 15 neonatal diagnoses and 7 procedures (see Table S1). We constructed a list of the ICD-10 diagnosis and OPCS procedure codes used to define the individual morbid events that were equivalent to the original Australian NAOI codes. The ICD-10-AM list of diagnoses mapped directly to the standard ICD-10 version. The list of Australian ICD-10-AM procedure codes were translated into OPCS codes by an expert neonatal clinician (SO).

We identified individual morbid events before inpatient discharge after birth. We defined the first hospital inpatient stay to include all episodes of care within the birth admission plus any inpatient stay resulting from transfer to another NHS hospital if that admission started the same or following day after discharge from the birth hospital.

To investigate concurrent validity, the incidence of each element of the E-NAOI in the HES database was compared with the incidence reported by Lain et al. for the Australian NAOI[8] as well as to incidence figures in published population-based studies from high income countries, where available. We used an iterative process based on the comparative data available and expert clinical input to decide which of the original components should be included in the E-NAOI. Before excluding any individual morbid conditions with apparently poor ascertainment in the HES data, we considered whether alternative codes could be used to identify these babies. The list of morbid conditions was reviewed by expert clinicians (SO and HA) to ensure that current neonatal health concerns in England identifiable in HES were captured. Amendments to the original NAOI are described in Box 1.

Statistical analysis

To investigate predictive validity, the rates of hospital readmission and infant death within the first year were calculated for babies discharged home alive from the birth episode. Chi-square tests were used to compare the differences in each of these rates for infants identified by the E-NAOI as having morbidity was compared to infants without any events.

We used multivariate logistic regression models to estimate the crude and adjusted effect of maternal and infant characteristics on the rate of the E-NAOI. Maternal factors were age (<20, 20-34 and ≥35) and parity (primiparous or multiparous). Infant characteristics were sex, multiplicity and preterm birth (≤37 weeks).

To examine between-trust variation in the adjusted E-NAOI, predicted rates were calculated by summing the individual probabilities of an adverse event for all women who delivered at

the same NHS trust. Risk-adjusted rates were produced for each NHS trust by dividing the trust's unadjusted rate by its predicted rate and multiplying this ratio by the national mean.

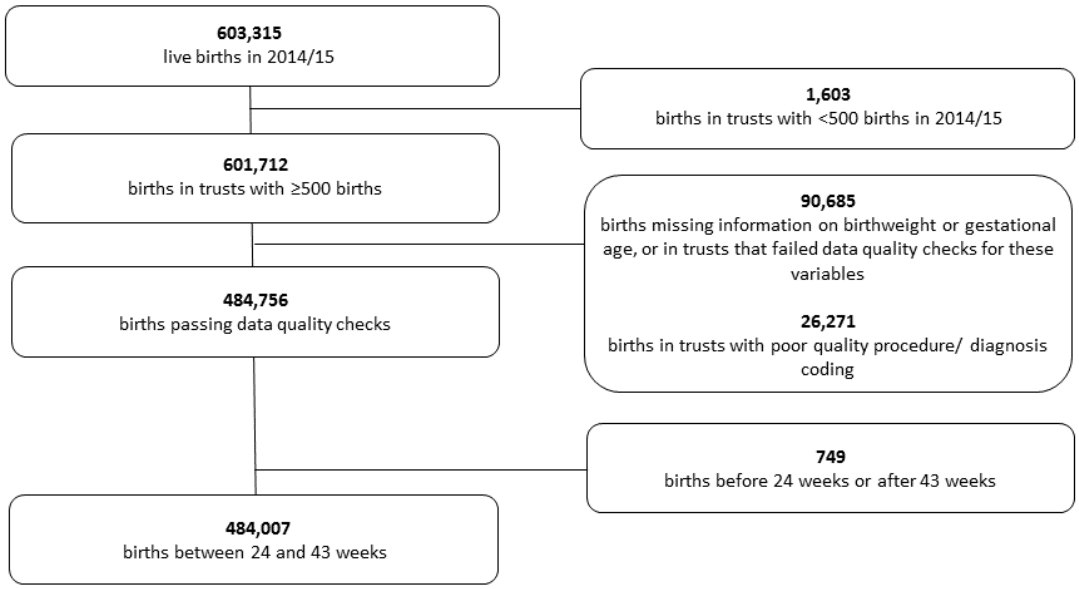
Funnel plots were used to examine the variation in the adjusted E-NAOI values between trusts. These plots 'test' whether the rate of an NHS trust differs from the national rate for England by more than would be expected from chance alone. Assuming that differences are due to random (sampling) errors, the chance of an organisation being within the limits is 95% for the inner funnel and 99.8% for the outer funnel.

All analyses were performed in STATA version 15.0 (StataCorp, College Station, TX, United States).

Results

The initial mother-baby linked dataset contained 603,315 live births, which corresponds to 91% of the estimated 662,222 live births in England during the time period.[15] Application of the data quality checks and study inclusion criteria reduced the dataset to 484,007 liveborn infants (Figure 1). Excluded records had broadly similar demographic characteristics, but were slightly more likely to relate to older, primiparous mothers and to preterm births (Table S2).

Figure 1. Data flow diagram



For most of the 15 conditions and procedures within the composite NAOI, there was a straightforward way to translate the Australian codes into English equivalents. The

adjustments to construction of the NAOI to address potential data quality issues in HES and current neonatal health concerns in England are described in Box 1.

Among the 484,007 live-born infants in the analysis, 5.4% had one or more of the E-NAOI conditions or procedures recorded before their first hospital discharge. Table 1 gives the frequency of the E-NAOI and of each E-NAOI component condition for early preterm (<34 weeks), late preterm (34-36 weeks) and term births (≥37 weeks). The incidence of an adverse outcome was much higher in the early preterm births (84.6%) compared to late preterm (20.1%) and term births (3.1%), partly because all infants less than 32 weeks' gestation are included in the NAOI and comprise 72% of the early preterm group.

The most common conditions among infants of all gestational ages were ventilatory support (mechanical ventilation and/or CPAP or high flow nasal cannulae) and respiratory distress syndrome, which themselves were highly correlated (76% of infants with respiratory distress syndrome required ventilatory support). For most components, the incidence measured in the English NHS was comparable to the incidence reported in the original Australian study. Notable differences between the English and Australian figures are described in Table 1.

Assessment of validity

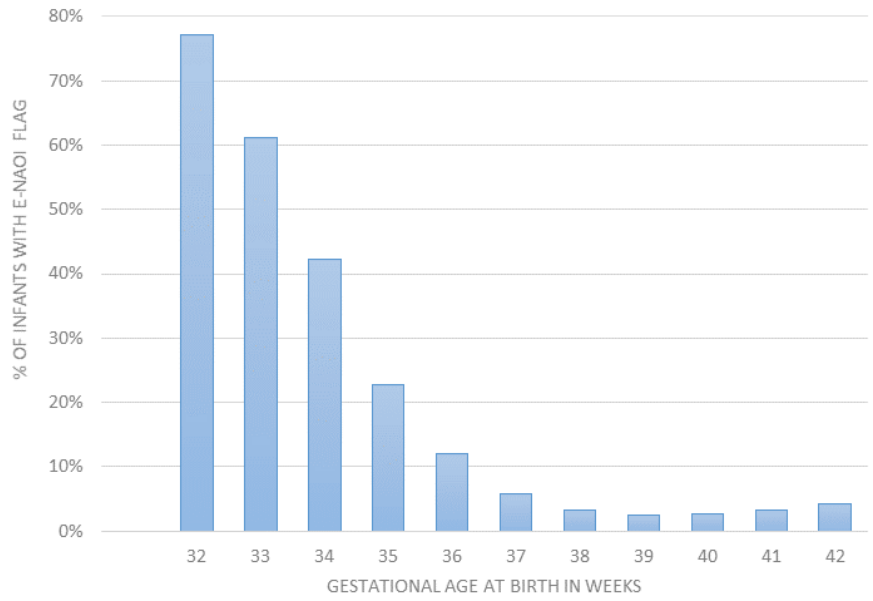
The proportion of infants identified as having one or more of the conditions in the E-NAOI fell from 77.2% at 32 weeks of gestation to 2.4% at 39 weeks of gestation, but increased to 4.3% at 42 weeks (Figure 2). The overall pattern of adverse events by week of gestation is consistent with expectations and similar to that described by Lain et al.[8] Patterns of E-NAOI

incidence also varied by mode of birth according to expectations, with higher rates observed among babies born by emergency compared with elective caesarean section.

The distribution of maternal and infant characteristics stratified by whether or not an infant had an E-NAOI event is shown in Table 2. Primiparity, maternal age over 34, male infant sex, multiple and preterm birth were associated with increased risk of adverse neonatal outcome (Table 2).

Figure 2. Rate of neonatal morbidity by gestational age at birth identified by the E-NAOI.

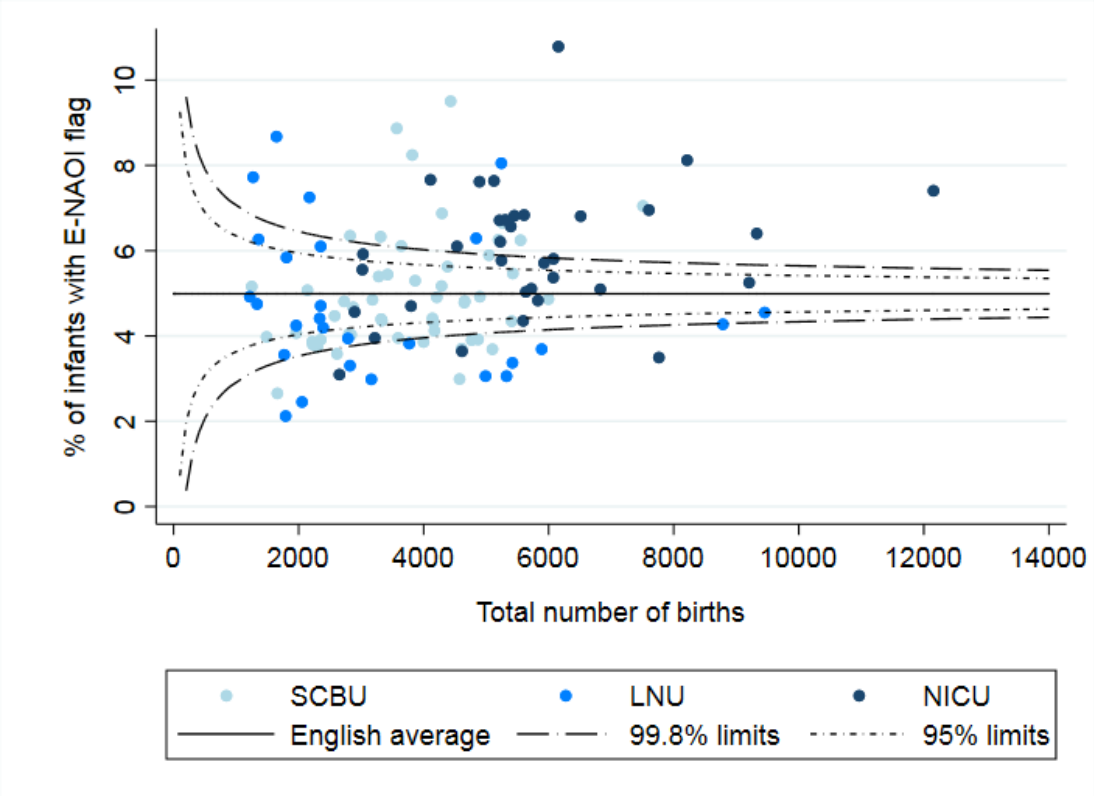
Note: gestational age <32 completed weeks is a component of the E-NAOI.



Among babies discharged home alive, the E-NAOI was strongly associated with the risk of death following discharge home and with hospital readmission. Infants identified by the E-

NAOI were over twice as likely to be admitted to hospital overnight in their first year of life (15.7% v 7.1%; p<0.001) and over 15 times more likely to die within a year of birth (0.81% v 0.05%; p<0.001) than infants not identified by the NAOI. Similar findings were observed when these rates were calculated for term infants only (Table 3).

Figure 3. Funnel plot showing the proportion of infants identified by the E-NAOI in English NHS trusts in 2014/15. Rates are adjusted for maternal (age, parity) and infant (sex, preterm, multiple) characteristics



The adjusted proportion of neonates identified with an E-NAOI condition varied from 2% to 11% between NHS trusts of birth. There was a slightly higher mean rate observed among NHS trusts with a neonatal intensive care unit [NICU] (5.5%) compared to those with a local neonatal unit [LNU] (5.4%) and special care baby unit [SCBU] (5.3%) but this difference was small compared to the differences between organisations (Figure 3).

Discussion

Main findings

Using routine hospital data in England from April 2014 to March 2015, we were able to adapt the Australian NAOI to produce a similar composite indicator for measuring severe adverse neonatal outcomes within NHS trusts. The resulting E-NAOI included 23 components (16 diagnoses and 7 procedures). The selection of individual components was driven by the quality of the routine hospital data as well as known neonatal health concerns in England, which necessitated a number of adaptations to the original composite measure developed using routine Australian hospital data, but these changes were relatively minor. For instance, one of the changes was the exclusion of neonatal blood transfusion. Lain et al reported the use of transfusion in 18.08% of early preterm infants but only 0.10% of term infants,[8] therefore the overall impact of not including this procedure in the E-NAOI is likely to be small. Nonetheless, the weaknesses in data quality identified by this work deserve to be addressed by NHS trusts, and there are various ways in which trusts could verify data quality. For example, blood transfusion is recorded in the National Neonatal Research Database (NNRD) database, and trusts could use this to ensure it is correctly coded within HES.

The resulting E-NAOI demonstrated good concurrent validity. First, the incidence of the individual components of the composite indicator as measured in the English data were often consistent with the incidence reported in Australia. They were also similar to figures published by population-based studies, where reported. Second, the incidence of events decreases by gestational age until term, in line with expectations. The E-NAOI also demonstrated good predictive ability, as indicated by a two-fold increased risk of overnight

hospital admission and a 15-fold increased risk of death within the first year among infants flagged as having a severe adverse outcome at birth. Although neither hospital readmission nor infant death are perfect measures to validate the indicator, they have been widely used as proxies for longer term neonatal morbidity.[16 17]

Caution should be used when extrapolating the E-NAOI to estimate longer term morbidity, as the E-NAOI represents morbidity in the neonatal period only. Some conditions such as birth trauma (primarily localised paralysis due to brachial plexus injury) are usually resolved without readmission, whereas others are likely to have longer-term implications.

The reasonable level of validity demonstrated in this initial study suggests that further evaluation of its value as a performance indicator is warranted. A particular focus could be whether the performance of the overall E-NAOI could be improved when used for specific purposes. For example, although we found evidence of significant variation between trusts in the adjusted rate of the E-NAOI, we speculate that when used for local quality improvement, a version that only included amenable conditions may give different results. Decisions about which events are amenable to improvement are conceptually challenging. For example, different commentators may disagree about the extent to which low birthweight and preterm birth are preventable through best practice. The relative merits of this approach are not addressed in the present study and would be more thoroughly investigated in conjunction with a local quality improvement initiative. We recommend further consensus and validation work in this area.

Strengths and limitations of the study

The study has several methodological strengths. The dataset is large and drawn from a linked, population-based dataset. Furthermore, the linkage with mortality data and hospital admission episodes after birth allowed the predictive validity of the composite measure to be evaluated.

Some commentators have questioned the accuracy with which hospital administrative data captures individual neonatal morbidities, with particular concern about under-reporting.[18] However, the E-NAOI includes both procedures and diagnoses and is therefore less susceptible to under-ascertainment of individual morbid events because a) severely ill neonates may have several different diagnoses and require multiple procedures, b) procedures are more reliably reported than diagnoses and c) the more severe the condition, the more likely it is to be reported.[19]

Although a composite measure has many advantages, a limitation of this study is the need to create dichotomous categories to represent severe neonatal morbidity out of what is in reality a spectrum of morbidity. For instance, mechanical ventilation and CPAP were included, but the relatively more common procedure of oxygen supplementation is not recognised.

A second limitation is the between-trust variation in use of procedures (and therefore E-NAOI incidence) due to availability of services and differences in practice. In addition, we cannot rule out the possibility of differences in local coding practices or definitions of particular morbid conditions.

Finally, we dropped a number of records because of poor data quality, however the excluded records shared broadly similar characteristics to the included records (Table S2).

In summary, the composite E-NAOI is a uniform and cost-effective way of monitoring adverse neonatal outcome that demonstrates reasonable concurrent and predictive validity and could be applied in other countries with similar routine hospital administrative datasets. The indicator has the potential to be used for national surveillance, clinical audit and research, and could be further validated and refined through linkage with the NNRD which contains neonatal electronic patient records from all NHS neonatal units.

Ethics

The study is exempt from UK National Research Ethics Service (NRES) approval because it involved the analysis of an existing dataset of anonymised data for service evaluation. Hospital Episode Statistics (HES) data were made available by NHS Digital (Copyright 2015, re-used with the permission of NHS Digital. All rights reserved). Approvals for the use of HES and ONS data were obtained as part of the standard NHS Digital data access process (NIC 383345).

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Author contributions

The study was conceived by HK and DC; HK, DC, IGU, SO and JvdM agreed the study design and definitions; KH prepared the data extract; HK, DC, SO and HA were involved in analysis; all authors contributed to writing the manuscript and reviewed the final version submitted.

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We would like to thank Samantha Lain for supplying the list of Australian-modified ICD-10 procedure codes used to develop the original Australian NAOI.

Table 1. Incidence (per 100 births) for conditions and procedures indicative of neonatal morbidity

Component	Incidence before first hospital discharge in HES (%), by gestational age group			Incidence before first hospital discharge (%) reported by Lain et al, 2012[8], by gestational age group			Decision to include in E-NAOI
	24-33 weeks (n = 8,280)	34-36 weeks (n = 25,272)	37-43 weeks (n = 450,455)	24-33 weeks (n = 9,352)	34-36 weeks (n = 24,934)	37-43 weeks (n = 482,489)	
Diagnosis							
Birthweight <1500g	44.18	0.85	0.01	43.74	0.93	0.01	*Included – comparable with Lain [8]*
Gestational age <32 completed weeks	51.93	0.00	0.00	N/A			*Included – comparable with published incidence [15]*
Neonatal death within 28 days (includes deaths after 28 days if the infant was never discharged home)	5.40	0.41	0.07	7.49	0.47	0.07	*Included - comparable with Lain and published UK incidence [3 8]*
Respiratory distress syndrome	55.74	8.80	0.62	49.04	7.64	0.51	*Included – comparable with Lain [8]*
Seizure	0.99	0.25	0.14	1.47	0.39	0.16	*Included – comparable with Lain and published UK incidence [8 20]*
Intraventricular haemorrhage (grades 3 and 4)	2.19	0.02	0.00	2.65	0.05	0.00	*Included – comparable with Lain [8]*
Cerebral infarction	0.13	0.02	0.01	N/A			*Included – comparable with published UK incidence [20]*
Periventricular leukomalacia	0.75	0.01	0.00	N/A			*Included – comparable with published UK incidence [20]*
Birth trauma (intracranial haemorrhage paralysis due to brachial plexus injury, skull or long bone fracture)	0.25	0.09	0.07	0.33	0.08	0.09	*Included – comparable with Lain [8]*
Hypoxic ischemic encephalopathy	1.23	0.34	0.19	0.39	0.17	0.07	*Included – comparable with published UK incidence [20 21]*
Necrotising enterocolitis	5.36	0.20	0.01	2.93	0.14	0.01	*Included – comparable with Lain [8]*
Broncho-pulmonary dysplasia	7.87	0.03	0.00	6.08	0.03	0.00	*Excluded –a wider category capturing all chronic respiratory disease included instead*
Sepsis/septicaemia (streptococcus staphylococcus, E.coli, unspecified gram negative)	10.08	0.90	0.21	10.88	1.52	0.30	*Included - comparable with Lain and published UK incidence [8 22]*

Component	Incidence before first hospital discharge in HES (%), by gestational age group			Incidence before first hospital discharge (%) reported by Lain et al, 2012[8], by gestational age group			Decision to include in E-NAOI
	24-33 weeks (n = 8,280)	34-36 weeks (n = 25,272)	37-43 weeks (n = 450,455)	24-33 weeks (n = 9,352)	34-36 weeks (n = 24,934)	37-43 weeks (n = 482,489)	
Pneumonia	2.45	0.56	0.18	2.15	0.36	0.11	*Included – comparable with Lain [8]*
Other respiratory (primary atelectasis, respiratory failure)	2.36	0.21	0.08	N/A			*Included*
Chronic respiratory disease originating in the perinatal period	13.89	0.07	0.01	N/A			*Newly added diagnosis*
Bacterial meningitis	0.74	0.09	0.04	N/A			*Newly added diagnosis – comparable with published UK incidence [23]*
Procedure							
Resuscitation (intubation and/or chest compression)	14.87	1.05	0.30	21.11	1.54	0.47	*Included – comparable with Lain [8]*
Ventilatory support (mechanical ventilation/CPAP/high flow nasal cannulae)	70.52	13.99	1.82	57.03	7.13	0.66	*Included - higher than Lain et al but not implausible*
Central venous or arterial catheter	30.62	2.45	0.35	34.12	3.83	0.34	*Included – comparable with Lain [8]*
Pneumothorax requiring intercostal catheter	3.57	0.67	0.18	1.87	0.33	0.04	*Included - higher than Lain et al but not implausible*
Any IV fluids	2.08	1.35	0.29	46.64	8.87	0.95	*Included - lower than Lain et al. Suggests undercoding*
Transfusion of blood or blood products	0.47	0.11	0.02	18.08	0.86	0.10	*Excluded - Much lower than Lain et al and published literature*
Any body cavity surgical procedure	7.93	1.49	0.24	4.56	1.01	0.19	*Included – comparable with Lain [8]*
Therapeutic hypothermia	0.02	0.24	0.10	N/A			*Newly added procedure - comparable with published UK incidence [24]*
Composite							
Any diagnoses or procedure	84.57	20.13	3.10	81.88	18.32	2.40	

Table 2. Association of E-NAOI with maternal and infant characteristics

Risk factor	No. of infants	(%)	No. infants with E-NAOI event	E-NAOI rate (%)	Adjusted RR* of E-NAOI among births with this characteristic (95%CI)
Maternal characteristics					
Age <20	17,928	3.71	1,064	5.93	0.96 (0.89 to 1.02)
Age 20-34	367,164	75.88	19,119	5.21	Reference
Age >=35	98,757	20.41	5,877	5.95	1.09 (1.05 to 1.13)
Primiparous	176,472	36.46	10,860	6.16	1.29 (1.25 to 1.32)
Multiparous	307,535	63.54	15,200	4.94	Reference
Infant characteristics					
Female	235,702	48.70	10,991	4.66	Reference
Male	248,242	51.30	15,068	6.07	1.32 (1.28 to 1.35)
Term	450,454	93.07	13,978	3.10	Reference
Preterm	33,553	6.93	12,091	36.04	17.54 (17.06 to 18.04)
Multiple	13,399	2.77	3,008	22.45	1.14 (1.08 to 1.19)

* Adjusted for maternal age, parity, infant sex, preterm and multiple birth. 158 and 63 records were missing maternal age and infant sex, respectively

Table 3. Rates of hospital readmission or death among infants discharged home, up to their first birthday, for conditions and procedures indicative of neonatal morbidity

E-NAOI component	Any hospital readmission in first year (%)	Overnight hospital readmission in first year (%)	Death in first year (%)
All infants not identified by E-NAOI (n=457,939)	23.16	7.09	0.05
All infants identified by E-NAOI (n= 26,068)	36.80	15.69	0.81
Term infants not identified by E-NAOI (n=436,477)	22.65	6.79	0.05
Term infants identified by E-NAOI (n= 13,4978)	30.17	11.59	0.92
Individual E-NAOI components			
Birthweight <1500g	55.41	28.30	0.87
Gestational age <32 weeks	54.54	27.22	0.78
Respiratory distress syndrome	42.01	18.14	0.56
Seizure	47.60	19.80	2.33
Intraventricular haemorrhage (grades 3 and 4)	65.22	30.43	1.45
Cerebral infarction	46.97	12.12	N/A
Periventricular leukomalacia	64.91	28.07	N/A
Birth trauma (intracranial haemorrhage paralysis due to brachial plexus injury, skull or long bone fracture)	29.62	11.41	N/A
Hypoxic ischemic encephalopathy	38.63	14.51	1.60
Necrotising enterocolitis	66.86	39.21	1.54
Sepsis/septicaemia (streptococcus staphylococcus, E.coli, unspecified gram negative)	45.82	22.81	1.02
Pneumonia	39.44	17.40	1.00
Other respiratory (primary atelectasis, respiratory failure)	42.41	18.15	0.74
Chronic respiratory disease originating in the perinatal period	68.14	38.34	1.89
Bacterial meningitis	36.80	15.24	0.74
Resuscitation	41.84	19.73	1.01
Ventilatory support (mechanical ventilation and/or CPAP)	38.63	16.79	0.57
Central venous or arterial catheter	51.74	26.14	1.27
Pneumothorax requiring intercostal catheter	39.67	17.70	0.61
Any IV fluids	26.66	10.46	0.17
Any body cavity surgical procedure	63.48	40.14	1.63
Therapeutic hypothermia	36.40	13.70	1.50

Box 1. Adaptations made to the E-NAOI

Adaptations to overcome potential data quality issues

- Based on the observation that the rate of neonatal blood transfusion recorded in HES was implausibly low at all gestations, we did not consider the coding of transfusion to be reliable in HES. Others have reached similar conclusions when examining the coding of obstetric blood transfusions in HES.[25]
- The coding for sepsis was amended to include codes P36.0 to P36.8 but to exclude code P36.9 (unspecified bacterial sepsis of the newborn) due to concerns that P36.9 is over-used to record suspected rather than confirmed sepsis. Without this exclusion, rates of neonatal sepsis reported in HES were implausibly high at 2.6%. With the exclusion, the rates observed are in line with the published literature.[22]

Adaptations to reflect current neonatal health concerns in England

- IVH was restricted to grades 3 and 4 since grade 2 IVH is of less prognostic significance.[26]
- Respiratory distress syndrome was expanded to include all chronic respiratory disease originating in the perinatal period as a relevant diagnosis indicating serious adverse outcome.[27]
- Therapeutic hypothermia was included as a relevant procedure indicating serious adverse outcome. The use of this therapy to treat perinatal asphyxial encephalopathy has been increasing in the UK since the publication of the TOBY trial in 2008.[28] Its use indicates serious concern about the clinical condition of the baby at birth.
- Bacterial meningitis was included as a relevant diagnosis with prognostic significance at least as relevant as that of generalised bacterial sepsis. It is associated with both short term mortality and long term neurodevelopmental complications.[23]

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Text S1. Details of trust-level data quality checks and comparison of included and excluded records

NHS trusts were excluded from the analysis if they failed one or more of the following assessments:

Birth status

- More than 30% of birth records were missing the birth status field

  and/or

- The total stillbirth rate was less than 1 per 1,000 or more the 10 per 1,000. These cut-offs were set based on the trust-level stillbirth rates reported in the 2014 MBRRACE perinatal mortality report.[1]

  and/or

- More than 20% of stillbirths had 'unknown timing'

Gestational age

- More than 30% of birth records were missing the gestational age field

  and/or

- The proportion of all births that took place between 39 and 42 completed weeks of gestation was less than 60% or more than 90**%**

Birthweight

- More than 30% of birth records were missing the birthweight field

NAOI component procedures and diagnoses

- The trust had a recorded incidence of one or more of the NAOI components that was above or below 5 standard deviations of the national mean incidence.

[1] Manktelow BN, Smith LK, Seaton SE, et al. MBRRACE-UK Perinatal Mortality Surveillance Report, UK Perinatal Deaths for Births from January to December 2014. Leicester: The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester; 2016.

Table S1. Definition of E-NAOI component procedures and diagnoses and incidence (per 100 births) among all eligible infants (n = 484,007)

Component	Codes	Incidence
Birthweight <1500g	HES baby tail: birthweight <1500g	0.81
Gestational age <32 weeks	HES baby tail: gestational age <32 weeks	0.89
Neonatal death within 28 days (includes deaths after 28 days if the infant was never discharged home)	HES: Discharge method 4; ONS: death within 28 days of birth;	0.18
Respiratory distress syndrome	ICD-10: P22.0	1.99
Seizure	ICD-10: P90; R56	0.16
Intraventricular haemorrhage (grades 3 and 4)	ICD-10: P52.2	0.04
Cerebral infarction	ICD-10: I63	0.01
Periventricular leukomalacia	ICD-10: P91.2	0.01
Birth trauma (intracranial haemorrhage paralysis due to brachial plexus injury, skull or long bone fracture)	ICD-10: P10.0-3; P13.0; P13.2-3; P14.0-1	0.08
Hypoxic ischemic encephalopathy	ICD-10: P91.6; P91.8; P91.5	0.22
Necrotising enterocolitis	ICD-10: P77	0.11
Sepsis/septicaemia (streptococcus staphylococcus, E.coli, unspecified gram negative)	ICD-10: P36.0-8; B95.1; B96.2	0.41
Pneumonia	ICD-10: P23; J12-18	0.24
Other respiratory (primary atelectasis, respiratory failure)	ICD-10: P28.0; P28.5	0.13
Chronic respiratory disease originating in the perinatal period	ICD-10: P27	0.25
Bacterial meningitis	ICD-10: G00-03; G05	0.06
Resuscitation	OPCS: X50; X56; HES baby tail: biresus 5 - 6	0.58
Ventilatory support (mechanical ventilation and/or CPAP)	OPCS: E85.1-2; E85-8-9	3.63
Central venous or arterial catheter	OPCS: L91.0-5; O15.2; O15.3	0.97
Pneumothorax requiring intercostal catheter	OPCS: T12.2; T12.4 ICD-10: P25.1	0.26
Any IV fluids	OPCS: X29; X35.8-9	0.37
Transfusion of blood or blood products	OPCS: X33; X34.0-3; X32.1; X32.8-9; X47	0.03
Any body cavity surgical procedure	OPCS: A01-08; A10-22; A38-51; A57; B01-25; C01-09; G01-22; G24-82; H01-50; H62-70; J01-09; J16; J18-23; J26-72; J76; K01-12; K14; K17-48; K52-56; K66-75; L01-02; L04-12; L16-25; L29-30; L33-34; L37-38; L41-42; L45-46; L48-53; L56-62; L65-70; L73-82; M01-08; M16-83; Q03-11; Q22-54; T01-17; T28-57; V03-68; X45-46; X53-55; X58	0.44
Therapeutic hypothermia	OPCS: X51.1-2	0.11

Table S2. Characteristics of included and excluded records

Characteristic	**Included records (%)**	**Excluded records (%)**	**P value**
Maternal age <20	3.71	3.18	<0.001
Maternal age 20-34	75.88	73.71	
Maternal age >=35	20.41	23.12	
Primiparous	36.46	42.25	<0.001
Male infant	51.30	51.26	<0.001
Multiple birth	2.77	2.32	<0.001
Short gestation/low birth weight (ICD-10 P07)	7.64	8.45	<0.001

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page number
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Introduction para 1-4
Objectives	3	State specific objectives, including any prespecified hypotheses	Introduction para 5
Methods			
Study design	4	Present key elements of study design early in the paper	Abstract; Intro para 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods para 1-3
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Methods para 3-4
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Methods para 5-7 and 9. Table S1
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Table S1
Bias	9	Describe any efforts to address potential sources of bias	Methods para 7 and 9; Table S2
Study size	10	Explain how the study size was arrived at	Methods para 3
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Methods para 8-9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Methods para 8-11
		(*b*) Describe any methods used to examine subgroups and interactions	N/A
		(*c*) Explain how missing data were addressed	Methods para 1; Text S1
		(*d*) If applicable, explain how loss to follow-up was addressed	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility,	Methods para 3; Figure 1

		confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	Methods para 3; Figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Table 2
		(b) Indicate number of participants with missing data for each variable of interest	Table 2
		(c) Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Report numbers of outcome events or summary measures over time	Tables 1 and 3, Table S1
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Tables 1 and 3; Figures 2 and 3
		(*b*) Report category boundaries when continuous variables were categorized	Table 1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Table 3
Discussion			
Key results	18	Summarise key results with reference to study objectives	Discussion para 1-2
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Discussion para 3-9
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Discussion para 10
Generalisability	21	Discuss the generalisability (external validity) of the study results	Discussion para 3-4 and 10
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Funding statement

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

10. Discussion

This programme of work has sought to answer a number of questions, each addressing a different element of the overall aim: to determine the extent to which electronic data captured routinely as part of clinical care and hospital administration can be used to evaluate English NHS maternity services.

In the next section, the main findings of this thesis are summarised in relation to the original objectives. Following this, there is a discussion of how the findings have furthered our understanding of how the analysis of routinely collected maternity date *can* and *cannot* support the evaluation of English NHS maternity services, before considering further opportunities for improving these datasets, and for future research.

10.1. Summary of findings

Chapter 3 reviewed the advantages and limitations of existing hospital administrative and clinical datasets for the purposes of evaluating patterns and outcomes of care in hospital-based maternity services in the English NHS. This review highlighted several opportunities to improve the analysis and interpretation of these data, sometimes through lessons learned in other specialties. This review concluded that, although routinely collected data may not provide the perfect data source for evaluating maternity care quality, until such a time that centrally-available electronic maternity records become the norm, routine hospital administrative data, linked with other sources of clinical data where possible, will be the key data source for national evaluations. Particular challenges related to the analysis of these

data include assessing the completeness and accuracy of data on key variables, defining obstetric populations and outcomes and adjusting for potential confounders.

In Chapters 4 and 5, some of the current weaknesses in the secondary analysis of routine maternity datasets are addressed through the development and validation of novel methods for handling of missing or inconsistent information. This work sought to overcome concerns about data quality related to two key data items: method of delivery and maternal parity. These data items are particularly important for the construction of maternity statistics and yet suffer from high data incompleteness. Specifically, in chapter 4, a new approach for assessing the completeness of information on method of delivery is proposed. This technique draws upon a unique feature of the HES database to internally validate levels of agreement between equivalent data items, demonstrating high overall levels of consistency. In chapter 5, an alternative 'look-back' approach using historical records was applied to determine women's parity status. The results demonstrated that the technique can be used to derive accurate information on the multiparous status of women, although misclassification rates are higher for some subgroups of women. Taken together, these chapters demonstrate how current methods for analysis can be improved, and serve to highlight how maternity statistics are sensitive to data inconsistencies and the choice of definition selected for key obstetric parameters.

In the next section, the novel techniques developed in objective 2 were applied to research questions about the clinical and organisational management of pregnant women, using a series of case studies on topical subject areas in maternity care.

Specifically, in Chapter 6, a subgroup of women giving birth following a primary caesarean section was defined, making it possible, for the first time, to investigate the demographic

and obstetric factors associated with the uptake and success of VBAC in this group. The exclusion of women who are not candidates for VBAC represents an important development as it provides a more appropriate denominator for the estimation of VBAC rates. The study's results revealed that just over half of women in England with a primary caesarean section, who are eligible for a trial of labour, attempt a VBAC for their second birth. Of those who attempt a VBAC, almost two-thirds of women have a successful vaginal delivery. Both of these statistics were previously unknown on a national basis, since only overall VBAC rates has previously been calculated. The study also revealed substantial variation in the uptake and success of VBAC, according to maternal demographic and clinical characteristics and indication for primary caesarean section. This information could be used to improve candidate selection and patient choice for the 50,000 women in England each year who give birth following a primary caesarean section, and many hundreds of thousands more around the world.

In Chapter 7, a retrospective cohort study examining the association between induction of labour at term and rare perinatal outcomes, including death, was conducted in a national cohort of nulliparous women aged 35 years and over. The main methodological contribution here was to define an appropriate comparison group (i.e. women who are expectantly managed) using English hospital administrative data in which gestational age was only available in completed weeks and not in days. The results suggest that induction of labour at 40 weeks of gestation in this group was associated with a third of the risk of perinatal death compared with expectant management, extending the results of a recently published RCT. If these associations are causal, the results indicate that bringing forward the routine offer of

induction of labour from the current recommendation of 41-42 weeks to 40 weeks of gestation in this group of women may reduce overall rates of perinatal death.

In Chapter 8, three different sources of routinely collected data (hospital administrative data, electronic maternity records and obstetric staffing rotas) were linked in order to address an important health policy question in maternity care. Specifically, the linked data were used to examine whether rates of obstetric intervention and outcome change "out-of-hours," i.e., when consultants are not providing dedicated, on-site labour ward cover. The study found no difference in the adjusted rates of morbidity among neonates born according to consultant presence, although women who delivered out-of-hours were slightly less likely to have an obstetric intervention than women who delivered in-hours. Sensitivity analyses produced results that were broadly consistent with the results derived from the overall cohort. Overall, these data provide some reassurance that current models of labour ward staffing in the UK allow for good planning and risk management.

Finally, in Chapter 9, the feasibility and validity of adapting an Australian composite indicator for severe adverse neonatal outcome for use in English hospital administrative data was evaluated. The study demonstrated that a composite measure can be derived using HES data, and recommended a number of minor adaptations to the original indicator that address potential data quality issues as well as current neonatal health concerns in England. This E-NAOI composite measure demonstrated good concurrent and predictive validity and may represent a cost-effective way to monitor neonatal outcomes. Its further development and use could overcome reliance on individual diagnosis codes that may suffer from issues of low statistical power and under-recording in routine data.

10.2. Strengths and limitations

The specific strengths and limitations of each of the analyses presented in this thesis are discussed in detail within the relevant chapter. In this section, some of the over-arching advantages and weaknesses of currently available routinely collected maternity data sources in England are summarised, and illustrated using examples from the earlier chapters.

10.2.1. Case ascertainment and data completeness

Using the method of defining mothers' delivery records described in Chapter 4, over 96% of all deliveries in England are captured by HES. This high ascertainment rate has remained stable over the last decade, and the consistency of the HES data dictionary over this time means that this definition can be applied to historical HES data to examine longitudinal birth patterns. Being able to identify delivery records reliably is a fundamental requirement for evaluating maternity services, and the high case ascertainment rate in HES minimises the possibility of selection bias.

However, as this thesis illustrates, careful data quality assessments and methods for handling missing or inconsistent data are essential in evaluations of maternity care, in order to determine the most suitable definitions for the exposure, outcome and confounder variables of interest. These data quality assessments are most effective at identifying potential issues when their development combines both methodological and clinical insights. While for variables in the HES 'maternity tail', it is relatively straightforward to assess the level of missing data, it is more difficult to determine data completeness for the diagnosis and procedure fields. This is because, in these fields, a particular code is either present or not; in other words, the coding system offers no way to distinguish between a null value and

a missing value. Although a comparison of HES diagnosis and procedure codes against a sample of medical records is one means of externally validating these data, such studies can be time consuming, costly and technically challenging, as well as raising ethical and information governance issues related to access and data linkage. Instead, the work in this thesis employed a variety of alternative methods to examine internal coding consistency (see Chapters 4 and 5) and concurrent and predictive validity of particular codes (see Chapter 9), and to identify organisations with potentially divergent coding practices.

Each results chapter illustrates that the level of data quality of routine maternity data varies considerably between hospitals. A common method of dealing with poor levels of completeness is to only include those NHS trusts with high levels of data quality in the analysis, for example as in Chapters 7 and 9. This approach has been demonstrated by others to be a valid way of constructing birth cohorts;[52 59] however, it is essential that the characteristics of included and excluded records are compared to determine the degree to which the remaining cohort is nationally representative.

10.2.2. Definition of obstetric populations and key exposure and outcome variables

This thesis demonstrates that routinely collected data can provide detailed information on *certain* processes and outcomes of maternity care for *some* important subgroups of pregnant women. However, the analysis of relevant processes and outcomes using HES maternity data is limited by the OPCS and ICD-10 codes available. Newly recognised diagnoses or novel procedures can take many years to be allocated a specific code, and the desired granularity of clinical detail is not always available. MIS data contain slightly more detailed information on some diagnoses, but neither data source captures information on

the timing of diagnoses, preventing a true understanding of the sequence of events along the maternity pathway. For example, because antenatal appointments are not currently recorded electronically, a diagnosis of gestational diabetes will not appear in the data until the mother's delivery record, and it therefore is not possible to know at which week of gestation this condition was diagnosed.

Key data items missing from HES include both outcomes variables and exposure variables needed to define obstetric subpopulations. Examples of exposure variables which are not well captured in HES, but which are generally present in MIS, include: fetal presentation at delivery, birth position, labour augmentation and type of pain relief. Gestational age at birth, a vital piece of information for many analyses of maternity data, is recorded in the HES maternity tail in completed weeks. This limits the usefulness of this data item since assumptions have to be made about the sequence of events leading up to the birth, as discussed in Chapter 7. The RCOG MIS Pilot Project asked participating NHS trusts to submit this variable in days of gestation. Whilst all trusts complied with this request, upon analysis it became clear that approximately half of participating trusts had simply converted completed weeks into days by multiplying the number of weeks by 7. Therefore, gestational age in days was only truly available in 50% of the MIS sample.

An example of a particular outcome that is not well captured in HES is severe postpartum blood loss (PPH) of 1500ml or more, an adverse outcome that occurs in approximately 3% of all deliveries.[5] Severe PPH is an important component of a composite maternal morbidity outcome measure that has been constructed using routine Australian data.[38] Many women lose some volume of blood during delivery without any negative consequence; it is therefore crucial to be able to distinguish minor and moderate PPH from severe PPH. In HES, the ICD-

10 code for PPH captures all postpartum blood loss under one code (O.72), making such a distinction impossible and preventing a reliable maternal morbidity composite indicator from being derived using HES.[75] Fortunately, estimated blood loss in millilitres is routinely captured in most electronic maternity record systems and was collected as part of the RCOG MIS Pilot Project. Severe PPH could therefore be included as an outcome measure in Chapter 8, and has recently been measured on a national basis for the first time by the new National Maternity and Perinatal Audit (NMPA), which collected MIS extracts from all NHS trusts in England covering births in 2015/16.[5]

Neonatal outcomes are an important category of outcome for maternity service evaluations and capturing these is an important methodological contribution of this thesis. Neonatal diagnoses are recorded in the baby's record using ICD-10 codes. However, it has not been possible to link mother and baby records, for example to investigate the impact of maternal characteristics and intrapartum care processes on neonatal outcomes. Chapters 7 to 9 of this thesis make use of a linked mother-baby HES dataset which enables some of these associations to be explored for the first time. Chapter 8 additionally links this dataset with MIS data, which routinely captures some immediate neonatal outcomes not recorded in HES, for example Apgar score at 5 minutes.

A linked MIS-HES dataset, such as that used in Chapter 8, can overcome several of the limitations of both data sources. For example, MIS data contains more clinical detail about the booking appointment and intrapartum period. However, MIS are unable to capture outcomes following discharge from maternity services, some of which can be captured using HES if the mother or baby is readmitted to hospital. The pooling of MIS data, linked with HES, could represent a promising solution for the creation of a more detailed national birth

registry for England and this approach has recently been taken by the new NMPA.[5] However, a challenge of applying the MIS approach on a larger scale, discussed in detail in the first NMPA report, is the creation of a minimum dataset made up of extracts from over twenty different MIS systems in use by NHS maternity units in England. Each system may contain different variables, and record these in different levels of detail. Much of the detailed information therefore gets lost when the individual datasets are combined to meet a minimum specification. Another limitation of this approach is that MIS do not generally capture information on antenatal attendances. Furthermore, separate systems are in use to capture information about ultrasound scans and babies admitted to neonatal care, and these would also need to be linked to provide a truly comprehensive data source.

Finally, neither HES nor local electronic maternity records currently capture information on maternity service user experience and therefore cannot be used to build robust conclusions regarding quality in the broadest sense of the term. If it was possible to measure women's satisfaction with their maternity care, this would undoubtedly be an important secondary outcome for some of the studies in this thesis where women can make an informed choice, for example about whether to attempt a VBAC, or to have an induction of labour.

10.2.3. Risk adjustment

HES contains various variables that are commonly used in risk adjustment. Age and other sociodemographic variables are standard fields and coexisting diseases/obstetric conditions can be derived from the diagnosis fields. This thesis demonstrates how these variables can be used to develop logistic regression models that can control for certain maternal demographic and clinical confounders (see Chapters 6 to 9).

However, as previously discussed, some risk factors relevant to obstetric care are unavailable in HES, or are recorded in insufficient detail, leading to residual confounding. For example, in Chapter 6, it was not possible to control for maternal height, BMI or tobacco use, three risk factors which may affect the likelihood of attempted and/or successful VBAC. Nonetheless, this thesis demonstrates how it is possible to obtain further information about obstetric history through linkage with historical HES data (see Chapter 5), and certain information about maternal behavioural characteristics through linkage with MIS data (see Chapter 8), in order that these factors can be controlled for in evaluations.

In all observational studies, because the allocation of the intervention is not randomised, and the reason for intervention may be related to the risk of future health outcomes, the resulting imbalance in the underlying risk profile between the treated and comparison group can lead to biased results. The risk of indication bias risk can be minimised by restricting a cohort to a relatively homogenous group of deliveries, for example by excluding multiple and preterm infants with a high probability of an adverse outcome (see Chapter 8). Sensitivity analyses can also be carried out to assess the possible impact of indication bias (Chapters 7 to 9).

10.3. Implications and recommendations for future work

This thesis contains lessons for national organisations responsible for administering routine maternity datasets, as well as for the secondary users of these data.

10.3.1. Recommendations for organisations responsible for collecting and administering routine data

Some countries, such as Denmark, Finland, Norway and Sweden, have well-established methods of integrating data linkage into their routine perinatal health surveillance systems and making these data available for research.[60] However, this is not a universal practice even in high-income countries with access to electronic hospital administrative data.

In England, a new National Maternity Dataset[76] may eventually provide the principal data source for service evaluation. Unfortunately, this is still in development and unavailable for secondary use. The main alternative source of data is routine administrative health datasets like HES, linked where possible to other clinical data. Broader adoption of data linkage in England could, subject to sufficient quality assurance,[77 78] yield substantial gains for perinatal health research and surveillance. In particular, existing databases in England that routinely capture information on babies admitted to neonatal care,[79] culture positive bloodstream infections,[80] and mental health admissions,[81] present exciting opportunities for data linkage. Some of this work is already being planned as part of the new NMPA.[5]

The analyses undertaken as part of this thesis demonstrate a clear discrepancy between NHS maternity providers in the amount and quality of information available in routine data sources. Services should ensure they have robust systems in place for data entry, follow standard coding definitions where these exist, and hold regular training and data quality assurance exercises to improve coding consistency. These activities, and the maintenance of adequate hardware and software required to support them, need to have sufficient dedicated staff and financial resources allocated by NHS commissioners.

Organisations responsible for administering hospital administrative data should also increase efforts to improve their completeness and consistency. An important element of this could be to focus on the minority of NHS trusts with repeatedly poor completeness of the HES 'maternity tail' and provide support to help these organisations to improve their data collection systems. Clinical and informatics teams should be informed and encouraged to work together to find solutions to local challenges.

Finally, electronic data collection is currently focused on booking and the intrapartum period, leading to a paucity of information about processes and outcomes during pregnancy and after birth. The lack of information impedes the interpretation of labour events and the evaluation of care during pregnancy and the postnatal period. System suppliers should therefore develop and implement solutions to support the collection of information during and after pregnancy, such as electronic handheld records.

10.3.2. Recommendations for secondary users of routine maternity data

The work presented in this thesis highlights the need for a careful assessment of data quality and for the transparent reporting of how incomplete and inconsistent data are handled when producing maternity statistics, particularly at an organisational level. Publishers of maternity statistics and researchers using routine maternity data should always describe details of how data quality was assessed, and incomplete and consistent data were handled, in their analyses. Further work is also required to validate HES data against a random sample of maternity notes to estimate the level of miscoding of procedures and diagnoses in this population. This would be an important contribution to the further evaluation of the E-NAOI

developed in Chapter 9, and other composite adverse outcome measures being considered for use as performance indicators in England.

This thesis also contains lessons on assessing internal validity that are relevant for the broader programme of maternity service evaluations being undertaken in England. Several new initiatives based on routine data sources have been launched in recent years[5 82 83] or are planned in the near future.[25 76] It is imperative that these initiatives avoid some of the common pitfalls of using routine comparative data to assess the quality of maternity care, in particular the need for cautious handling of missing or inconsistent data, careful definition of obstetric populations and outcomes, and appropriate risk-adjustment for case mix.

10.3.3. Conclusion

In conclusion, until such a time that centrally-available electronic maternity records become the norm, hospital administrative datasets, linked with other sources of clinical data where possible, are likely to remain a key data source for national analysis service evaluations. The work presented in this thesis highlights how maternity statistics are sensitive to data inconsistencies and the choice of definition selected for key obstetric parameters. In light of this, methods for addressing the challenges posed by analysing routine data are crucial to improve the usefulness of the information being produced to evaluate NHS maternity services.

Whilst routine data sources are not perfect and there is certainly a need to improve their completeness and consistency, in many circumstances, having imperfect data will be better than having no data. Taken together, the novel techniques developed, validated and applied

as part of this programme of work advance our understanding of the ways in which routinely collected maternity data *can* and *cannot* be used to support the evaluation of English NHS maternity services, and thereby address many of the broader issues raised about the use of routine data for performance monitoring in healthcare.

Appendix 1. MIS Pilot Project Survey

Background

The RCOG aims to set standards to improve women's health and the clinical practice of obstetrics and gynaecology in the British Isles and across the world.

Increasing demands are being placed on hospitals to provide information on clinical activities and outcomes. Maternity services are by no means an exception.

The College is committed to supporting hospitals to produce robust and clinically useful information in a timely manner. We are planning to launch a pilot study, the aim of which is to use the detailed clinical data contained within hospitals' maternity information systems (MIS) to develop more meaningful information to support clinical governance. We expect this data to be useful for a variety of purposes, including benchmarking, quality improvement, and patient information.

Instructions for completing and returning survey:

1. Please ensure that one survey is completed for each maternity unit within your organisation. All questions refer to individual units, not the organisation as a whole.
2. Completion of this survey may require a multi-professional effort. We would be grateful if the Clinical Director could ensure that the survey is completed and returned to the RCOG.
3. This form can either be printed or completed electronically using Microsoft Word.
4. The survey has 9 questions in total and will take approximately 5 minutes to complete.
5. Please answer all questions, unless instructed by '→*go to'* instruction next to the tick box.
6. Please return the completed survey:
   - By email to Hannah Knight at hknight@rcog.org.uk
   - By post to Hannah Knight at: RCOG, 27 Sussex Place, London NW1 4RG
7. If you have any questions about this survey, please contact Hannah Knight at hknight@rcog.org.uk or telephone 020 7772 6472.

Details of maternity unit

1. Name of maternity unit Click here to enter text.

Details of person completing the survey

2. Your name Click here to enter text.
3. Job title/role Click here to enter text.

4. **Does your maternity unit have a computerised MIS?**

   ☐ Yes

   ☐ No →***end of survey. Thank you for taking part***

5. **If yes, which MIS software provider does your unit use?**

   ☐ EuroKing - **HSS**

   ☐ Evolution - **CSC**

   ☐ Circonia (CMiS) - **HD Clinical**

   ☐ Medway Maternity - **System C Healthcare**

   ☐ Other (please specify) Click here to enter text.

6. **How long has this MIS been in place at your maternity unit?**

   ☐ Less than 1 year

   ☐ 1-3 years

   ☐ More than 3 years

   ☐ Unsure

7. **Is the data contained in the MIS used to generate reports about clinical activities in your unit, for example: number of deliveries; delivery outcomes; patient subgroups, e.g. preterm births?**

   ☐ Yes

   ☐ No

8. **Would your unit be interested in participating in a pilot project to link MIS data for the purposes outlined above? Please note that this would involve supplying an extract from your MIS which would be stored securely and analysed at the RCOG. If your unit is selected, you may be required to liaise with your local Caldicott Guardian and arrange the MIS data transfer with your unit's IT department. At the end of the pilot we would provide your unit with a personalised report of clinical activity and outcomes, which would include risk-adjustment for case-mix variation.**

   ☐ Yes

   ☐ No

   ☐ Don't know / would like more information

9. **Please use this space for any comments or questions about the proposed pilot project**

   Click here to enter text.

Appendix 2. MIS Pilot Project Data Items

1. The following data items are required for all registerable births (including live births before 24 weeks of gestation and stillbirths after 24 weeks of gestation) that took place in your trust (including home births) between 1st April 2012 and 31st March 2013.

2. The data are required at the level of ONE ROW PER BABY (i.e. 2 rows for twins, 3 rows for triplets etc). In the case of multiple births, the maternal information (demographics, obstetric history, antenatal care) should be identical but neonatal information (e.g. mode of delivery, birth weight) may differ.

3. Preferred formats for the output are detailed below in Column C. These are largely based on national code definitions; however, if your system captures data in a different format or uses an alternative coding system, you do not need to re-code the data. Please simply send the raw data extract together with a data dictionary or similar to enable us to interpret the data.

4. If possible, please save the extract as a comma-separated value (CSV) file. For fields with multiple, non mutually-exclusive options (highlighted in green), please use a different delimiter (e.g. ; or |) to separate data items within a field.

5. The data extract must be transferred securely in an encrypted format as per the Data Sharing Agreement. Please contact Lynn Copley on 020 7869 6609 / lcopley@rcseng.ac.uk to discuss data transfer options.

6. If you have any queries regarding these instructions please contact Hannah Knight on 020 7772 6472 / hknight@rcog.org.uk

The preferred format of the data item is expressed in data type and length.

The data type is represented in either alphanumeric or numeric form. i.e.:

- an - indicating an alphanumeric data item
- n - indicating a numeric data item

The length is expressed in a numeric form e.g. 6, which would indicates a data item that captures 6 characters (Note - spaces are counted as characters).

In some cases, the length is proceeded with 'MAX' to indicate that the length is variable but has an upper limit. For instance a format of 'max Examples of formats are:

- an2 - a data item in an alphanumeric format which captures 2 characters.
- max an2 - a data item in an alphanumeric format which captures a maximum of 2 characters.
- n3 - a data item in a numeric format which captures 3 numeric characters
- an7 - n:nnnnnnn - a data item in a alphanumeric format with specific data types for each character. Barring the second character, all characters are numeric. The second character is alphanumeric.
- n.nn - a data item in a numeric format which captures three numeric characters separated by a full stop (after the first character).

DATE and DATE TIME data items are in alphanumeric format, however, the format of these data items also explain the specific form of each character. i.e.:

- an10 - CCYY-MM-DD
  CCYY denotes the year, *MM* denotes the month and *DD* denotes the day in the month.

- an19 - YYYY-MM-DDThh:mm:ss
  YYYY denotes the year, *MM* denotes the month and *DD* denotes the day in the month.
  T is a prefixed value denoting that the subsequent characters relate to time (i.e. trusts will submit the letter *T*).
  hh denotes the hour, *mm* denotes the minute and *ss* denotes the second.

Data item	Description	Format
	DEMOGRAPHICS	
Mother's NHS number	The NHS Number of the mother in a maternity episode	n10 (nnnnnnnnnn)
Postcode	The postcode of usual address, as nominated by the mother	max an8
Mother's date of birth	Date of birth of the mother in a maternity episode	Preferred format: an10 (CCYY-MM-DD)
Mother's ethnicity	The ethnicity of the mother in a maternity episode as specified by herself	Preferred categories and codes listed below (based on 2001 census). If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. **White** A - White British B - White Irish C - Any other White background **Mixed** D - White and Black Caribbean E - White and Black African F - White Asian G - Any other Mixed background **Asian or Asian British** H - Indian J - Pakistani K - Bangladeshi L - Any other Asian Background **Black or Black British** M - Caribbean

		N - African P - Any other Black background **Other Ethnic Groups** R - Chinese S - Any other ethnic group Z - Not Stated 99 - Not known
Father's ethnicity	The ethnicity of the father as specified by himself, or by the mother if the father is not present	Preferred categories and codes listed below (based on 2001 census). If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. **White** A - White British B - White Irish C - Any other White background **Mixed** D - White and Black Caribbean E - White and Black African F - White Asian G - Any other Mixed background **Asian or Asian British** H - Indian J - Pakistani K - Bangladeshi L - Any other Asian Background **Black or Black British** M - Caribbean N - African P - Any other Black background **Other Ethnic Groups** R - Chinese S - Any other ethnic group Z - Not Stated 99 - Not known
OBSTETRIC HISTORY		
Gravida	Number of previous pregnancies (including miscarriages and abortions)	max n2
Parity	Number of previous registerable births (any birth >24 weeks of gestation, or with any signs of life)	max n2
Caesarean section	Has the mother delivered any previous baby by caesarean section?	Preferred format: N = no; Y = yes
Instrumental delivery	Were any of the woman's previous babies delivered with instrumental assistance?	Preferred format: N = no; Y = yes
Preterm birth	Were any of the woman's previous babies born before 37 completed weeks of gestation?	Preferred format: N = no; Y = yes
Low birth weight	Did any of the woman's previous babies weight less than 2500g at birth?	Preferred format: N = no; Y = yes
Stillbirth	Has the woman ever had a stillbirth (intrauterine fetal death after 24 completed weeks of gestation)?	Preferred format: N = no; Y = yes
Pre-eclampsia, eclampsia	Did the woman have preeclampsia or eclampsia during any previous pregnancy?	Preferred format: N = no; Y = yes
Placenta accreta	Did the woman have placenta acreta during any previous pregnancy?	Preferred format: N = no; Y = yes
ANTENATAL CARE		
Assisted conception	Did the mother conceive through a method of assisted conception (e.g. IVF/IUI)	Preferred format: N = no; Y = yes
Date of LMP	Date of the last menstrual period as reported by the mother (if known)	Preferred format: an10 (CCYY-MM-DD)
Gestation at booking	Estimated gestational age at booking in days	max n3
Maternal weight at booking	The weight of the mother in kilograms at the Booking Appointment	maxn3.maxn3
Maternal height	The height of the mother in metres	n1.maxn2
BMI at booking	The body mass index of the mother at the Booking Appointment	n2.n1
Smoking status at booking	The mother's self-reported smoking status at the Booking Appointment	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 01 - Current smoker 02 - Ex-smoker - Stopped after conception 03 - Ex-smoker - Stopped between conception and 12 months before conception 04 - Ex-smoker - Stopped more than 12 months before conception 05 - Non-smoker - history unknown 06 - Never smoked 09 - Unknown
Alcohol (units per week)	The typical number of units of alcohol the mother drinks, per week, as reported at the Booking Appointment	max n3
Confirmed EDD	The Estimated Date of Delivery, as agreed by ultrasound scan, LMP or Clinical Assessment	Preferred format: an10 (CCYY-MM-DD)
Antenatal complications/diagnoses	Any obstetric condition/s diagnosed in this pregnancy	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 01 - Severe pre-eclampsia requiring pre-term birth 02 - Haemolytic anaemia, elevated liver enzymes and Low platelet count (HELLP) 03 - Eclampsia 05 - Liver cholestasis of pregnancy 06 - Gestational diabetes mellitus 07 - Gestational hypertension 08-Gestational proteinuria 09 - Antepartum haemorrhage 11 - Feto-maternal haemorrhage 18 - Symphysis pubis dysfunction 19 - Placenta praevia 20 - Severe pre-eclampsia
Group B Streptococcus screening	Was the mother screened for Group B Streptococcus?	Preferred format: N = no; Y = yes
Pre-existing clinical conditions	As identified at the Booking Appointment and based on the woman's past medical history, the diagnosis or type of diagnosis presenting a risk or complicating factor for this pregnancy	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 01 - Hypertension 02 - Cardiac disease 03 - Renal disease 04 - Mental health disorder 05 - Thromboembolic disorder

		06 - Haematological disorder 07 - Central nervous system disorder 08 - Diabetes 09 - Autoimmune disease 10 - Cancer 12 - Infectious hepatitis A 13 - Serum Hepatitis B 14 - Hepatitis C 16 - Endocrine disorder 17 - Respiratory disease 18 - Gastrointestinal disorder 19 - Musculoskeletal disorder 20 - Gynaecological problems
Intended delivery location	Planned place of delivery (type)	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 0 - In NHS hospital - delivery facilities associated with midwife ward 1 - At a domestic address 2 - In NHS hospital - delivery facilities associated with consultant ward 3 - In NHS hospital - delivery facilities associated with GMP ward 4 - In NHS hospital - delivery facilities associated with consultant/GMP/midwife ward inclusive of any combination of two of the professionals mentioned 5 - In private hospital 6 - In other hospital or institution 7 - In NHS hospital - ward or unit without delivery facilities 8 - None of the above 9 - Not known
LABOUR AND DELIVERY		
Actual delivery location	Location in which baby was delivered	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 0 - In NHS hospital - delivery facilities associated with midwife ward 1 - At a domestic address 2 - In NHS hospital - delivery facilities associated with consultant ward 3 - In NHS hospital - delivery facilities associated with GMP ward 4 - In NHS hospital - delivery facilities associated with consultant/GMP/midwife ward inclusive of any combination of two of the professionals mentioned 5 - In private hospital 6 - In other hospital or institution 7 - In NHS hospital - ward or unit without delivery facilities 8 - None of the above 9 - Not known
Transferred in	Was the woman transferred to this unit for her antenatal care, labour or delivery (as opposed to booking at this hospital)?	Preferred format: N = no; Y = yes
Smoking status at delivery	The mother's self-reported smoking status at delivery	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 01 - Current smoker 02 - Ex-smoker - Stopped after conception 03 - Ex-smoker - Stopped between conception and 12 months before conception 04 - Ex-smoker - Stopped more than 12 months before conception 05 - Non-smoker - history unknown 06 - Never smoked 09 - Unknown
Number of infants this delivery	Number of registerable infants delivered	n1
Onset of labour	The method used to induce (initiate) labour, rather than to accelerate it.	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 1 - Spontaneous: the onset of regular contractions whether or not preceded by spontaneous rupture of the membranes 2 - Not applicable: caesarean section carried out prior to onset of labour or immediately following the onset of labour, when the decision was made before labour 3 - Surgical induction by amniotomy 4 - Medical induction, including the administration of agents either orally, intravenously or intravaginally with the intention of initiating labour 5 = Combination of surgical induction and medical induction 9 = Not known
Type of medical induction (if applicable i.e. Option 4 in the previous question)	The agent used for medical induction of labour	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 01 - Mifepristone 02 - Misoprostol 03 - Prostaglandin 04 - Oxytocin 05 - Unknown
Labour augmentation		Preferred format: N = no; Y = yes
Time of onset of established labour	Date/time when established labour is confirmed - regular painful contractions and progressive cervical dilatation	Preferred format: an19 YYYY-MM-DDThh:mm:ss
Time of onset of second stage	Signs or evidence of full dilatation of cervix	Preferred format: an19 YYYY-MM-DDThh:mm:ss
Anaesthesia in labour and delivery	Type of anaesthesia used within the labour & delivery episode	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 01 - General anaesthetic 02 - Epidural or caudal anaesthetic 03 - Spinal anaesthetic 09 - Pudendal block anaesthetic 97 - Other anaesthetic or analgesic only 98 - No anaesthetic administered
ECV before labour	Was external cephalic version performed before the onset of labour?	Preferred format: N = no; Y = yes
Lead maternity care professional	The professional category of the clinician with overall responsibility for care during the pregnancy	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 060 - Consultant Obstetrician 160 - General medical practitioner 170 - Midwife
Senior person present at delivery	The professional category of the most senior clinician present during the delivery	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 060 - Consultant Obstetrician 160 - General medical practitioner 170 - Midwife
Presentation at onset of labour/delivery	The presentation of the fetus at onset of labour/delivery	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 01 - Cephalic 02 - Breech 03 - Transverse/oblique 04 - Not known XX - Other

Method of delivery	The method for delivering baby	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 0 - Spontaneous Vertex 1 - Spontaneous Other Cephalic 2 - Low forceps, not breech 3 - Other Forceps, not breech 4 - Ventouse, Vacuum extraction 5 - Breech 6 - Breech Extraction 7 - Elective caesarean section 8 - Emergency caesarean section 9 - Other
Perineal tears	Whether or not there was a traumatic lesion of the genital tract	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 01 - None 02 - Labial tear 03 - Vaginal wall tear 04 - Perineal tear - first degree 05 - Perineal tear - second degree 06 - Perineal tear - third degree 07 - Perineal tear - fourth degree 09 - Cervical tear 10 - Urethral tear 11 - Clitoral tear 12 - Anterior incision
Episiotomy	Whether or not an episiotomy was performed	Preferred format: N = no; Y = yes
Maternal critical incident	Instance of a critical incident occurring	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 01 - Undiagnosed breech 02 -PPH >=500ml and <=999ml 03 - PPH >= 1000ml and <=1499ml 04 - PPH >= 1500ml 05 - Return to theatre 06 - Hysterectomy / laparotomy 07 - Anaesthetic complications 08 - Intensive care admission 09 - Venous thromboembolism 10 - Pulmonary embolism 11 - Unsuccessful forceps or ventouse
Date and time of birth	Date and time of birth of the baby	Preferred format: an19 YYYY-MM-DDThh:mm:ss
Delivery outcome	Outcome of delivery	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 10 - Live birth 20 - Stillbirth 30 - Miscarriage 40 - Termination of Pregnancy < 24weeks 50 - Termination of Pregnancy >= 24weeks XX - Other inc vanishing/papyraceous twin, ectopic
Birth weight	Weight of the baby at birth in grams	max n4
Gestational age	Gestation at date of birth in days	max n3
Birth order	Sequence in which the baby was born (if multiple)	n1
Sex of baby	Sex of the baby	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 0 - Not Known (not recorded) 1 - Male 2 - Female 9 - Not Specified
Cord blood gases	pH of umbilical (venous) blood sample	n.n2
Apgar score at 1 minute	The Apgar score of the neonate 1 minute after delivery	max n2
Apgar score at 5 minutes	The Apgar score of the neonate 5 minutes after delivery	max n2
Apgar score at 10 minutes	The Apgar score of the neonate 10 minutes after delivery	max n2
Baby's NHS number	The NHS Number of the baby	n10 (nnnnnnnnnn)
Neonatal procedures/diagnoses	A neonatal diagnosis, as captured to the point of the baby's discharge from maternity services or neonatal services	Preferred categories and codes listed below. If these are not the categories recorded in your MIS, please provide any relevant information needed to interpret your data. 01 - Shoulder dystocia 02 - Cord prolapse 03 - Acute fetal compromise 04 - Fetal acidaemia 05 - Meconium Aspiration Syndrome 06 - Acute blood loss 07 - Jaundice requiring phototherapy 08 - Erb's Palsy 09 - Neonatal abstinence syndrome 10 - Birth trauma to the newborn 11 - Fetal laceration at caesarean section 12 - Cord pH < 7.1 venous 13 - Neonatal seizures 14 - Undiagnosed fetal abnormality 15 - European Congenital Anomalies or Twins (Eurocat)
Date admitted to NICU/SCBU, if applicable	Date/time on which baby was admitted to Neonatal Unit (NNU)	Preferred format: YYYY-MM-DDThh:mm:ss
Antibiotic treatment for Group B Streptococcus	Was antibiotic treatment given to the neonate for Group B Streptococcus?	Preferred format: N = no; Y = yes
DISCHARGE		
Maternal Death	Date/time of death of mother during the antenatal, intrapartum and postpartum periods. The postpartum period only covers death to the point the woman gets discharged from maternity services.	Preferred format: YYYY-MM-DDThh:mm:ss
Neonatal Death	Date and time of death of baby, before 28 completed days of birth	Preferred format: YYYY-MM-DDThh:mm:ss
Date of maternal discharge	Date that the mother is discharged home	Preferred format: an10 (CCYY-MM-DD)
Date of neonatal discharge	Date that the neonate is discharged home	Preferred format: an10 (CCYY-MM-DD)

NHS
Health Research Authority

Confidentiality Advisory Group
On behalf of the Secretary of State for Health

Hannah Knight
Royal College of Obstetricians and Gynaecologists
27 Sussex Place
Regent's Park
London
NW1 4RG

hknight@rcog.org.uk

Skipton House
80 London Road
London
SE1 6LH

Tel: 020 797 22557
Email: HRA.CAG@nhs.net

1 August 2013

Dear Ms Knight

Study title: **Maternity Information System Data Linkage Pilot**
CAG reference: **CAG 2-06(a)/2013**

Thank you for your *service evaluation / audit* application, submitted for approval under the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Secretary of State for Health on whether an application should be approved, and if so, any relevant conditions. This application was considered on 19 April 2013.

Secretary of State for Health approval decision

The Secretary of State for Health, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application is approved, subject to compliance with the standard and specific conditions of approval.

This letter should be read in conjunction with the outcome letters dated 3 May 2013 and 14 June 2013.

Context

Purpose of application

This application from the Royal College of Obstetricians and Gynaecologists (RCOG) detailed a pilot project to collect patient information from electronic maternity information systems (MIS) and Hospital Episode Statistics (HES) data in order to create a database to enable the development of robust and clinically meaningful performance indicators for maternity care. The database would be used to develop new indicators for evaluating maternity services, including maternal and neonatal outcome.

Confidential patient information requested

Support was requested to allow access to identifiable data from 15 maternity services over a 12 month period and link to HES inpatient and maternity data already held by the Royal College of Surgeons (RCS).

In order to link to HES data identifiable data would be submitted from MIS and provided to the HSCIC. A look up table with identifiable data and HESID would be sent to the applicant. The HESID would then be used to link MIS and HES datasets.

It was confirmed that the RCS would process the data on behalf of the RCOG.

CAG advice conclusion

CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission, **Confirmed 12 July 2013**

2. Please ensure that the Data Protection registration for RCOG is updated to include relevant purposes and data and notify the Confidentiality Advice Team once this is completed. **Confirmed.**

3. Please ensure that reasonable efforts are made to inform the cohort of the processing and ensure that these include details of how patients can opt out at a local level. **Confirmed 16 July 2013.**

As the above conditions have been accepted and/or met, this letter provides confirmation of final approval. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Annual review

Please note that this approval is subject to submission of an annual review report to show how you have met the conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report 4 weeks prior to the anniversary of your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements.

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Application form	1.6	27 March 2013
Query sheet	1.1	28 March 2013
Correspondence between applicant and Health and Social Care Information Centre		26 March 2013
Response letter		17 May 2013

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item are listed below.

There were *no* declarations of interest in relation to this item.

Yours sincerely

Claire Edgeworth
Deputy Confidentiality Advice Manager

Email: HRA.CAG@nhs.net

Enclosures: Standard conditions of approval

Copy to: Health and Social Care Information Centre - dais@hscic.gov.uk

NHS
Health Research Authority
Confidentiality Advisory Group

Standard conditions of approval

The approval provided by the Health Research Authority is subject to the following standard conditions.

The applicant will ensure that:

1. The specified patient identifiable information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant.

4. All staff with access to patient identifiable information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to patient identifiable information have received appropriate ongoing training to ensure they are aware of their responsibilities.

6. Activities are consistent with the Data Protection Act 1998.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. The Confidentiality Advice Team is notified of any significant changes (purpose, data flows, data items, security arrangements) prior to the change occurring.

10. An annual report is provided no later than 12 months from the date of your final confirmation letter.

11. Any breaches of confidentiality / security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken / to be taken.

Data Sharing Agreement

1.0 Organisations

This Data Sharing Agreement (Agreement) is drawn up between;

Royal College of Obstetricians and Gynaecologists (RCOG)
27 Sussex Place, London NW1 4RG.

In conjunction with

The Clinical Effectiveness Unit (CEU) at the Royal College of Surgeons of England (RCS)
35-43 Lincoln's Inn Fields, London WC2A 3PE

And;

[INSERT NAME] NHS Trust (hereafter referred to as the Participating Unit)

2.0. Purpose of Agreement

This agreement authorises the release of patient-level maternity data items (Appendix 1; hereafter referred to as the Data Extract) held on the Participating Unit's electronic Maternity Information System/s (MIS) to the RCOG'S Office for Research and Clinical Audit. The Data Extract will be part of a database that includes data from NHS trusts volunteering to participate in the RCOG's MIS Pilot Project. The combined Data Extracts will be hereafter referred to as the Database.

3.0 Roles and Responsibilities

The RCOG'S Office for Research and Clinical Audit (ORCA) is conducting the MIS Pilot Project for which the Data Extract is required.

All data for this project will be held on a secure server based at the CEU. The CEU is ORCA's 'sister unit' at Royal College of Surgeons of England. The ORCA staff responsible for this project hold contracts of employment with both the RCOG and the CEU. A resource sharing agreement is in place which permits the use of the CEU's secure Server and allocates an area of the Server for RCOG projects, to which only the Permitted Users (Appendix 2) have access. The Permitted Users will process the Data Extracts supplied by Participating Units to create the Database.

The Participating Unit will supply a Data Extract from their local MIS system/s covering the period 01/04/2012–31/03/2013, and arrange the secure transfer of the Data Extract to the CEU, as per clause 6.

4.0 Purpose for which the data is to be used

The Database is being established to enable the maternity data captured by NHS Trusts to be held securely in a central repository on the CEU's secure server for the purposes of indicator development and service evaluation. At the end of the Pilot, the Participating Unit will receive an individual report providing comparative information on various clinical practices and outcomes for benchmarking.

To provide a rich set of information to the Participating Units, the Project will link Data Extracts at individual patient level to Hospital Episode Statistics data. This process will use the Data Linkage Service at the Health and Social Care Information Centre (HSCIC). Patient identifiers contained within the Data Extract will be separated from patient health and treatment data, and only the patient identifiers will be sent to the HSCIC for linkage purposes. In producing the indicators, the analysts will use the cleaned Database (with patient identifiers removed) to ensure patient confidentiality.

The primary output from this project will be individual reports for participating NHS trusts. The Project may also produce research articles, conference papers and a Project report describing the methodological developments and overall findings of the project. The Participating Unit will not be identifiable in any public document without the prior agreement of the Participating Unit. Participating Units will be advised of all publications resulting from the Database prior to publication, and, if appropriate, invited to contribute. Anonymised results generated using the Database may also be included in the PhD thesis of one of the researchers.

The Confidentiality Advisory Group of the Health Research Authority has approved the processing of the Database under Section 251 of the NHS Act 2006 and Health Service (Control of Patient Information) Regulations 2002 that permit access to patient identifiable information without consent. CAG reference: CAG 2-06(a)/2013

5.0 Period of agreement

This agreement commences on **[INSERT DATE]** and terminates on **[INSERT DATE]** unless extended by the mutual agreement of both parties in writing, at which point an Amendment will be issued by the RCOG to replace this document**.**

6.0 Transfer of MIS data from the Participating Unit to the CEU

The Data Extract will be transferred securely in an encrypted format.

Before transfer the Participating Unit will encrypt the Data Extract using a product that provides '256-bit AES encryption' with a password length of 12 which MUST include numbers, letters and symbols, and should be a mix of UPPER and lower case characters.

The encrypted Data Extract will be transferred to the CEU Data Manager (Lynn Copley) at the CEU using a secure mechanism, such as Secure File Transfer Protocol (SFTP). The encrypted Data Extract may be sent electronically to lcopley@rcseng.ac.uk or on a disk via secure courier to:

Lynn Copley
CEU Data Manager
Clinical Effectiveness Unit
Royal College of Surgeons of England
35-43 Lincoln's Inn
London WC2A 3PE

The Participating Unit must send the password separately from the Data Extract and must not share the password with any person other than the CEU Data Manager at any time.

7.0 Specific Conditions

Use of this Database is for the sole purpose set out above.

No contact will be made with any individual(s) that could be identified from the information supplied. Any reports, papers or statistical tables that are published or released to other organisations will fully protect the identity of individuals in accordance with current Office for National Statistics Disclosure Control of Health Statistics guidance. http://www.ons.gov.uk/ons/guide-method/best-practice/disclosure-control-of-health-statistics/index.html

8.0 Data sharing

The Database will not be released to any other individual(s) or organisation(s). Information to third parties will only be provided in the form of non-disclosive aggregate statistical tables or conclusions.

Access to a mother's NHS number and date of birth is restricted to one nominated person the CEU Data Manager, who will receive and handle all processing of this data. The role of the CEU Data Manager is currently being filled by Lynn Copley.

The CEU Data Manager will undertake the process of separating the patient identifiers contained within the Data Extract from patient health and treatment data. Once the patient identifiers have been removed, access to the database will be restricted to the individuals named in Appendix 2 (Permitted Users). No individual other than those named in Appendix 2 can access the Data under this Agreement. In the case of staff changes, the CEU will inform the RCOG, and vice versa, of these changes prior to new staff members gaining access to the Data listed in this Agreement.

RCS Data Protection registration does not identify a requirement to release information under the Freedom of Information Act 2000. Data held by CEU under this agreement will therefore not be subject to releases under FOI.

9.0 User Obligations

The RCOG and CEU formally wish to acknowledge their explicit commitment to maintaining the confidentiality, safety, security and integrity of all confidential and sensitive data to which their respective organisations are privy to and which may be held under their guardianship.

Users of the Database are obliged to fully comply with The Data Protection Act 1998, together with all other related and relevant legislation and Department of Health directives covering issues of Data sharing and including:

- British (International) Standard ISO 27001;
- The Caldicott Report 1997;
- The Freedom of Information Act 2000;
- Section 251 of the Health and Social Care Act 2006;
- Confidentiality: NHS Code of Practice 2003;
- NHS Records Management Code of Practice (Part 1, 2006 & Part 2, 2009);
- The NHS Information Security Management Code of Practice 2007;
- The Computer Misuse Act 1990;
- The Electronic Communications Act 2000;
- The Regulation of Investigatory Powers Act 2000;
- The Copyright, Designs and Patents Act 1988;
- The Re-Use of Public Sector Information Regulations 2005;
- The Human Rights Act 1998
- NHS Care Record Guarantee

10.0 Storage of Data

In signing this agreement, the CEU will ensure that the Data Extract is stored on a secure, password protected system whereby access is restricted to only those who are named within this agreement. Access to the network is controlled and monitored. All users are issued with a unique username and password. The network folder containing the Database will have restricted access to authorised users only, as named in this agreement (Appendix 2). Encrypted back-ups of the CEU's secure server are undertaken on a regular basis and stored securely.

Further details are given in the RCS System Level Security Policy Document for the CEU's secure server (copy available on request).

11.0 Data Retention

The Database will be retained on the CEU's secure server for the duration of the project but no longer than the duration of this Agreement. Patient identifiable data will be destroyed once data cleaning and linkage with the Hospital Episode Statistics database has been successfully performed. An extension of the retention period beyond **[INSERT DATE]** is subject to a formal review by all signatories.

12.0 Data Destruction

In signing this Agreement, the CEU will ensure that all data is securely destroyed using file shredding software. Similarly, physical media will be destroyed using a high specification shredder with the functionality to irreversibly destroy the disc. All data will also be removed from any back-ups. Confirmation that this has occurred will be given in writing to the Participating Unit.

13.0 Breach of Conditions

Notification of breach The CEU and ORCA agree to immediately report to the Participating Unit incidents of breach of any of the terms of this Agreement.

Right to terminate access In the event of the breach of any of the terms of this Agreement the Participating Unit has the right to immediately terminate this Agreement and to request the return of the Data Extract.

14.0 Changes to Terms of Agreement

The Participating Unit has the right to withdraw consent for the use of their Data Extract at any time.

The RCOG and CEU have the right to request changes to this Agreement so that it remains consistent with current standards and legislation by writing to the Participating Unit. These changes will be considered by the Participating Unit and if appropriate an updated Agreement will be issued.

If the person signing for the CEU should leave their post or no longer holds the responsibility for this Agreement , then it is incumbent on that person to arrange a new signatory to this Agreement and to inform the RCOG and Participating Unit of this requirement immediately.

15.0 Agreement Signatures

For and on behalf of:

The Royal College of Surgeons of England

Signed 

Print Name: David Cromwell

Post/Title: Director (Clinical Effectiveness Unit)

Date: 15/04/2018**[INSERT DATE]**

Address:
Clinical Effectiveness Unit
The Royal College of Surgeons of England
35-43 Lincoln's Inn Fields
London WC2A 3PE

For and on behalf of:

Royal College of Obstetricians and Gynaecologists

Signed

Print Name: Matthew Gosden

Post/Title: Director (Knowledge, Information Management & Technology)

Date: 15/04/2018**[INSERT DATE]**
[INSERT DATE]
Address:
Royal College of Obstetricians and Gynaecologists
27 Sussex Place
London NW1 4RG

For an on behalf of:

[INSERT TRUST NAME]

Signed
Print Name:
Date:
Address:

Appendix 1. Data items

Data items	
Demographics	**Delivery**
Mother's NHS number	Actual delivery location
Mother's date of birth	Transfers in
Postcode	Smoking status at delivery
Mother's ethnicity	Number of infants this delivery
Mother's employment status	Onset of labour
Mother's occupation	Type of medical induction
Mother's country of birth	Labour augmentation
Mother's marital status	Time of onset of established labour
Father's ethnicity	Time of onset of second stage
Father's occupation	Analgesia in labour and delivery
Obstetric History (for all previous deliveries)	ECV before labour
Date of delivery	Lead maternity care professional
Mode of delivery	Senior person present at delivery
Gestation	Presentation at onset of labour/delivery
Birth weight	Method of delivery
Outcome (livebirth/stillbirth)	Perineal tears
Pre-eclampsia, eclampsia, HELLP	Maternal critical incidents
Placenta accreta	Date of birth
Prenatal/Antenatal Care	Time of birth
Assisted conception	Outcome
Date of LMP	Birth weight
Confirmed EDD	Gestational age
Gestation at booking	Sex of baby
Maternal weight at booking	Cord blood gases
Maternal height	Apgar score at 1 minute
BMI at booking	Apgar score at 5 minutes
Smoking status at booking	Apgar score at 10 minutes
Cigarettes per day	Baby's NHS number
Alcohol (units per week)	Neonatal procedures/diagnoses
Gravidity (number of previous pregnancies)	Date admitted to NICU/SCBU, if applicable
Parity (number of previous deliveries)	Antibiotic treatment for Group B Strep
Antenatal complications/diagnoses	**Discharge**
Pre-existing clinical conditions/co-morbidities	Maternal death
Group B Streptococcus screening	Neonatal death
Intended delivery location	Date of maternal discharge
	Date of neonatal discharge

Appendix 2. Permitted Users

Job title	Named individual
Data Manager, CEU	Lynn Copley
Director, CEU; Senior Methodologist, ORCA	David Cromwell
MIS Pilot Project Lead, ORCA	Hannah Knight
Senior Methodologist, ORCA	Ipek Gurol-Urganci
Administrative Assistant, ORCA	Elly Hibbert

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Below are the references cited in the narrative sections of this thesis. References cited within chapters that comprise a published paper can be found at the end of the paper itself.

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