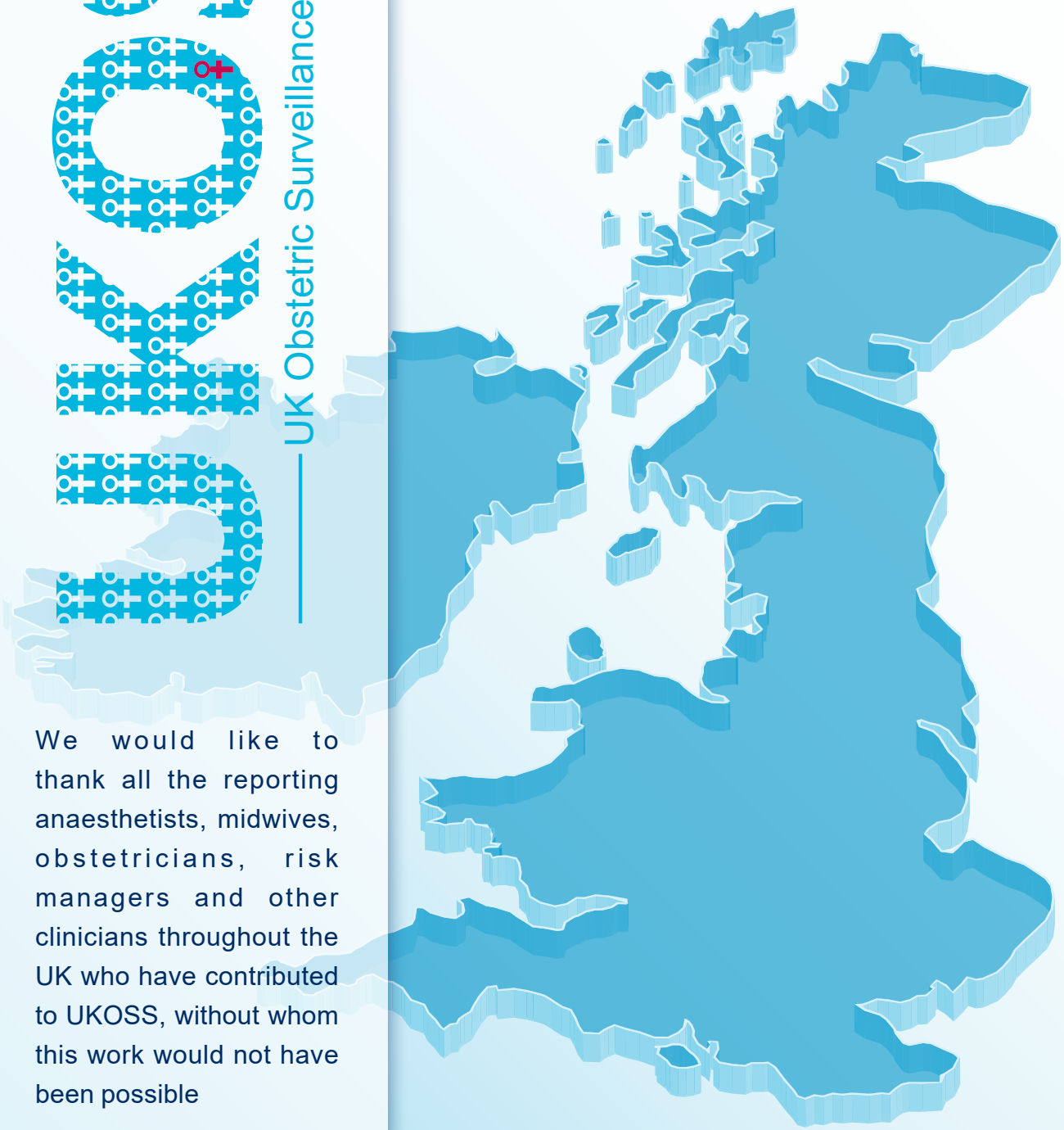
UKOSS

UK Obstetric Surveillance System

Thirteenth Annual Report 2019



We would like to thank all the reporting anaesthetists, midwives, obstetricians, risk managers and other clinicians throughout the UK who have contributed to UKOSS, without whom this work would not have been possible

Royal College of Obstetricians & Gynaecologists

NPEU

UNIVERSITY OF OXFORD

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1. Introduction

The UK Obstetric Surveillance System (UKOSS), a joint initiative between the National Perinatal Epidemiology Unit (NPEU) and the Royal College of Obstetricians and Gynaecologists, was launched in February 2005. This national system has been used to study a range of rare disorders of pregnancy through a system of ongoing data collection, made possible through multi-centre collaborations across the UK. UKOSS is also supported by the Royal College of Midwives, the Obstetric Anaesthetists Association, the NCT, the Faculty of Public Health and Public Health England.

In the UK, where maternal death is rare, UKOSS provides a platform to generate robust evidence about the risk factors for severe life-threatening complications related to pregnancy and childbirth. Clinicians from all hospitals with consultant-led maternity units in the UK report cases for conditions that are under surveillance, within a designated period, through this routine reporting system. This minimises the possibility of selection bias and inclusion of false positive cases. Furthermore, UKOSS enables collection of detailed information to answer specific clinical questions which cannot be otherwise answered by studies that use routinely collected data (1). Since its inception, UKOSS has successfully generated evidence to guide prevention and management of major obstetric complications, inform policy, service planning and address patient safety issues and emerging public health issues (1-7). This has encouraged Australia, New Zealand and several countries in Europe to establish similar systems (8). A project in Assam, India, became the first to adapt the methodology in an LMIC setting (9).

Studies using UKOSS may be undertaken by any investigator who identifies a suitable topic and secures funding (10). Suitable disorders to study are those which are uncommon (usually no more than one case per 2000 births annually in the UK); are an important cause of maternal or perinatal morbidity or mortality; and which have research questions that can be addressed using the UKOSS methodology (prospective descriptive, cohort or case-control studies). Examples of questions that have been addressed using UKOSS studies are provided in Box-1. This report outlines the studies undertaken during the fourteenth year of surveillance using UKOSS.

2. Methods

Case notification is now maintained through online report submission requested from all consultant-led obstetric units in the UK every month with an approach of ‘nil-reporting’. We anticipate that all women who experience a condition investigated through UKOSS will be admitted to a consultant-led unit even if their initial care is provided in a different maternity setting. Nominated clinicians (from anaesthetists, midwives and obstetricians to risk managers and data analysts) in each hospital with a consultant-led maternity unit in the UK report to UKOSS. Every month, the nominated individuals are sent a report request email containing a unique link to an online report submission page with a list of conditions currently under surveillance (Figure 1). They are asked to complete a box indicating the number of cases which have occurred in the previous month, or if none, to complete the box with ‘0’. As a guide, only conditions with an estimated incidence of less than one in 2000 births are surveyed, and thus the most common response is a nil return. Nil returns are, however, extremely important as they allow us to confirm the number of women in the denominator birth cohort for each study and to ensure that cases are not missed.

On receiving a case report the UKOSS central team dispatches a data collection form to collect more detailed information about each case. The data collection forms are developed individually for each condition and are designed to be short and easily completed from a woman’s case notes without requiring reference to any other sources of information. The data collection forms seek confirmation of the appropriate case definition and additional information about risk factors, management and outcomes according to the protocol relating to each condition. UKOSS does not collect any personally identifiable information, such as women’s names, addresses, dates of birth, hospital or NHS numbers. Reporting clinicians are asked to keep their own record of the names of women they have reported, in order that they can retrieve the woman’s case notes to complete the data collection form. The collection of information only, for the purpose of studying incidence and identifying means to improve patient care, which is not individually identifiable and does not lead to any change in management for the individual patient is acceptable without requiring individual patient consent (11, 12). The UKOSS methodology has Research Ethics Committee approval.

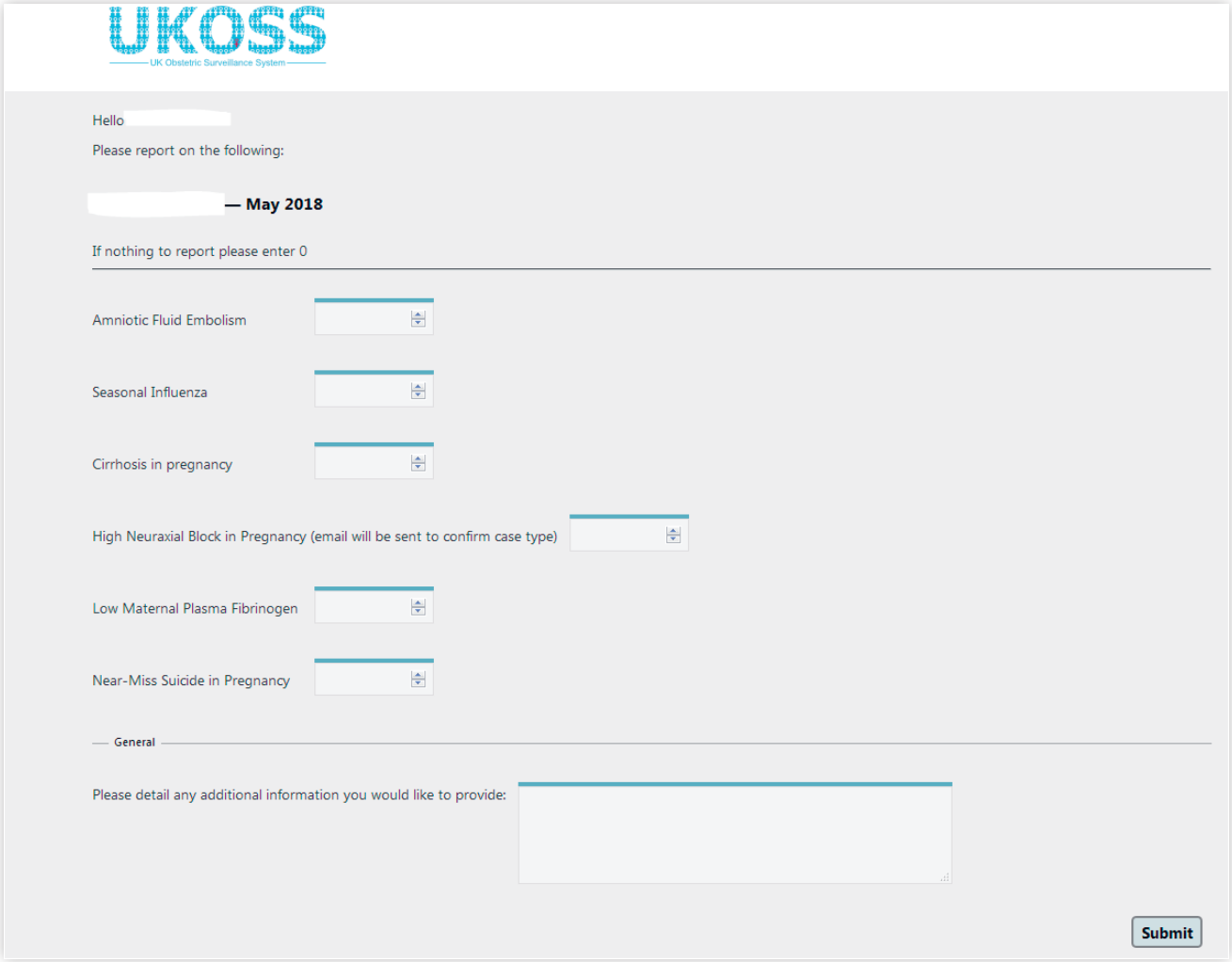
In order to perform case-control or cohort studies, information is also collected about control or comparison women for some studies. For these studies only, clinicians who report a case are asked to follow specific instructions to identify appropriate comparison women and complete a similar data collection form from their case notes. The process of selecting comparison women is individual to each study.

Box 1: Examples of questions which can be addressed using UKOSS studies

1. Estimating disease incidence
    - Analysis of the UKOSS severe sepsis study showed that the incidence of confirmed severe maternal Group B streptococcal sepsis was very low(13).
2. Describing the prevalence of factors associated with near-miss maternal morbidity
    - A UKOSS study estimated that in 2007-8 more than 1 in every 1200 women delivering in the UK was extremely obese (BMI 50kg/m^2 or greater) (14).
3. Quantifying risk factors for severe morbidity
    - UKOSS surveillance of uterine rupture showed a significant association with induction or augmentation of labour in women with a previous caesarean delivery (6).
    - UKOSS surveillance also showed that women with prior caesarean delivery and placenta praevia diagnosed antenatally had an increased odds of having placenta accreta/increta/percreta (15).
    - UKOSS surveillance of 2009/H1N1 influenza showed a significant association with poor pregnancy outcomes (16).
4. Investigating different management techniques
    - Use of total versus subtotal hysterectomy was examined in the UKOSS study of peripartum hysterectomy for severe haemorrhage but no significant differences in complication rates between the two techniques were found (1, 2).
5. Investigating disease progression
    - A comparison of the characteristics of women who died identified through the MBRRACE-UK Confidential Enquiry into Maternal Death with UKOSS data on control women showed that 66% of the increased risk of maternal death from direct and indirect causes at the population level could be attributed to medical comorbidities(17).
6. Auditing of national guidelines
    - UKOSS surveillance of antenatal pulmonary embolism (PE) showed that very few women who had a PE were not receiving thromboprophylaxis according to Royal College of Obstetricians and Gynaecologists guidelines (18, 19).
7. Responding to emerging public health issues
    - Surveillance of ZIKV associated adverse pregnancy outcomes was rapidly instituted in 2016 in response to the WHO declaration of a global public health emergency (20).
8. Informing public health policy
    - A UKOSS study showing poor perinatal outcomes in pregnant women with 2009/H1N1 influenza (16) was used as evidence to recommend universal immunisation of pregnant women against seasonal influenza (21).
9. Investigating a clinical decision rule
    - A UKOSS study of pulmonary embolism was used to investigate the development of a clinical decision rule about imaging amongst woman with suspected PE (22).

Figure 1: Sample UKOSS Electronic Report Submission Page

(This replaced the original postcard notification system in 2017)



3. Participation

All 196 units with consultant-led maternity units in the UK contribute to UKOSS. This represents 100% participation of eligible units and effectively means that the denominator for all UKOSS studies is the entire birth cohort in the UK. The mean monthly report rate during 2018 was 98% (Figure 2), the highest since UKOSS began in 2005 which can largely be attributed to the new online reporting system. Regional return rates vary between 93% and 100% (Figure 3). These continued high report return rates are a testament to the support and dedication of reporting clinicians throughout the UK.

Figure 2: UKOSS national monthly report return rates January-December 2018

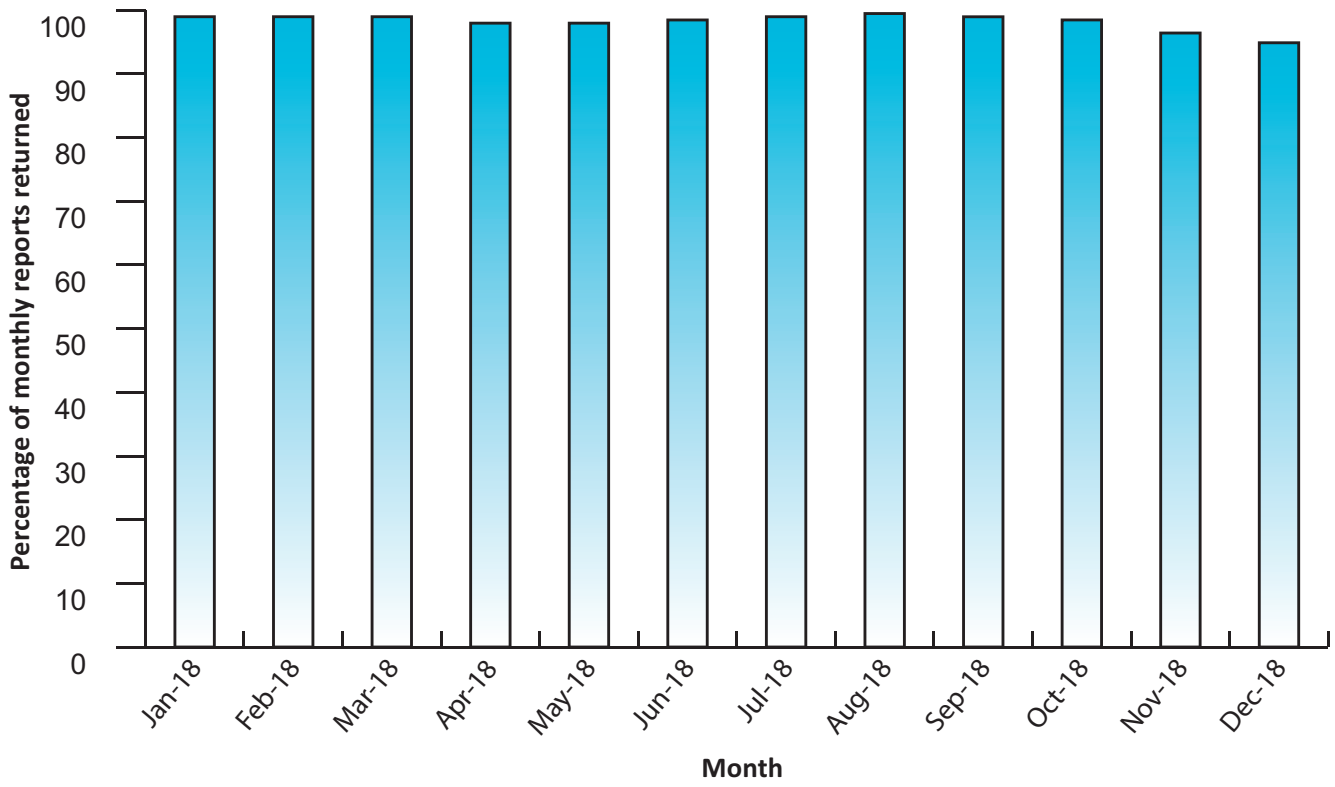
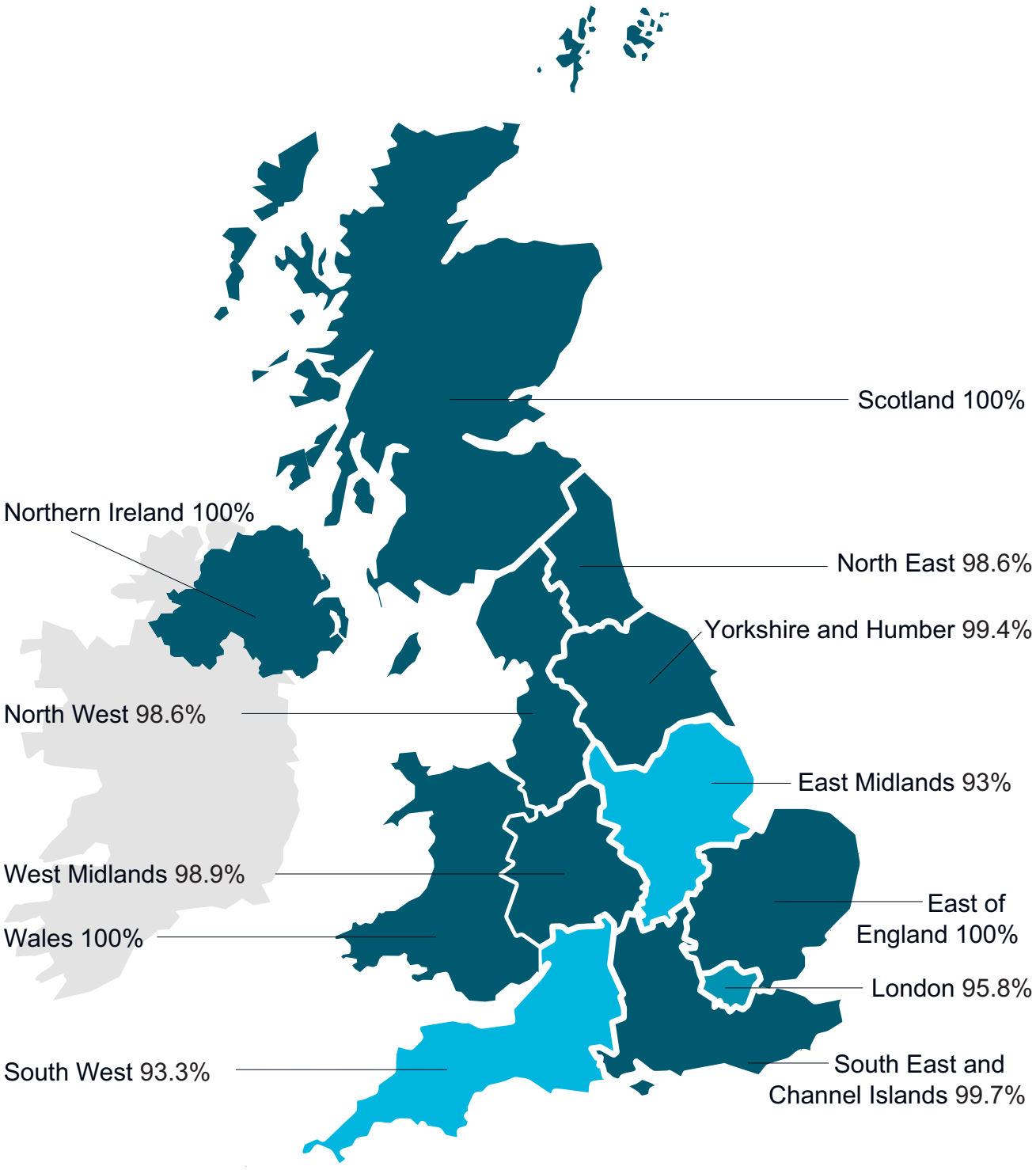


Figure 3: Map showing regional return rates during 2018

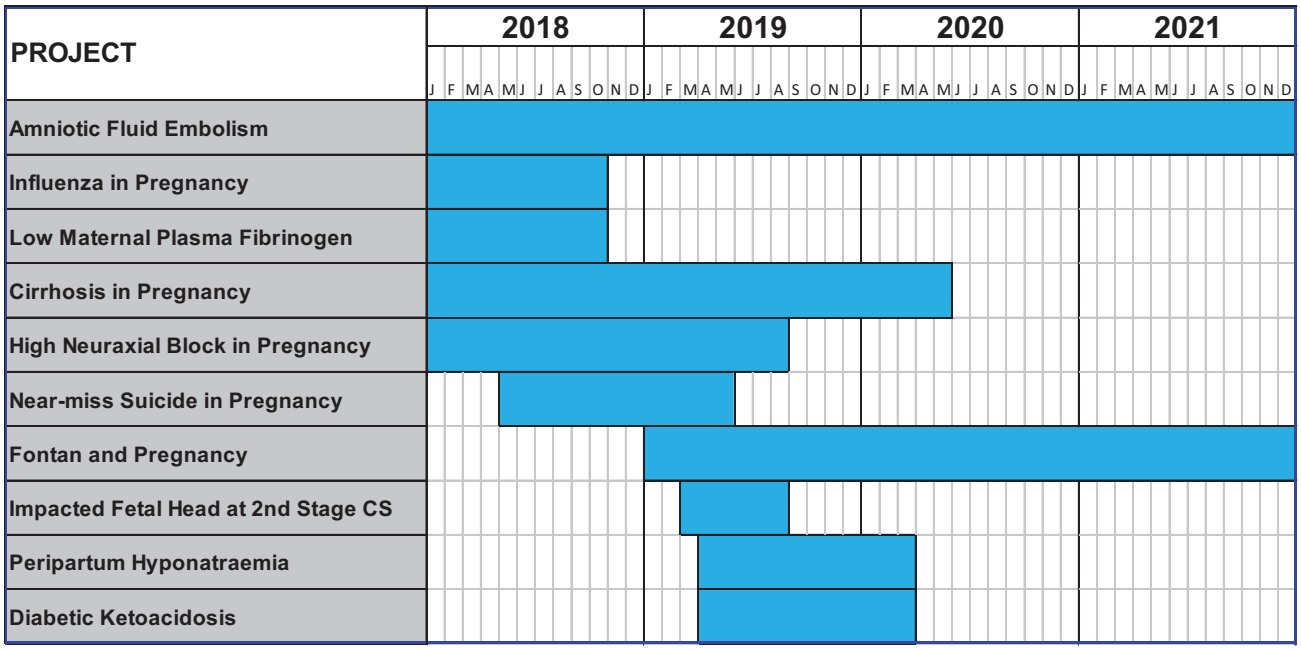


4. Studies

Unless otherwise specified, the results included in this report represent analysis of cases reported and data available up to April 2019. Please note the data presented are provisional (unless specified), not peer reviewed and definitive conclusions should not be drawn from them.

4.1 Study Timetable

Figure 4: Provisional UKOSS Study Data Collection Timetable 2018-2021



4.2 Studies completed in 2018

4.2.1 Low Maternal Plasma Fibrinogen

Key Points

- Obstetric haemorrhage remains an important cause of maternal mortality in the UK.
- Evidence suggests the incidence of obstetric haemorrhage in high-resource settings is increasing.
- It is unclear whether fibrinogen replacement at or below a level of 2g/L affects blood loss.
- Further observational evidence is required before potentially developing a randomised controlled trial of coagulation management.

Background

Obstetric haemorrhage is an important cause of maternal mortality in the UK. In the 2012-2014 Confidential Enquiry thirteen women died as a direct consequence of haemorrhage; a number that is unchanged from the previous report (23). With evidence suggesting that the incidence of obstetric haemorrhage is increasing in high-resource settings, a better understanding of the mechanisms of injury and, more importantly, the clinical sequelae in obstetric patients is needed (24-26).

Women with a plasma fibrinogen <2g/L and continuing bleeding represent a high-risk group that is associated with both progressive haemorrhage and the increased use of blood products and invasive procedures (24, 25). Two double-blind RCTs have investigated the role of fibrinogen replacement in PPH. Pre-specified subgroup analysis of the second RCT showed that, if the fibrinogen level was >2g/L during severe PPH, fibrinogen replacement did not affect blood loss or the need for transfusion but that an effect below 2g/L could not be excluded (27). This supports a RCOG recommendation that fibrinogen replacement is not necessary if plasma fibrinogen is above 2g/L (24). However, a possible effect of fibrinogen replacement at fibrinogen levels of below 2g/L cannot be excluded on the basis of the trial data (27, 28).

It is clear from the previous UKOSS study of massive transfusion (26) that the haematological parameters observed amongst groups of women with different causes for their obstetric haemorrhage are very variable, and hence differences in the underlying cases of haemorrhage in the trial participants may have had a substantial impact. The aim of this study is to obtain further observational evidence before potentially developing a randomised controlled trial of coagulation management.

Case Definition

Any woman with either a laboratory Clauss fibrinogen <2g/L OR Fibtem <10mm OR TEG functional fibrinogen <200mg/dL at any time during pregnancy or postpartum before first discharge, irrespective of cause.

Surveillance Period

November 2017 – October 2018

Interim Results

Up to April 2019, 161 cases of low maternal plasma fibrinogen were reported. So far information has been received for 140 (87%) cases. Of these, 13 were reported in error/did not meet the case criteria.

Interim Conclusions

Data collection is being finalised and analysis will commence shortly.

Investigators

Marian Knight, NPEU; Simon Stanworth, NHSBT; Rachel Collis, Cardiff and Vale UHB; Peter Collins, Cardiff and Vale UHB.

Funding

This study is being funded as part of the programme of the Policy Research Unit in Maternal Health and Care.

4.2.2 Seasonal Influenza in Pregnancy

Key points

- Women continue to die in the UK from influenza in pregnancy from subtypes of influenza other than A/H1N1.
- It is unclear whether there is also an ongoing burden of severe morbidity from seasonal influenza.
- The aim of this study is to identify women hospitalised with seasonal influenza in pregnancy, and a group of control women, in order to investigate risk factors, management and outcomes.

Background

Pregnancy is known to be a risk factor for severe influenza, as evidenced by the influenza A/H1N1 pandemic in 2009-10. However, women continue to die in the UK from influenza in pregnancy from subtypes of influenza other than A/H1N1, and while it is clear that these deaths are usually in unvaccinated women, it is unclear whether there is also an ongoing burden of severe morbidity from seasonal influenza. This project, therefore, aims to collect data nationally using the UK Obstetric Surveillance System, on all women hospitalised with seasonal influenza in pregnancy, and a group of control women, in order to investigate risk factors, management and outcomes.

Case Definition

Any pregnant woman hospitalised with confirmed or suspected influenza in pregnancy. Include women admitted with secondary pneumonia in whom preceding influenza infection is confirmed on testing.

Surveillance Period

November 2016 – October 2018

Interim Results

Up to April 2019, 574 cases of seasonal influenza have been reported. Data have been received for 495 (86%) cases. Of these 46 were reported in error/did not meet the case criteria, two were duplicates and four data collection forms could not be completed due to lost hospital notes. We began requesting two control forms with each case from November 2017 onwards and to date we have requested 888 controls and received data for 700 (79%).

Interim Conclusions

Data collection is still being finalised but it is clear that cases peaked over both winter periods.

Investigators

Marian Knight, Jenny Kurinczuk, Maria Quigley, NPEU; Peter Brocklehurst, University of Birmingham; Patrick O'Brien, UCL.

Funding

This study is part-funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme and by the Department of Health as part of the programme of work of the Policy Research Unit in Maternal Health and Care.

4.3 Ongoing studies

4.3.1 Amniotic Fluid Embolism

Key points

- Amniotic fluid embolism (AFE) is a leading cause of direct maternal mortality in the UK; however estimates of incidence and mortality vary widely.
- AFE is associated with older maternal age, multiple pregnancy, placenta praevia, induction of labour, instrumental vaginal and caesarean delivery in the UK population.
- There is no evidence of an increase in incidence over the nine years of UKOSS surveillance.
- Further investigation is needed to establish whether earlier treatments can reverse the cascade of deterioration leading to severe outcomes.
- This study forms part of a wider multi-country study using the International Network of Obstetric Surveillance Systems (INOSS).

Background

AFE remains one of the leading causes of direct maternal mortality in high-income countries. Estimates of incidence vary from 1.9 to 7.7 per 100,000 maternities. Estimates of the case fatality of this condition also vary widely from 11% to 43%. There is also little consistency in the factors reported to be associated with the occurrence of AFE and very limited data regarding factors associated with severe outcomes.

Case Definition

A clinical diagnosis of AFE (acute hypotension or cardiac arrest, acute hypoxia or coagulopathy in the absence of any other potential explanation for the symptoms and signs observed)

Or A pathological diagnosis (presence of fetal squames or hair in the lungs)

Surveillance Period

February 2005 – ongoing

Interim Results

Up to April 2019, 283 cases were reported. Information has been received for 270 of these (95%). Of these, 22 do not meet the case definition, 44 were subsequently reported by clinicians as not cases, 18 were found to be duplicates and the hospital notes for one were reported as lost.

Interim Conclusions

The UK data up until 31 January 2018 (n=161 cases) has been pooled with data on women with AFE collected by INOSS members in Australia, France, the Netherlands and Slovakia. Data on a sample of control women without AFE from the UK and Australia has also been pooled. In total, we have data on 218 women with AFE according to the UKOSS case definition and 4,938 control women without AFE. 30% of the women with AFE according the UKOSS case definition died or had permanent neurological injury. Various differences in management were apparent between the women with AFE who did and did not experience a severe outcome. We are currently finalising the write-up of this multi-country study.

Investigators

Kate Fitzpatrick, Marian Knight, NPEU; Derek Tuffnell, Bradford Teaching Hospitals NHS Foundation Trust.

Funding

Wellbeing of Women have funded this multi-country study.

WELLBEING OF WOMEN

4.3.2 Cirrhosis in Pregnancy

Key points

- Cirrhosis is defined as permanent scarring of the liver as a result of continuous long term damage.
- There are few reports of pregnancy in women with cirrhosis although some small studies have suggested that there is an increased incidence of adverse maternal and perinatal outcomes in women with cirrhosis.
- This study will establish the incidence of cirrhosis in pregnant women in the UK and describe the management and perinatal outcomes of pregnancies affected by cirrhosis.

Background

Cirrhosis is defined as permanent scarring of the liver as a result of continuous long term damage and it is estimated to affect 45/100,000 women of child-bearing age(29). There are few reports of pregnancy in women with cirrhosis, and therefore data regarding pregnancy outcomes and optimal management are sparse. Several studies have suggested that there are higher rates of both maternal and neonatal mortality in women with cirrhosis(29-34), and women with portal hypertension and oesophageal varices appear to be at higher risk; however none have been large enough to accurately quantify the risks. Other maternal complications include higher rates of anaemia, post-partum haemorrhage, pre-eclampsia, placental abruption and maternal death(32, 34). Fetal complications are reported to include miscarriage, pre-term delivery and intrauterine growth restriction(30-32, 34).

Management of cirrhosis largely relates to treatment of the underlying pathology. There is no consensus on the optimal treatment for variceal bleeding and there are concerns over the use of injection sclerotherapy and octreotide(29). Endoscopy and ligation banding appears to be safe but there are no randomised controlled trials. Furthermore, there are limited data regarding the best way to deliver women with cirrhosis. There are concerns over women labouring as the process involves repeated Valsalva manoeuvres which raises intra-abdominal pressure and therefore increases the risk of variceal rupture(29).

This study will also aim to establish the maternal outcomes associated with cirrhosis, and to determine the effect of pregnancy on disease progression.

Case Definition

All pregnant women with an established history of cirrhosis defined by either confirmation by liver biopsy OR on the basis of radiological findings (nodular liver with enlarged spleen) with either a history of complications of liver disease (ascites, variceal bleeding, encephalopathy, pervious bacterial peritonitis) or supportive laboratory findings (low platelets, low albumin, prolonged prothrombin time or INR).

Surveillance Period

June 2017 – May 2020

Interim Results and Conclusions

Up to April 2019, 50 cases of cirrhosis were reported with data received for 43 (86%) cases. Of these, two cases were duplicates and four were reported in error. This study has been extended for a further 12 months and will now end in May 2020.

Investigators

Catherine Williamson, Victoria Geenes, Michael Heneghan, Leonie Penna, King's College London; Marian Knight, NPEU.

Funding

The Lauren Page Trust.

4.3.3 Diabetic Ketoacidosis in Pregnancy

Key points

- Diabetic ketoacidosis (DKA) is a medical emergency that carries a risk of serious morbidities and mortality.
- The rate of diabetes is increasing in the reproductive population.
- The incidence of DKA in pregnancy in the UK is currently not known.
- The aim of this study is to describe management and perinatal outcomes of affected pregnancies to inform current clinical practice and future research.

Background

DKA in pregnancy is an infrequent complication of diabetes but one that nevertheless carries significant risks of morbidity and mortality for both mother and baby (35). Currently the estimated incidence of DKA in pregnancy is derived from figures in the general diabetic population, therefore the true rate of DKA in pregnancy is not known. The prevalence of diabetes (types 1 and 2) is increasing in the reproductive population, thus the complication is likely to become more common and hence improving the evidence-base for prevention and management is important. Clinicians caring for these women need to have accurate information with which to counsel them about the complication.

Case definition

Any pregnant woman with diabetes (types 1 & 2, MODY or GDM) who is admitted to hospital for the management of ketoacidosis (irrespective of the level of blood glucose).

Surveillance Period

April 2019 – March 2020

Interim results and conclusions

This study is at a very early stage and data collection has only recently commenced; it is thus not possible to draw any conclusions.

Investigators

David Churchill and A Viswanath, New Cross Hospital, Wolverhampton; Lucy Mackillop, Oxford University Hospitals; Marian Knight, NPEU; M Strachan, Western General Hospital.

Funding

This study is funded by the NIHR Research for Patient Benefit Programme.

4.3.4 Fontan and Pregnancy

Key points

- The Fontan repair is performed as a palliative procedure to improve survival in infants born with a functionally univentricular circulation.
- Pregnancy in women with a Fontan repair is rare and data regarding management of these women is sparse.
- The results of this study will help optimise the future management of pregnant women with a Fontan circulation to obtain the best outcomes for mother and baby.

Background

The Fontan repair describes a palliative surgical procedure that is undertaken for patients born with congenital heart defect that cannot support a biventricular circulation. Congenital heart disease is the most common congenital abnormality, affecting one in one hundred babies, and the number of adults who have undergone a Fontan repair is increasing (36). Historically women were advised against pregnancy because it was felt to be too high risk, but in the last 10 years we have more retrospective data to show that these women are able to carry a pregnancy, albeit with a relatively high rate of complications (36-38).

Women with a Fontan circulation are known to have a higher rate of miscarriage (some studies report rates of almost 70%(36)) and a higher rate of postpartum haemorrhage than any other congenital heart disease group (39) . There is no consensus on whether women with a Fontan circulation should routinely be offered anticoagulation during pregnancy (either at prophylactic or therapeutic dosing levels).

The aims of this study are to prospectively collect data on a cohort of women embarking upon pregnancy with a Fontan repair to describe current pregnancy management and outcome and to evaluate if pregnancy has a detrimental impact upon cardiac function in the short term.

Case Definition

All women with prior Fontan repair who have a pregnancy, regardless of outcome.

Surveillance Period

January 2019 – December 2021

Interim Results and Conclusions

Up to April 2019, 6 cases were reported, one of which was reported in error. We have received data for 3 (50%) of the cases.

Investigators

Matthew Cauldwell and Mark Johnson, Chelsea and Westminster; Michael Gatzoulis, Royal Brompton; Philip Steer, Imperial College.

Funding

This study is being funded by Borne.

4.3.5 High Neuraxial Block

Key points

- High (complete or total) spinal block is a known complication of epidural or spinal anaesthesia.
- Incidence estimates very widely.
- The recent UKOSS Cardiac Arrest in Pregnancy study identified anaesthetic causes, including high spinal, as the leading cause of maternal cardiac arrest in the UK.
- This study aims to identify the risk factors for the development of high spinal block associated with obstetric anaesthesia in the UK.

Background

High (complete or total) spinal block is a known complication of central neuraxial blockade (epidural or spinal anaesthesia). The terms high, total or complete are used interchangeably to describe a sensorimotor block above that which is required for the surgery and which is associated with significant cardiovascular /respiratory compromise, sometimes culminating in cardiorespiratory arrest.

The incidence of high spinal block associated with obstetric anaesthesia is not known. Estimates vary between 1:2,971(40) and 1:16,200(41) anaesthetics. More recently a retrospective study in the USA suggested an incidence of high spinal block of 1:4336 anaesthetics(42). However the majority of the studies that include high spinal as a complication of central neuraxial block, come from the era before the widespread use of low dose techniques in obstetric anaesthesia ('mobile epidurals'). Importantly, the recent UKOSS Cardiac Arrest in Pregnancy study identified anaesthetic causes, including high spinal, as the leading cause of maternal cardiac arrest in the UK(43). While the outcomes for cardiac arrest in this setting were good, it behooves obstetric anaesthesia to identify the potential risk factors and causes of high spinal block in obstetrics to reduce this complication. This study will provide the most accurate description of the incidence of high spinal block in obstetric patients to date, with implications for improved safety.

Case Definition

Any pregnant or postpartum woman who develops a high block in association with spinal and/or epidural anaesthesia /analgesia that requires ventilatory support* and /or cardiopulmonary resuscitation**.

*Ventilatory support includes the additional use of 'bag/mask' ventilation, or ventilation assisted by the use of a supraglottic airway device or endotracheal tube.

**Cardiopulmonary resuscitation includes the use of basic and advanced life support.

Surveillance Period

September 2017 – August 2019

Interim Results and Conclusions

Up to April 2019, 100 cases of high neuraxial block have been reported. So far information has been received for 84 (84%) cases. Of these, 10 were reported in error/did not meet the case criteria.

Investigators

Gary Stocks, Imperial College Hospitals; Nuala Lucas, Northwick Park Hospital; Marian Knight, NPEU.

Funding

This study is funded by a grant from the Obstetric Anaesthetists Association (OAA).

4.3.6 Hyponatraemia in Pregnancy

Key points

- Hyponatraemia occurs when the levels of sodium in the blood are abnormally low which can result in excessive levels of water in the body.
- Little is known about hyponatraemia in pregnant women. It is thought that drinking excessive amounts of water during labour may lead to hyponatraemia but to date, too few studies have been conducted to make any definitive conclusions.

Background

There is little known about hyponatramia in pregnancy with most knowledge limited to a growing number of case reports of women and neonates who have had a seizure or confusion around the time of labour and delivery. These women were otherwise well so excessive drinking and oxytocin infusion diluted in 5% dextrose have been implicated in these cases (44-46). Very few studies into hyponatraemia in pregnancy have been conducted so clinicians currently have a limited understanding of the disorder with regard to risk factors, outcomes and management. This study will enable co-ordinated investigation of cases nationally which will help to guide future clinical management and grounds for further research.

Case definition

Any woman with symptomatic hyponatraemia (Na <125mmol/l) in labour or in the immediate 48 hours following delivery (not caused by sepsis or pre-eclampsia) where other likely cases have been clinically excluded.

Symptoms may include any of the following – disorientation, agitation, seizures, coma and focal neurological deficits.

Surveillance Period

April 2019 – March 2020

Interim Results and Conclusions

This study is at a very early stage and data collection has only recently commenced; it is therefore not possible to draw any conclusions.

Investigators

Arani Pillai, Nottingham University Hospitals NHS Trust; Nuala Lucas, Northwick Park Hospital; Cathy Nelson-Piercy, Guy's and St. Thomas' Foundation Trust.

Funding

This study is funded by a grant from the Obstetric Anaesthetists Association (OAA).

4.3.7 Impacted Fetal Head at Caesarean Section

Key points

- Emergency caesarean sections (CS) performed in the second stage are increasing.
- Emergency CS carries a greater risk of complications for the mother and the baby than elective CS or a CS earlier in labour.
- Complications are usually related to manipulations required to deliver the baby.
- There is currently no national guidance on what techniques to employ for management of an impacted fetal head at CS.

Background

Caesarean section accounts for 26% of all deliveries in the UK(47) of which at least 5% are done at full dilatation (and it is believed that this is on the increase(48)). Emergency CS performed in the second stage of labour carries a greater risk of complications for the mother and baby than elective CS or a CS earlier in labour (49). In particular, it may be complicated by the fetal head being deeply impacted in the maternal pelvis (50). There may be moulding of the head in the pelvis making it technically more challenging for the surgeon to reach beneath the head leading to longer delivery times. Due to the nature of the second stage, the uterus is thinned and stretched by labour making uterine tears more likely. Complications are usually related to manipulations required to deliver the baby and risks of complications for both mother and baby are further increased if there has been a prior unsuccessful attempt at instrumental delivery (51). There is currently no national guidance on management of impacted fetal head at CS.

Case Definition

The MIDAS study of Impacted Fetal Head at Caesarean Section will be collecting the following:

Second Stage Caesarean Sections (numbers only)

Any woman with a singleton fetus in cephalic presentation who had an emergency caesarean section during the second stage of labour (ie. when the cervix was fully dilated).

Second Stage Caesarean Sections with prior attempt at operative vaginal delivery (numbers only)

Any woman with a singleton fetus in cephalic presentation who had an emergency caesarean section during the second stage of labour (ie. when the cevix was fully dilated) after a prior attempt at operative vaginal delivery.

Second Stage Caesarean Sections with Impacted Fetal Head (detailed data)

Any woman with a singleton fetus in cephalic presentation who had an emergency caesarean section during the second stage of labour (ie. when the cervix was fully dilated) in whom delivery required tocolysis or a technique to assist delivery of the fetal head (prophylactically or as a result of difficulty with delivery) or where the operating surgeon deemed there to be ‘difficulty’ in delivering the fetal head.

Surveillance Period

March 2019 – August 2019 (6 months only)

Interim Results and Conclusions

Up to April 2019, 124 cases of impacted fetal head were reported. We have received data for 49 (40%) cases and three cases were reported in error. 497 cases of second stage caesarean sections and 192 of caesarean sections with prior attempt at operative vaginal delivery have been reported.

Investigators

Lead Investigator Dr Kate Walker, Queen’s Medical Centre, Nottingham with co-investigators Nia Wyn Jones, Susan Ayers, Rueben Ogollah, Elenor Mitchell, Nicola Tempest, Rachel Plachinski, Jon Dorling, Phoebe Pallotti, Lucy Bradshaw and James Thornton.

Funding

This study is being funded by the NIHR HTA programme as part of a wider project entitled MIDAS (Management of an impacted fetal head during emergency caesarean section).

FUNDED BY NIHR | National Institute for Health Research

4.3.8 Near Miss Suicide in Pregnancy

Key points

- Mental illness is a leading cause of maternal mortality in the UK.
- The largest proportion of late, direct maternal deaths result from suicide.
- Antenatal suicide attempts occur less frequently than postnatal attempts although they clearly increase risk of harm to the fetus.
- There are currently no studies that have explored near miss suicides during pregnancy despite it becoming increasingly recognised that studying near miss events can provide important additional information to guide prevention strategies of rare events.

Background

Mental illness is estimated to affect one in ten pregnant or postpartum women and, in the UK, has persistently been found to be a leading cause of maternal mortality (52, 53). Although maternal deaths are rare (8.8 per 100,000 maternities)(52), recent confidential enquiries into maternal mortality found that almost one in five women who died during birth had a mental illness and almost a quarter of those who died in the postnatal period died from mental health related causes (54). Among this group of women the largest proportion of deaths resulted from suicide; in the UK and Ireland there was a rate of 2.3 deaths by suicide during or up to one year after the end of pregnancy per 100,000 maternities between 2009-13.

It is becoming increasingly recognised that studying near miss events (or life-threatening situations) can provide important additional information to guide prevention strategies of rare events(55), however no previous studies have explored near miss suicides during pregnancy. Three quarters of maternal suicides occur during the postnatal period, making suicides during the antenatal period a rare event. There is also evidence to suggest that suicide attempts may occur less frequently during pregnancy than following birth, although robust incident figures are not currently available.

Antenatal suicide attempts also increase the risk of potential harm to fetal development, particularly in the case of drug overdoses during pregnancy which can have teratogenic or fetotoxic effects (56). However, no national data on near miss suicides during pregnancy exists, and very little is known about the epidemiology, neonatal outcomes, warning signs or clinical management proceeding and following a near miss suicide event during pregnancy within the UK. Finding ways to recognise and respond appropriately to women at particular risk signifies a key public health goal. Current insufficient research in this area is likely to limit efforts to effectively identify women at high risk of suicide and prevent further tragedies in the future.

Case Definition

Any woman with self-inflicted injury or poisoning, during pregnancy, requiring an admission to a general hospital for:

Either	Level 2 critical care (ie. patients requiring more detailed observation or intervention including support for a single failing organ system or post-operative care and those ‘stepping down’ from higher levels of care)
Or	Level 3 critical care (ie. patients requiring advanced respiratory support alone or monitoring and support for two or more organ systems. This level includes all complex patients requiring support for multi-organ failure)
Or	A liver unit

Surveillance Period

May 2018 - May 2019

Interim Results and Conclusions

Up to April 2019, 23 cases were reported. Detailed information has been received for 5 (22%) and 12 cases were reported in error. Data collection is being finalised and analysis will commence shortly.

Investigators

Abigail Easter and Louise M Howard, Institute of Psychiatry, Psychology and Neuroscience London; Jane Sandall, Department of Women and Children's Health, King's College London.

Funding

This study is funded as part of a King's Improvement Science Fellowship (funded by King's Health Partners).

4.4 Future Studies

4.4.1 Antithrombin / Protein C deficiency in Pregnancy

Key points

- Thrombosis and thromboembolism continue to be the leading direct cause of maternal death in pregnancy in the UK.
- Among the most important risk factors for venous thromboembolism in pregnancy is the presence of thrombophilia such as antithrombin deficiency.
- Work to reduce risk of VTE in this group of women could contribute to reducing maternal mortality.

Background

Thrombosis and thromboembolism remain one of the biggest causes of maternal death during pregnancy in the UK(54) and therefore preventing thrombosis continues to be an important intervention in pregnancy. Inherited thrombophilias, including antithrombin and protein C deficiency, are important risk factors for venous thromboembolism (VTE). Pregnant women are already at increased risk of VTE due to their hypercoagulable state so those with antithrombin deficiency are therefore at very high risk of VTE. There is a lack of straightforward guidance or a strong evidence base for management of antithrombin deficiency in pregnancy and it is currently unknown how this cohort of women is managed in the UK. It is believed that protein C deficiency may increase the risk of pregnancy loss but the incidence of miscarriage and stillbirth in women with severe protein C deficiency is unknown. This study will estimate the current prevalence of antithrombin III and heterozygous protein C deficiency among pregnant women in the UK and describe treatment methods and outcomes with a view to developing guidance to identify women at risk, improve management and reduce VTE risk in this group.

Case Definition

Antithrombin Deficiency:

Any pregnant woman with known antithrombin deficiency and found to have an antithrombin level below the lower limit of normal for their local reference laboratory.

Protein C Deficiency:

Any pregnant woman with known protein C deficiency and found to have a protein C level below the lower limit of normal for their local reference laboratory.

Main Research Questions

- What is the prevalence of antithrombin/protein C deficiency in pregnancy in the UK?
- How are pregnant women with antithrombin/protein C deficiency managed in the UK?
- What factors influence clinician's choice of treatment and when to treat?
- What is the incidence of maternal morbidity and mortality in this cohort?
- What is the incidence of neonatal morbidity and mortality in this cohort?

Investigators

Rachel Farnell, Sue Pavord and Ingrid Granne, Oxford University Hospitals NHS Trust.

Funding

NIHR | Oxford Biomedical Research Centre

This study is being funded by Oxford Centre for Haematology and Biomedical Research Centre Haematology Theme.

4.4.2 Extremely preterm prelabour rupture of membranes

Key points

- Extremely preterm labour rupture of membranes (EPPROM) is a rare complication of pregnancy; it is frequently quoted to have an incidence of less than 1% (57, 58) but the exact incidence is unclear.
- It is currently unknown how women who experience EPPROM are counselled and managed across the UK.
- National guidance for EPPROM is vague and stymied by the lack of good quality scientific evidence.

Background

EPPROM is a rare complication of pregnancy that carries significant maternal morbidity, neonatal morbidity and neonatal mortality. The true incidence of women requiring ongoing conservative management for 'prolonged EPPROM' is difficult to establish from current literature due to different inclusion criteria and gestational age windows. It is unclear how this unique group of women is counselled and managed as there is currently a paucity of good quality data available and guidance for clinicians. 'Little Heartbeats', a national PPROM charity, has expressed concern that expectant mothers in the UK are presented with huge variation in information on prognosis and advice on termination. When conservative management is chosen, a variation exists in location of management, use of monitoring, antibiotics and steroids. There is urgent need to develop an understanding of the characteristics of babies that survive EPPROM and accurate complication rates.

Case definition

Any pregnant woman who has experienced rupture of membranes in pregnancy between 16+0 to 22+6 weeks gestation:

EXCLUDES:

- Cases in which membranes ruptured before 16+0 but were only diagnosed in the 16+0 – 22+6 period.

Main Research Questions

- What is the current incidence of EPPROM in pregnancy in the UK?
- How is EPPROM managed in pregnancy in the UK?
- What are the outcomes for mother and infant based on gestational age of membrane rupture?

Investigators

Angharad Care, Zarko Alfirevic and Laura Goodfellow, Liverpool Women's Hospital.

Funding

This study has been funded by Wellbeing of Women.

4.4.3 New Therapies for Influenza

Background

Pregnant women are recognised as a group at increased risk of influenza related morbidity and mortality. Due to limited treatment options, antiviral drug resistance remains a public health concern, and alternative treatments are needed in case of widespread resistance. This observational study aims to evaluate the safety of new approved therapies in pregnant women with complicated influenza. It will form part of a wider multi-national study.

Case Definition

Any pregnant woman in the UK hospitalised with complicated influenza who receive at least one dose of specific new therapies at any time during pregnancy.*

*Data collection for this study will be minimal with case notification to be the only contribution required by UKOSS reporters.

Main Research Questions

- What is the incidence of the use of new therapies in pregnancy?
- What is the incidence of maternal morbidity and mortality in this cohort?
- What is the incidence of neonatal morbidity and mortality in this cohort?

Investigators

Naisab Qizilbash and Steve Albrecht, Oxon Epidemiology; Marian Knight, NPEU.

Funding

This study is being funded by external funding sources.

5. Publications

5.1 The UK's pandemic influenza research portfolio: a model for future research on emerging infections

Published Article

Simpson RC, Beever D, Challen K, De Angelis D, Fragaszy E, Goodacre S, Hayward A, Lim WS, Rubin GJ, Semple MG, Knight M, on behalf of the NIHR hibernated influenza studies collaborative group. The UK's pandemic influenza research portfolio: a model for future research on emerging infections. Lancet Infect Dis. Published online April 18, 2019 http://dx.doi.org/10.1016/S1473-3099(18)30786-2

Key points

- The 2009 influenza A H1N1 pandemic was responsible for considerable global morbidity and mortality and pregnant women were disproportionately affected.
- In 2009, several research studies in the UK were rapidly funded and activated for clinical and public health actions, including a UKOSS study which subsequently informed actions for both prevention and treatment of influenza in pregnancy.
- However, some studies were too late for their results to have an early and substantial effect on clinical care, because of the time required to call for research proposals, assess, fund, and set up the projects.
- A portfolio of projects was therefore funded by the National Institute for Health Research in 2012, including a further UKOSS study, and then 'hibernated' ready for activation in the event of a further pandemic.
- All studies are now on standby awaiting activation in the event of a pandemic being declared.
- This portfolio of hibernated influenza studies could provide a model for planning research in public health emergencies, including emerging infections, going forward.

5.2 Binational cohort study comparing the management and outcomes of pregnant women with a BMI >50-59.9 kg/m^2 and those with a BMI >60 kg/m^2

Published Articles

McCall SJ, Li Z, Kurinczuk JJ, et al. Binational cohort study comparing the management and outcomes of pregnant women with a BMI >50-59.9 kg/m^2 and those with a BMI >60 kg/m^2. BMJ Open 2018;8:e021055.

Key points

- Several studies have investigated the prevalence, outcomes and managements of extreme obesity in pregnancy (BMI ≥50 kg/m^2). While it may be the case that the risks rise exponentially with BMI, it is possible that above a certain BMI, the risks of maternal and perinatal complications as a result of obesity do not increase due to the competing risks of other comorbidities.
- The aim of this study was to combine information from a UKOSS study of pregnant women with a BMI ≥50 kg/m^2 with information from a similar cohort of women identified through the Australasian maternity Outcomes Surveillance System (AMOSS) and compare the management, maternal and perinatal outcomes of women with a body mass index (BMI) ≥60 kg/m^2 with women with a BMI >50-59.9 kg/m^2.

- The sociodemographic characteristics and previous medical histories were similar between the 111 women with a BMI ≥60 kg/m^2 and the 821 women with a BMI >50-59.9 kg/m^2.
- Women with a BMI ≥60 kg/m^2 had higher odds of thromboprophylaxis usage in both the antenatal (24% vs. 12%; OR 2.25, 95% CI 1.39 to 3.64) and postpartum periods (78% vs. 66%; OR 1.68, 95% CI 1.04 to 2.70).
- Women with BMI ≥60 kg/m^2 had nearly double the odds of pre-eclampsia/eclampsia (adjusted OR 1.83 (95% CI 1.01 to 3.30)).
- No other maternal or perinatal outcomes were statistically significantly different. Perinatal mortality was 18 per 1000 births for those with BMI ≥60 kg/m^2; 12 per 1000 births for those with BMI >50-59.9 kg/m^2 (unadjusted OR 1.46, 95% CI 0.31 to 6.74).
- Women are managed differently on the basis of BMI even at this extreme as shown by differences in thromboprophylaxis usage. Pre-eclampsia risk is increased with higher BMI in these morbidly obese women and further research should investigate whether any weight reduction could reduce poor outcomes even if women remain extremely obese.

5.3 Maternal and perinatal outcomes in pregnant women with BMI >50: International collaborative study

Published Article

McCall SJ, Li Z, Kurinczuk JJ, Sullivan E, Knight M. Maternal and perinatal outcomes in pregnant women with BMI >50: An international collaborative study. PLoS One. 2019 Feb 4;14(2):e0211278. doi: 10.1371/journal.pone.0211278.eCollection 2019. PubMed PMID: 30716114; PubMed Central PMCID: PMC6361432.

Key points

- National studies examining pregnant women with BMI>50gm/m^2 have been limited in their ability to examine severe but rare maternal and perinatal outcomes.
- The aim of this study was to combine information from a UKOSS study of pregnant women with BMI>50kg/m^2 with data from a similar cohort identified through the Australasian Maternity Outcomes surveillance System (AMOSS) to examine the association between maternal BMI.50kg/m^2 during pregnancy and maternal and perinatal outcomes.
- 932 pregnant women with BMI>50kg/m^2 (617 UKOSS, 315 AMOSS) were compared with 1232 pregnant women with BMI<50 kg/m^2.
- Women with a BMI>50 kg/m^2 during pregnancy had significantly raised odds of preeclampsia/eclampsia (aOR: 4.88, 95%CI: 3.11-7.65), caesarean birth (aOR: 2.77, 95%CI: 2.31-3.32), induction of labour (aOR: 2.45, 95% CI: 2.00-2.99) or post caesarean wound infection (aOR:7.25, 95%CI: 3.28-16.07), compared to women with a BMI<50 kg/m^2.
- Infants born to women with a BMI>50 kg/m2 had raised odds of macrosomia (aOR: 8.05, 95%CI: 4.70-13.78) and of an Apgar score <7 at 5 minutes (aOR: 2.03, 95% CI: 1.13–3.6)) compared to women with BMI<50 kg/m^2, after adjusting for gestational age at delivery.
- Twelve of the infants born to women in the extremely obese cohort died in the early neonatal period or were stillborn.
- This study has shown that the combination of two national cohorts identified using the sam methodology increased the statistical power and precision to estimate the incidence of maternal and perinatal outcomes in extremely obese women.
- Extreme maternal obesity in both countries was associated with increased odds of potentially preventable outcome such as thrombotic events and wound infection, highlighting the need for a proactive approach to management.

5.4 Updates on completed studies

Manuscripts for **Amniotic Fluid Embolism, Severe Epilepsy in Pregnancy, Gastric Bypass in Pregnancy and Vasa Praevia** are completed and we anticipate they will be published within the next twelve months. Please keep an eye out for these papers, results of which will be listed on the ukoss website and in the quarterly newsletters.

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