UNIVERSITY OF SOUTHAMPTON

FACULTY OF MEDICINE

Urogynaecology

An Evaluation Of The Risk Factors Associated With Sustaining Perineal Trauma At Childbirth, Subsequent Birthing Outcomes And The Effects On Pelvic Floor Dysfunction.

by

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Thesis for the degree of Doctorate of Medicine

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ABSTRACT

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More than 85% of women sustain some form of perineal trauma during vaginal childbirth in the United Kingdom (UK), which equates to approximately 350,000 injuries a year. Obstetric anal sphincter injuries (OASIs), the most severe form of perineal laceration, are sustained in 2.9% of vaginal births and are a recognised major risk factor for long-term anal incontinence and faecal urgency. Careful consideration needs to be made regarding subsequent delivery after an OASI due to the risk of recurrence and the resultant potential for deterioration in symptoms of pelvic floor dysfunction.

The purpose of this research was to evaluate the risk factors associated with OASIs; to explore the birthing outcomes at subsequent delivery after sustaining an OASI and to delineate what influenced the risk of a recurrent injury. This was achieved through retrospective analysis of prospectively collected data in both single- and multi-centre settings. The symptomatic and personal effects of sustaining an injury on symptoms of pelvic floor dysfunction were evaluated through quantitative analysis of data and free text comments provided by means of a postal questionnaire.

This thesis demonstrated that OASIs were more likely with increased maternal age, in those of Asian ethnicity, after a prolonged pushing stage of labour, if the delivery was post-term and if the infant weighed more than four kilograms. Those delivering vaginally after a previous Caesarean section (CS) were at greater risk of an OASI than the primiparous population; even more so if the CS was an emergency. The risk of recurrent OASI (rOASI) was also greater than the primiparous risk, further predisposing women to symptoms of anal sphincter dysfunction. Increased maternal age, high offspring birth weight, and more severe grade of OASI were positive predictors for rOASI. Mediolateral episiotomy was protective against rOASI. Additionally, this thesis also showed the most important indicator for long-term symptoms of PFD following an OASI, regardless of subsequent deliveries and the mode of the subsequent deliveries, was the initial OASI.

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Research Thesis: Declaration of Authorship

I, DR JOANNA CAROLINE D'SOUZA, declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

AN EVALUATION OF THE RISK FACTORS ASSOCIATED WITH SUSTAINING PERINEAL TRAUMA AT CHILDBIRTH, SUBSEQUENT BIRTHING OUTCOMES AND THE EFFECTS ON PELVIC FLOOR DYSFUNCTION

I confirm that:

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3. Where I have consulted the published work of others, this is always clearly attributed;
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Signed:

Dr J. C. D'Souza

Date: Monday, 30th November 2020

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"Trust in the LORD with all your heart and lean not on your own understanding; in all your ways submit to Him and He will make your paths straight." Proverbs 3.5-6

"I can do all this through Him who gives me strength" Philippians 4.13

Definitions and Abbreviations

AI .....Anal Incontinence
ARM ……Ano-rectal Manometry
aOR.....Adjusted Odds Ratio
BBUSQ-22…… Birmingham Bowel and Urinary Symptoms Questionnaire
BLR .....Binary Logistic Regression
BMI.....Body Mass Index
CCIS .....Cleveland Clinic Incontinence Score
CG.....Clinical Guideline
CI .....Confidence interval
CS .....Caesarean Section
EAS .....External Anal Sphincter
EAUS.....Endoanal Ultrasound
ElLSCS .....Elective Lower Segment Caesarean Section
FIQLI .....Faecal Incontinence Quality of Life Instrument
IAS .....Internal Anal Sphincter
ICIQ-UI .....International Consultant on Incontinence Questionnaire – Urinary Incontinence
ICS .....International Continence Society
IUGA .....International Urogynaecological Association
MHQ…… Manchester Health Questionnaire
MLE .....Mediolateral Episiotomy
MoD .....Mode of Delivery
MPP.....Manual Perineal Protection
NHS.....National Health Service
NICE.....National Institute for Health and Care Excellence
NNT .....Number Needed to Treat
NRES .....National Research Ethics Service
NVD .....Normal Vaginal Delivery
OASI.....Obstetric Anal Sphincter Injury
OASIs .....Obstetric Anal Sphincter Injuries
OP.....Occipito-posterior
OR.....Odds Ratio
OVD .....Operative Vaginal Delivery
PFD .....Pelvic Floor Dysfunction
PFM .....Pelvic Floor Muscles
PIS.....Patient Information Sheet
PISQ-12 .....Pelvic Organ Prolapse/ Urinary Incontinence
PL …… Perineal Length
POP.....Pelvic Organ Prolapse
QoL.....Quality of Life
RCOG .....Royal College of Obstetricians and Gynaecologists
RCT/RCTs.....Random Control Trial(s)
rOASI .....Recurrent OASI
RR .....Relative Risk
SES.....Socio-economic Status
UHS NHS FT .....University Hospitals Southampton NHS Foundation Trust
UI.....Urinary Incontinence
VBAC.....Vaginal Birth After Caesarean
VD.....Vaginal Delivery

Chapter 1 Background

1.1 Anatomy of the Perineum and Anal Sphincter Muscles

1.1.1 The Perineum

The perineum constitutes the soft tissues which form the pelvic outlet. Divided by an imaginary line between the ischial tuberosities, the female perineum comprises two triangular regions and is superficial to the musculotendineous sheet of the pelvic diaphragm (pelvic floor). The anterior urogenital triangle comprises the superficial transverse perineal, bulbospongiosus and ischiocavernosus muscles, and is penetrated by the external urogenital organs – the urethra and vagina. The posterior anal triangle contains the terminal portion of the anal canal and the anal sphincter complex. Between these distinctive triangular areas is the fibromuscular mass of the perineal body, which at a superficial level contains the entwined fibres of the superficial transverse perineal, bulbospongiosus and external anal sphincter muscles, and at a deeper level, fibres of the levator ani muscle. The levator ani, a broad muscular sheet supporting the pelvic contents, is subdivided into three parts according to their attachments to the internal surface of pelvic sidewall – the iliococcygeus, pubococcygeus and ischiococcygeus. See Figure 1.

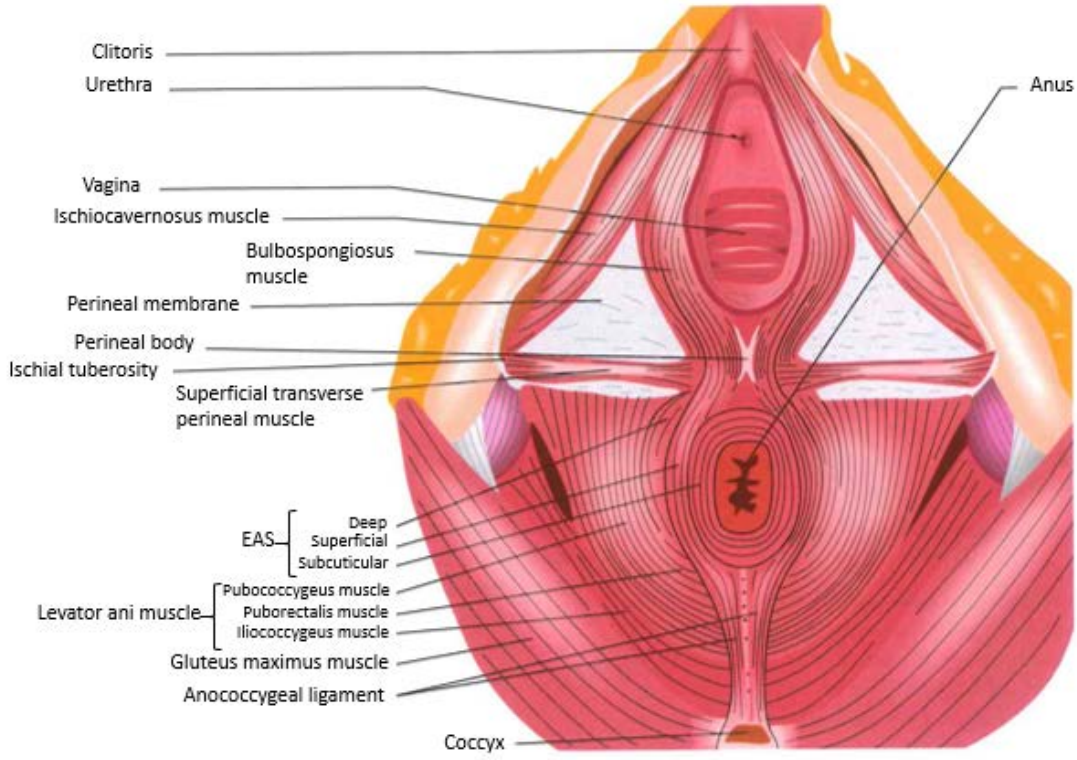

Figure 1: The Female Perineum

1.1.2 The Anal Sphincter Complex

The external and internal anal sphincters form a single unit but are distinct in the function and structure. They form the muscular support of the anal canal; the terminal two to four centimetres of the alimentary canal. See Figure 2.

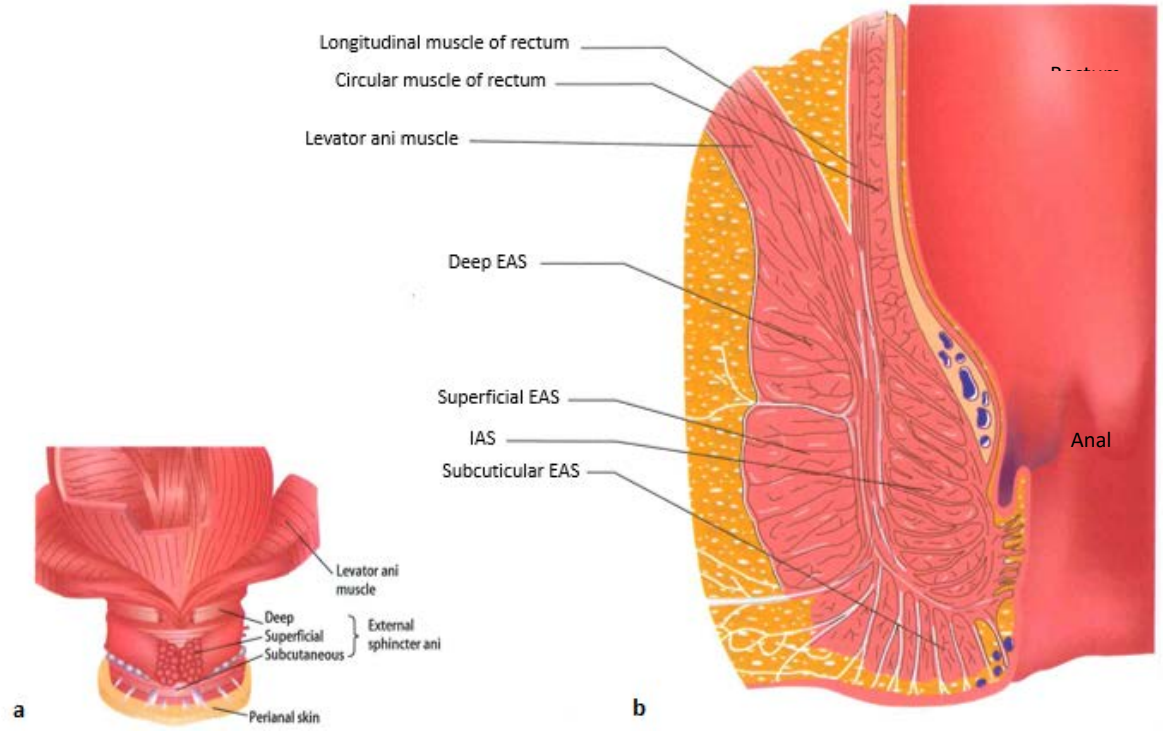

Figure 2: The Anal Sphincter Complex

a – Anal sphincter complex in relation to the levator ani. **b** – Coronal section of the anorectum.

IAS = internal anal sphincter, EAS = external anal sphincter. (Permission for reproduction granted by authors and publishers.(1)).

Internal anal sphincter

Deep to the inner epithelial and vascular subepithelium of the anal canal lies the internal anal sphincter (IAS), which is a thickened continuation of the circular smooth muscle of the rectum. It is approximately 3cm long and 3mm thick, terminating at the junction of the superficial and subcuticular external anal sphincter (EAS), approximately 6-8mm above the anal margin.(2) In contrast to the darker EAS, the IAS is light in colour. Its innervation is the same as the rectum; sympathetic from L5 and parasympathetic from S2-4. The IAS has an intrinsic, 20 – 40 cycles per minute, sinusoidal “slow wave” activity which is responsible for the anal resting tone, and contributes to 85% of the resting pressure (50 – 120mmHg in health).(3, 4) Disruption or weakness of the IAS muscle can lead to incontinence of flatus or passive leakage of faecal contents.

External anal sphincter

The external anal sphincter (EAS) is a longitudinal muscle, comprised of fibres from the puborectalis muscle (which forms a sling at the anorectal junction) and levator ani. The EAS extends to encircle the internal anal sphincter. It is subdivided into three, not always distinguishable, levels: a deep (proximal) thicker portion continuous with the puborectalis muscle, superficial (middle) portion which is attached to the perineal body anteriorly and anococcygeal ligament posteriorly, and the subcuticular (distal) which extends below where the internal anal sphincter terminates and forms a 15mm flat plate.(5) The EAS is innervated by the inferior rectal branch of the pudendal nerve, which originates from the ventral branches of sacral nerve roots S2-4. Unlike the IAS, the muscle is fatigable.(6) The EAS contributes a little to the resting anal tone, but it is primarily responsible for the voluntary contraction of the muscle. Injury to the EAS is therefore associated with a significant reduction in voluntary squeeze pressures and urge faecal incontinence.(2, 5)

1.1.3 Mechanism of defecation and anal continence

Although anatomically the anal sphincters form a relatively simple structure, their function in maintaining anal continence if far from simple. In addition to regulating faecal continence, they control defaecation through a delicate interplay of sensory function with both involuntary and voluntary motor mechanisms between the sphincter muscles, the rectum and the muscles of the pelvic floor.

Defaecation commences when the cerebral cortex receives input of sensory recognition of rectal filling. This is translated as a need to evacuate the rectum. The nerve supply of the rectum is entirely autonomic. Rectal filling coincides with a rise in rectal pressure, the sensation of which is recognised on initiation of the rectoanal inhibitory reflex (RAIR) which allows the descent of rectal contents to the upper anal canal. The EAS excitatory response to the RAIR prevents passive soiling. Through the process of “sampling”, there is conscious discrimination by the sensory anal canal epithelium of solid from liquid or gaseous luminal contents. Unless voluntarily inhibited, the parasympathetic driven defecation reflex is initiated. Continence is maintained as the lower IAS exhibits high resting pressures. The “slow wave” activity of the IAS, coupled with the contraction of the EAS and puborectalis muscles, results in the contents being returned to the rectum. Conscious deferment of defecation relies on contraction of these muscles to oppose the rise in rectal pressure until the pressure declines and the sensation of urgency abates. Thus, rectal function consists of the co-ordination of sensory perception with fine motor control allowing for timely, controlled defecation.(2, 5)

Faecal continence relies upon the intact sensory-motor function of the rectum which co-ordinates the excitatory and inhibitory functions of the anal sphincters and pelvic floor muscles. At rest the intrarectal pressure does not exceed the anal resting tone, so no leakage occurs. Should the intra-abdominal pressure suddenly rise (e.g. during coughing, laughing), the intrarectal pressure threatens continence by exceeding the anal sphincter resting pressure.(5) Loss of continence, therefore, may be the result of neurological damage or anatomical defects in any of the continence structures (See 1.4.1).

Several diagnostics tests have been developed to improve our understanding of anorectal structure and function. Anorectal evaluation begins through thorough clinical history of symptoms and a carefully performed digital rectal examination. These guide the clinician to which investigations are the most appropriate in the diagnosing the complaint. Diagnostics tests can also be used, and sometimes in absence of symptoms, to aid clinicians' decision-making regarding future management of their patients e.g. deciding the most appropriate subsequent delivery mode following childbirth related trauma to the anal sphincter complex.

For the purpose of this thesis the diagnostic tests that will be focused on are Anorectal Manometry (ARM), in the assessment of function, and Endoanal Ultrasonography (EAUS) for assessing the structure (see 1.3.8).

1.2 Perineal Trauma at Childbirth

Perineal trauma can either be spontaneous or iatrogenic (by surgical incision) trauma to the genitalia during childbirth. Anteriorly this can extend to affect the clitoris and urethra, laterally the labia, and posteriorly, the anal sphincter muscles. It is a common occurrence, affecting more than 85% of women having vaginal birth.(7) This equates to approximately 350,000 per annum in the United Kingdom (UK), of which 60-70% require suturing.(8) The extent of trauma is highly variable, as are the subsequent symptoms of pelvic floor dysfunction. The associated pain and fear associated with having sustained an injury can cause considerable distress and may interfere with the mother's ability to cope with the struggles of early motherhood. Nearly half of women will continue to have discomfort ten days postpartum, and ten percent will have long-term pain 18-months after vaginal delivery.(9, 10) (See 1.4 and 1.5 for further discussion on the impact of perineal trauma.)

1.2.1 Spontaneous Perineal Trauma

Spontaneous perineal trauma can be subdivided according to the extent of damage incurred (see Figure 3). The majority of women sustain first- and second-degree tears; superficial laceration to the vaginal epithelium and perineal skin, or a deeper laceration to the superficial perineal muscles and perineal body, respectively. First-degree tears only require suturing if there is excessive bleeding or potential for malalignment of traumatised tissues if left to heal naturally.

Second-degree perineal trauma usually extends through the hymenal remnant and posterior vaginal wall, through the perineal body and towards, but not including, the anal sphincter muscles. The perineal body is the weakest part of the perineum when stretched and offers the path of least resistance for trauma to take place. Occasionally deeper second-degree lacerations can also involve the pubococcygeus portion of the levator ani. These tears are managed using a continuous absorbable suture, which firstly incorporates closing the vaginal muscosa, the deep muscle layer (if required), and then a subcuticular layer in order to restore the perineal anatomy. These forms of trauma commonly heal very well and are not usually associated long term sequelae.

Spontaneous perineal trauma can extend further to partially or completely disrupt the anal sphincter muscles, and occasionally the rectal mucosa also. These are defined as third- and fourth-degree tears respectively, and collectively are referred to as Obstetric Anal Sphincter Injuries (OASIs) (see 1.3).

	Childbirth related perineal trauma classification[11]		
	1st degree tear:		Injury to perineal skin and/or vaginal epithelium
	2nd degree tear:		Injury to perineum involving perineal muscles and perineal body but no anal sphincter complex involvement
OASI (includes all subcategories of third- and fourth- degree tears)	3rd degree tear:		
		3a	<50% of the external anal sphincter (EAS) torn
		3b	More than 50% of the EAS torn
		3c	Both EAS and internal anal sphincter (IAS) torn
	4th degree tear:		Complete tear of EAS and IAS, with extension to the anorectal mucosa

Figure 3: Classification of childbirth related perineal trauma

1.2.2 Iatrogenic Perineal Trauma - Episiotomy

An episiotomy (or 'perineotomy') is one of the most commonly performed surgical procedures in women, being carried out to enlarge the vaginal orifice during the last part of the second stage of labour.(11) Episiotomies are defined as second-degree tears as the cut penetrates the vaginal epithelium and perineal skin, through to the superficial perineal muscles.

During the first half of the last century episiotomy was adopted as routine procedure (coinciding with the shift from home to hospital births) when childbirth became increasingly medicalised. Rate of use increased despite a lack of literary evidence supporting its benefits or risks, and was reported to be 51% in the 1970s; whilst some hospitals reported rates as high as 91%.(11) Its use became an area of controversy. Some argued that as the procedure reduces pressure on perineal tissues, it would decrease incidence of severe perineal trauma and overstretching of perineal muscles, as well as resultant long-term symptoms of pelvic floor dysfunction.(12) Others argued that episiotomy increased the risk of postpartum haemorrhage and caused long-term pain, sexual dysfunction and weakening of the pelvic floor.(11, 13, 14) It does however remain as a commonly necessary intervention in suspected fetal compromise during the second stage, shoulder dystocia, and in prevention of perineal trauma.(15) Nowadays the use is far more sparing, with the latest Hospitals Episode Statistic (HES) publication reporting an overall percentage at vaginal delivery of 20.2% in 2012. Rates of use of episiotomy during operative vaginal delivery are considerably higher (88.8% and 71.5% at forceps and vacuum extraction, respectively), reflecting the current UK guideline for intrapartum care.(8, 16, 17) The National Institute for Health and Care Excellence (NICE) Clinical Guideline (CG) No. 190 'Intrapartum Care for Healthy Women and Babies' recommends episiotomy only when there is clinical need such as operative vaginal delivery or second stage fetal distress. Routine implementation during spontaneous vaginal birth is not recommended.(17)

1.2.2.1 Types of Episiotomy

The two main types of episiotomy are mediolateral (MLE) and median/midline, although several other less commonly used types are described in the literature, such as: lateral, 'J'-shaped and radical lateral.(18) See Figure 4 below.

A midline episiotomy extends medially from the posterior fourchette through the perineal body towards the anus and is the preferred technique in the USA and Canada. Modifications to this technique have been noted with the aim of avoiding extension to the anal sphincter muscles, as midline episiotomy is a known risk factor for OASIs (see also 1.3.6.4). This involves additional bilateral transverse incisions perpendicular to the midline incision.(18, 19)

MLE is the technique widely used throughout Europe. Like the midline episiotomy, the incision starts at the posterior fourchette but is instead directed laterally and downwards to avoid possible involvement of the anal sphincter complex. However, the anal sphincters can still be damaged with this technique if the angle is cut too acutely (again see 1.3.6.4).

The aforementioned NICE CG190 guideline (17) states that the recommended episiotomy technique is a MLE "… *originating at the vaginal fourchette and usually directed to the right side. The angle to the vertical axis should be between 45 and 60 degrees….*"

The episiotomy technique referred to in this research is the MLE technique.

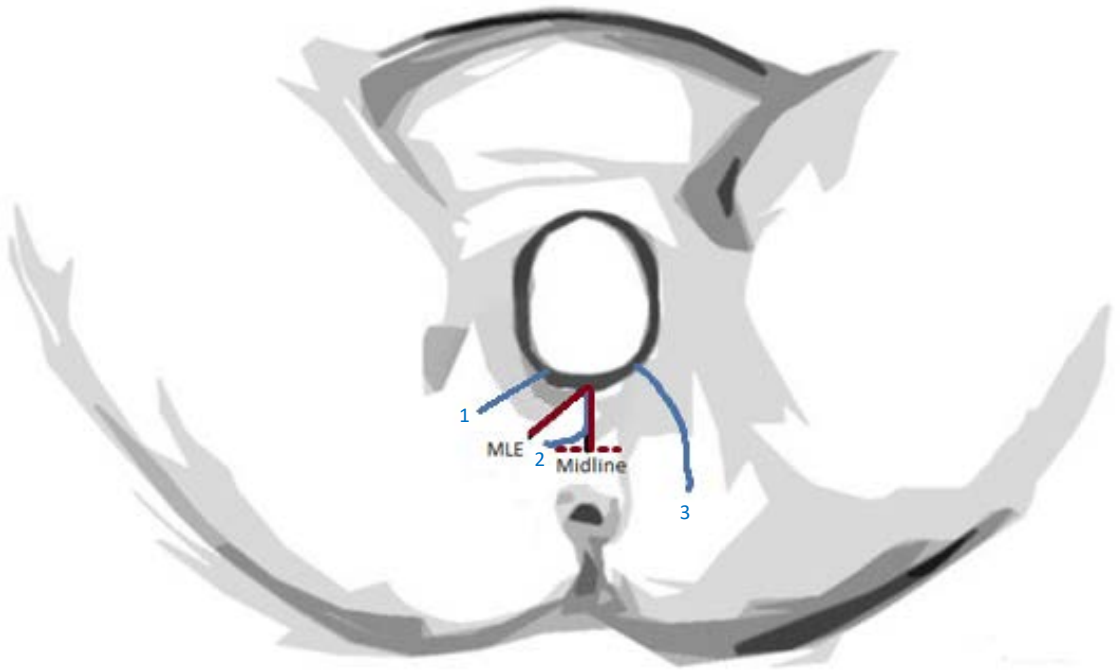

Figure 4: Types of Episiotomy

The two most common episiotomy techniques are in red – MLE and midline (modified also shown by dashed line). Less common techniques are in in blue (1. lateral (1-2cm lateral to the midline towards the ischial tuberosity), 2. 'J'-shaped (midline incision but curving laterally to avoid the sphincter muscles), 3. Radical lateral (fully extended laterally, part way round the rectum))(18)

1.3 Obstetric Anal Sphincter Injuries

OASIs are the most common cause of anal incontinence (AI) in women of childbearing age.(20) AI is both distressing and debilitating, encompassing symptoms of faecal urgency, flatus incontinence, liquid and solid stool incontinence and passive soiling. This can have severe social and psychological implications on the women and their families leading to isolation, limitations to occupational and social activities, negative impacts on relationships, reduced self-esteem and quality of life (QoL).(21-23) Due to the associated embarrassment, AI has been called the 'unvoiced symptom' as it is often under reported and commonly regarded as an expected consequence of childbirth.(23)

1.3.1 Diagnosis of OASIs

The internationally recognised classification for the diagnosis of OASIs can be seen in Figure 3 and pictorially in Figure 5 below.

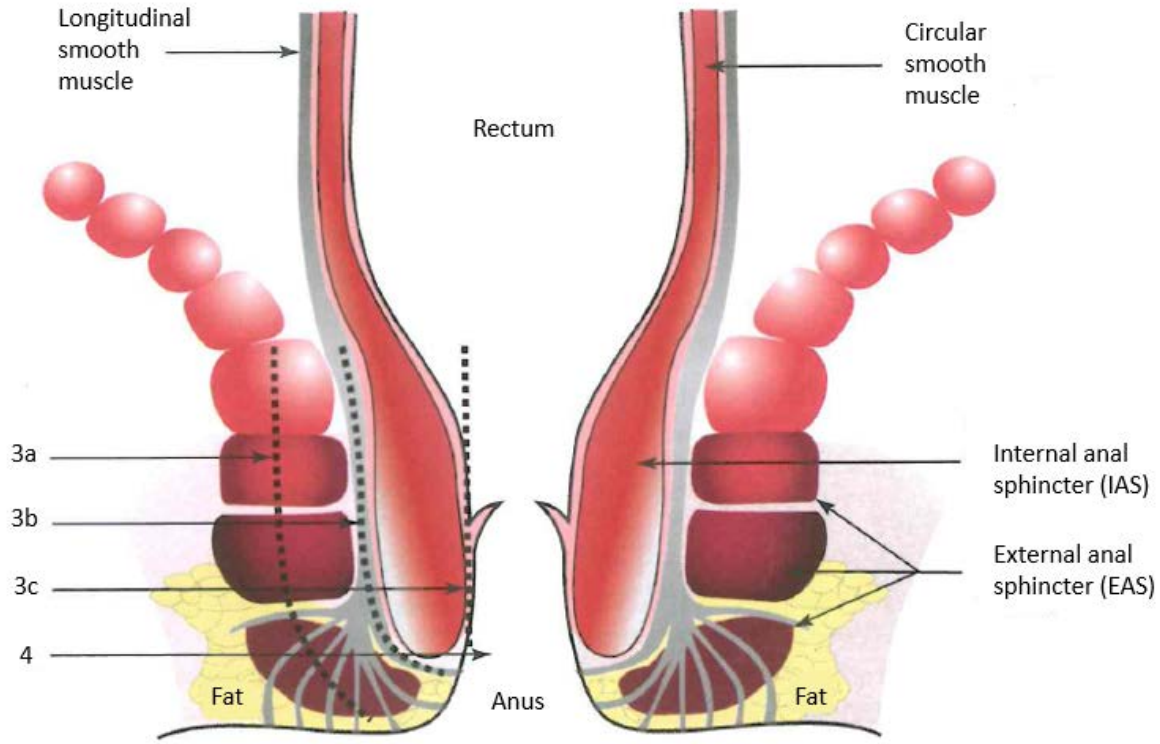

Figure 5: Classification of OASIs. (Permission for reproduction granted by authors and publishers (24))

Primary diagnosis in the immediate postpartum is of utmost importance, as leaving the anal sphincter muscles unrepaired or disrupted vastly increases the risk and prevalence of long-term faecal urgency and anal incontinence.(25-28) Diagnosing the extent of perineal trauma sustained at vaginal childbirth is based on careful inspection of the perineum and by digital rectal examination. Integrity of the anal sphincter muscles is determined through palpation between the

thumb and index finger. The detection is improved if inspection is immediately after delivery as well as through better awareness and training.(29)

1.3.2 Incidence of OASIs

The overall incidence in the UK inclusive of all parities and modes of vaginal childbirth is 2.9%, with a 3.6-fold increase incidence in the primiparous compared with the multiparous populations (6.1% vs. 1.7%).(8) In a European-wide review of OASI rates, a vast range of incidences was seen – from less than 0.5% in Poland and Romania to greater than 4.0% in Denmark and Iceland.(30) Rates as high as 6.4% have been reported in the USA.(31) It is unclear whether these trends reflect inter-country variation in population differences (e.g. ethnicity, maternal age and BMI at delivery, socioeconomic statuses etc.), differences in diagnosis and reporting of injuries, or differences in obstetric practices (e.g. use of forceps, or what type, in what circumstance or how frequently an episiotomy is performed), or all of the above.(30, 32)

Nordic studies have indicated that the size and the type of delivery unit within the same country has an influence on the incidence of OASI, where the largest and smallest units are associated with the highest risk of OASI. This could potentially be explained by the larger proportion of higher risk patients and higher risk procedures in the larger units, and a potential sparser use of preventative measures against perineal trauma in the management of second stage of labour in the smaller units.(33-35) For more information on risk factors for OASI and preventative measures, see 1.3.3 and 1.3.6, respectively.

A large, UK-based retrospective cohort study of singleton, cephalic primiparous deliveries showed a tripling in the incidence of OASIs over a decade from 1.8% in 2000 to 5.9% in 2011.(36) Although over time the population is changing (e.g. women are becoming mothers older, are more overweight and infant birth weight is generally increasing (all risk factors for OASIs, again see 1.3.3)), the authors concluded that the increase was more likely reflecting improved clinical training and better detection following the introduction of the Royal College of Obstetrics and Gynaecology (RCOG) Green-top Guidelines (GTG) no. 29 “The Management of Third- and Fourth-Degree Perineal Tears” in 2001 (revised in 2007 and 2015), and to advancements in national Hospital Episodes Statistics (HES) data capture.(37) Similar increasing trends were documented in some Scandinavian countries; e.g. Norway (<1% in the late 1960s to 4.3% in 2004), Sweden (0.5% in 1973 to 4.2% in 2004), and, although on much lower level, Finland (0.1% in 1987 to 1.0% in 2006).(32, 33, 38-40)

Recognition of this increasing trend has led to intervention programs to reduce the incidence. These will be explored further, later in this thesis (see 1.3.6.7).

1.3.2.1 'Occult' Injuries

In the early 1990's, Sultan et al. used EAUS at six weeks postpartum to demonstrate that 1/3 of women sustained an 'occult' injury; an OASI that was missed or undiagnosed at delivery.(41) Subsequent prospective studies revealed an average 'occult' incidence of ~25% (13 – 41%).(42-44) This highlighted the need to establish whether these injuries were truly occult or whether there was an under-diagnosis of OASIs at delivery. When women who were immediately postpartum were examined thoroughly by an experienced research fellow the prevalence of OASIs increased from 11 to 25%, and all of those clinically diagnosed injuries were identified on postpartum EAUS. Only 1.2% were truly 'occult' i.e. seen on EAUS but not on immediate postpartum examination.(29) This led to an awareness of the need for focused and intensive training in the diagnosis and management of perineal trauma at childbirth; now an integral component of the RCOG trainees' curriculum matrix. Conversely, in more recent years however, anxiety and fear of missing OASIs has resulted in over-diagnosis of second-degree perineal trauma as OASIs.(45) Similarly, false positive results on EAUS have also been described.(46)

1.3.4 Risk factors associated with OASIs

Risk factors associated with OASIs can be grouped according to whether they are related to the mother, the infant or the circumstance of the delivery. It is however difficult to isolate specific factors in their OASI potentiating effect due to the multifactorial nature of pregnancy and childbirth. Factors relating to the second stage of labour are largely modifiable, e.g. the instrument of choice at operative vaginal delivery or whether an episiotomy or manual perineal protection are performed. It can also be difficult to evaluate objectively the extent to which these interventions influence the risk of OASI due to user variability, differences in individual unit policies and circumstances of the labour itself. In contrast, factors relating to the mother and baby are generally non-modifiable, e.g. maternal age, fetal birth weight etc.

1.3.4.1 Maternal risk factors for OASIs

Parity

The most influential risk factor for OASIs is primiparity, with large registry studies concluding a two to seven fold risk when compared to women having previously delivered vaginally.(31, 33, 47, 48) The risk reduces with increasing birth order.(33, 34) However, parous women whom have only delivered by caesarean section (CS) previously are at an even higher risk than primiparous women (aOR 1.2 – 1.42).(31, 33, 47, 49) See 0 and Chapter 3 .

Maternal age

Women with increased age are at a higher risk of sustaining OASIs. A large cohort study (n = 10,314) showed women aged 31 -35 years to be at three-fold increased risk of sphincter injury (ref <20 years).(50) A possible explanation for this is decreased elasticity due to loss of function and strength of connective tissues with increasing age.(33, 51) One study showed the risk associated with maternal age to be indifferent among the parity groups, whereas another study showed advancing age to only be a risk factor in the primiparous population.(49, 52)

Ethnicity

Women of Asian ethnicity are at a significantly increased risk of OASIs compared with Caucasian women (aOR 1.37-2.5),(31, 33, 49, 52) whereas being of Black and Hispanic ethnicity has a protective effect (aOR 0.69).(31) A possible explanation for this is ethnic variation in perineal length (PL), pelvic anatomy and tissue composition - the result of which predisposes Asian women to perineal trauma.(53-57) In the late antenatal period or first stage of labour, the average PL is 39mm (37-41mm range), which increased by 50-60% in crowning. The risk of OASI is significantly higher in

those with a PL in the first stage of labour measuring <25mm (40% vs. 5.6%, p=0.004).(55) A lower rate of perineal laceration has been noted in Black women compared to Caucasian (p=0.003, aOR 2.1), which was speculated to be due to connective collagen content.(58)

Maternal BMI

Obesity in prevalent in over a fifth of the UK childbearing population and has a serious impact on general health, as well all obstetric implications.(59) Pre-pregnancy weight is relational to adverse perinatal outcomes.(60) This is a global issue and a progressive trend of year-on-year obesity-attributable risk was already being observed two decades ago.(61) There is also an established relationship between raised BMI (>29kg/m^2) and large for gestational age infants, but this could well be due to the increased incidence of gestational diabetes resulting in macrosomia rather than a true effect of maternal obesity.(61-63) Furthermore, a significant relationship has been seen between maternal height, fetal weight and risk of severe perineal trauma; where short stature combined with high birth weight results in a significantly increased risk of injury.(64)

Anal incontinence (AI) is more prevalent in the obese population.(65) Although OASI are the leading cause for AI in the female population, surprisingly an inverse correlation between obesity and incidence of OASI has been observed. Therefore, increase in BMI seems to have a protective effect against sustaining an OASI. It was speculated that this was due to the protective of cholesterol in modulating the oxytocin receptors of the uterine myometrium, thereby decreasing the risk of excessive contractions and possible resultant pelvic floor injury. Furthermore, due to restrictions in lung function, obese women are less likely to be in lithotomy which is associated with increased risk of OASI.(66, 67)

Socio-economic status (SES)

A social gradient has been identified in all major obstetric and perinatal complications, including pre-term delivery and small for gestational age. In contrast, a reverse social gradient has been observed with higher incidence of OASIs in primiparous women of higher SES groups.(68, 69) Raisanen et al. revealed that 40% of the disparity in OASI incidence between SES groups could be explained by age, higher birth weight and operative vaginal birth, whereas the remaining risk excess was explained by other unmeasured lifestyle or environmental factors, or inequalities in healthcare provision.(69)

1.3.4.2 Intrapartum risk factors for OASIs

The primiparous population are far more likely to require obstetric intervention; often with one procedure leading to another, e.g. regional anaesthesia leading to prolonged second stage, which

in turn increases the likelihood of operative delivery. It is therefore difficult to determine whether it is specific individual factors which influence the risk of sphincter injury, or whether it is interplay of multiple factors.

Mode of delivery

In comparison to spontaneous vaginal delivery, operative vaginal deliveries (OVD) are associated with a far greater risk of OASI. A Cochrane review of ten randomised control trials (RCTs) showed vacuum extraction to be preferable to forceps with regard to maternal injury sustained (OR 1.89), however it is associated with neonatal cephalohaematoma and retinal haemorrhages.(70, 71) Similarly, large registry studies have shown both modes are attributable risks for OASI when adjusting for other variables (forceps aOR 2.3 – 26.7, vacuum extraction aOR 1.45 – 8.2).(31, 33, 49, 52, 72, 73) Position of the presenting part at application of the forceps also influences the risk; the higher the application the greater the risk of OASI, with one study revealing a 20.1% risk at low, 23.3% at mid and 75% rate at high. However, this study was carried out in the USA where midline episiotomy is advocated.(74) Interestingly, as the rate of OASI has increased over the last decade the use of forceps has also increased (9.0 to 16.1%), whilst the use of vacuum extraction decreased (17.5 to 13.9%).(36)

Prolonged second stage

Prolonged second stage (>60min) is associated with primiparity, large birth weight and malpresentation, and is an independent risk factor for OASI (aOR 1.49 – 5.4).(31, 52, 72) Furthermore, the risk increases with each additional 60 minute increase in second stage duration.(52) Another study found a 6% increase in OASI risk with every additional 15 minutes before an operative vaginal delivery is performed.(75) Valsky et al. found the combination of a second stage longer than 110 minutes, with an infant head circumference greater than 35.5cm was associated with a five-fold increase in OASI.(76) A possible cause responsible for the increased risk of OASI with prolongation of the second stage is the presence of perineal oedema.(77)

Induction of labour

The effect of induction of labour on the incidence of OASI is inconclusive, and the process is associated with known other risk factors for OASI, such as primiparity, prolonged second stage, OVD and infant macrosomia. Oxytocin augmentation has been shown to increase the risk of OASI in women giving birth to infants weighing <4Kg (OR 1.8, 95% CI 1.5-2.2).(78) However, Prager et al. showed a two-fold increase in the risk of OASI with the use of Oxytocin, although this diminished when adjusting for mode of delivery.(79) A further study showed similar results after adjusting for other factors in multivariate analysis.(80)

Epidural anaesthesia

Regional anaesthesia, such as epidurals or spinals, are considered the only consistently effective means of relieving the pains of childbirth. Results of research concerning the association between OASI and epidural anaesthesia are contradictory. Some studies have shown a protective effect, others a potentiating effect, and some no effect. Roos et al. found epidural anaesthesia to be the only factor after multivariate analysis of risk factors to independently associated with sustaining an OASI ($p<0.002$). Furthermore, another study revealed an eight-fold increase in risk, which is likely to be partially attributable to the increased need for instrumental assisted birth.(28, 80-83)

Water birth

Giving birth in water, referred to as 'water birth' was first described in France in 1803, and since the 1980's has been well accepted as a birth choice. Buoyancy enhances mobility and has associations with more positive perception of managing pain. Most of research has reviewed the use of water immersion at first stage rather than birthing in water, with an overall opinion of greater satisfaction together with no compromise to maternal or neonatal wellbeing. However, much controversy surrounds the use of water birth in obstetric practice and its potential as a risk factor for OASI.(84)

Although retrospective studies have revealed a higher prevalence of perineal trauma at water birth these have been a less severe degree.(84-86) Otigbah et al., in a comparison between primipara having a water birth and a matched control having conventional vaginal deliveries, revealed that the water birth cohort had an increased incidence of intact perinea (41% vs. 29%, $p<0.05$), but cohort numbers were too small to draw meaningful conclusions concerning OASI.(84) A more recent prospective observational study also found a higher incidence of intact perinea with waterbirth, as well as a reduced incidence of more severe degrees of perineal trauma.(87) Dahlen et al. found no difference when comparing different birthing positions on land with water, aside from waterbirth being protective in comparison to the birthing stool (OR 1.4, 95% CI 1.12 – 1.75), which is known to be associated with OASIs.(88) An explanation for the potential protective effect of water birth could be due to reduced perineal tension and improved elasticity of, as well as blood supply to, the perineal tissues due to immersion in warm water.(89)

On the contrary to the above observations, several studies have shown immersion in water and water birth to be associated with an increased risk of OASI. McPherson et al. found water birth, and more particularly water immersion in labour, after multivariate analysis was significantly associated with sustaining OASIs ((OR 1.46, CI 1.02-2.10, p0.041) and (OR 2.29, CI 1.78-2.94, $p <0.001$), respectively).(90, 91) However, a recent Cochrane review (not including this study) concluded that there was insufficient evidence regarding the impact of immersion in water during the first stage

on risk of perineal trauma.(92) When comparing water birth with land birth, although water birth was associated with a reduced second stage ($p<0.001$), a greater incidence of OASI was observed (2.5% vs. 1.2%, RR 1.9 but 95% CI 0.58-6.23, $p>0.05$).(93) It has been speculated that this could be due to a shorter second stage not allowing the birth canal to accommodate changes required to prevent perineal oedema as well as lack of perineal surveillance and ability for the accoucheur to manually protect the perineum.(77, 91, 93) It would be interesting to know whether midwives consider water birth a risk to the perineum, as the very nature of a water birth renders the mother immune from interventions known or speculated to increase the risk of OASI, such as OVD, induction of labour and epidural anaesthesia, but also an inability to benefit from measures known to protect against injury, such as 'hands-on' perineal protection (see also 1.3.6.1). See Chapter 2 for our investigation into whether water birth is a risk factor for OASI.

1.3.4.3 Neonatal risk factors for OASIs

Birth weight

High birth weight has been uniformly concluded to be one of the most influential risk factors for sustaining an OASI. Infant macrosomia, a birth weight over 4000 grams, is associated with a 2.17 – 9.2-fold increased risk of OASI; more so if over 4500 grams (aOR 10.5 – 13.6).(31, 33, 40, 52) The risk of OASI increases by 1.47-times with every 500 gram incremented increase in weight, and 1.2-times per 200 gram increase.(73, 94)

Shoulder dystocia

Shoulder dystocia (SD) is a potentially catastrophic complication of childbirth. It occurs after the delivery of the fetal head when the anterior fetal shoulder impacts the maternal symphysis or the posterior fetal shoulder impacts the maternal sacral promontory (less common). It complicates 0.6 – 0.9% of vaginal births and is associated with infant macrosomia and increased need for obstetric intervention, which both contribute to the risk of sustaining an OASI.(95, 96) The single most powerful predictor for SD is infant macrosomia (for birth weight >4500g (aOR 39.5, 95% CI 19.1-81.4) and 4000-4499g (aOR 9.0, 95% CI 6.5-12.6) and is associated with a dystocia of soft tissue, i.e. an increased distribution of fat across the shoulders.(96) SD is an independent risk factor for OASI (aOR 1.98, 95% CI 1.11-3.54, $p=0.029$) and correlates with increasing weight, but is independent of head circumference. Therefore, a smaller head circumference is not necessarily a protective factor when followed by relatively large body/shoulders.(97) Interestingly, when controlling for the confounding effects of maternal diabetes and fetal macrosomia (of current and previous offspring), maternal obesity has been shown not increase the incidence of shoulder dystocia; in fact the attributable risk factors are similar to the non-obese women.(96)

Abnormal fetal presentation and head circumference

Persistent occipito-posterior (OP) presentation of the fetal head is associated with an increased risk of OASI (aOR 1.73 – 3.2) as the head circumference in this presentation is larger and therefore, greater pressure is exerted on the perineum.(40, 73) Although the incidence is low (about 10 – 34% at the onset of labour, reducing to about 5 – 8% at birth), OP position is associated with a higher complication rate, including prolonged second stage, shoulder dystocia and operative vaginal birth (68%), all of which are associated with an increased risk of OASI.(72, 98, 99)

When controlling for other risk factors, one study found that an increased head circumference was demonstrated to be protective against (in this case) a recurrent sphincter injury (aOR 0.91 per increase in cm, 95% CI 0.85-0.98, p=0.0014). There was a positive correlation between birth weight and head circumference in increasing the risk of OASI (Spearman's rank correlation 0.594, 95% CI 0.58-0.61, p<0.0001), but for fixed weight (adjusting for this correlation) a larger head circumference was associated with a lower risk of OASI. The authors speculated that this may be due to a slower speed of crowning, and the observation that in clinical practice OASI occur at the delivery of the shoulders.(97)

1.3.4.4 Adjusting for confounding factors

Studies to date, exploring the risk factors for OASI in the primiparous population, have been confounded by factors which are known to increase the risk of OASI. For example, the use of regional anaesthesia is associated with an increased need for OVD. Is regional anaesthesia and independent risk factor for OASI or is it seen to be due to the association with OVD? It would therefore be useful to establish the risk factors specifically associated with primiparous normal vaginal delivery (NVD). Furthermore, previous studies have used a control comparison incorporating all other degrees of perineal trauma e.g. first- and second-degree tears. This therefore adds both a potential bias and the possibility of missed diagnoses of OASIs. It would therefore be useful to carry out analysis with a control comparison of women with documented intact perinea. See 1.9 'Thesis Aims' and Chapter 1 , for how this research need has been addressed.

1.3.5 The Risk of OASI at Vaginal Birth After Caesarean Section (VBAC)

There is a consensus that women who delivered previously with single, uncomplicated caesarean section (CS), and with otherwise uncomplicated current pregnancy, should be encouraged to attempt a vaginal delivery.(100, 101) Although success rates of planned vaginal birth after caesarean section (VBAC) have been quoted to be 63.4 – 75% there has been a reported overall decline.(100, 102, 103) This, accompanied by rising rates of primary caesarean, has been a significant driver for the increased CS rate.(103)

Research has shown an association between VBAC and an increased risk of OASIS, when compared with both primiparous (adjusted OR 1.42, 95%CI 1.25-1.6. p<0.001)) and multiparous (OR 13.6; 95%CI, 4.7-39.3; p<0.001) women.(47, 104) VBAC delivery is also associated with increased instrumentation rate compared with primiparous vaginal delivery (39% vs. 30%, OR 1.15, 95%CI 1.01-1.3. p<0.0001). This further potentiates the risk of OASI; especially with the use of forceps (58% OASI with forceps at VBAC versus 33% vacuum, p=0.001).(103)

It was speculated that the increased rate of complicated delivery and OASI was due to relative cephalopelvic disproportion as cause for initial CS.(47) It has been suggested that risk factors which led to the initial caesarean are carried over to subsequent delivery.(33) Additionally, these are possibly intensified due to more propulsive, secundiparous contractions coupled with a 'nulliparous' perineum. It has therefore been suggested that the risk of OASI is similar to primiparous rather than multiparous population.(47, 105)

1.3.5.1 The need for further research

Although women undergoing VBAC delivery are at increased risk of an OASI, very little research has been carried out in establishing the maternal, intrapartum and neonatal factors influencing this risk. In addition to addressing this, it would be of interest to evaluate whether the factors surrounding the initial caesarean delivery - including the urgency of caesarean - influence the risk of sustaining an OASI at subsequent delivery. See 1.9 'Thesis Aims' and Chapter 1 for how this research need has been addressed.

1.3.6 Prevention of OASI

Interventions aimed to reduce the risk of perineal trauma at childbirth focus on decreasing perineal tension by dispersing the tension, decreasing the size of the passing object or by increasing elasticity of perineal tissues. Several interventions have been introduced; such as perineal massage, a warm compress applied to the perineum during the second stage, controlled delivery of the head in combination with manual perineal protection, the use of MLE, and a good rapport with, coaching by and trust in, the midwife. This section will focus on the main interventions highlighted in the RCOG "The Management of Third- and Fourth-Degree Perineal Tears" guideline for the prevention of OASI.(37)

1.3.6.1 Manual Perineal Protection (MPP) at crowning

MPP (also known as "hands-on") involves using one hand to slow the expulsion of the baby's head by exerting pressure on the occiput. This in turn causes flexion of the head, which promotes the presentation of the smallest diameter of the fetal head at the pelvic outlet - the suboccipitobregmatic diameter. The thumb and index finger of other hand are placed either side of the posterior introitus and are drawn in toward the midline supporting the perineum and dispersing perineal tension. Through effective communication, the mother is discouraged from pushing during crowning. The alternative is "hands-poised" or "hands-off", where the accoucheur has their hands poised in readiness and asserts pressure on the head if fast expulsion is anticipated. The NICE guideline for intrapartum care advocates both techniques based on a trial showing no significant difference in incidence of OASI.(17) More recently, Bulchandi et al.'s recent systematic review of earlier research focussing on MPP in prevention of OASI, revealed no significant protective effect in meta-analysis of five randomised control trials (RCTs) (n=6647; RR 1.03; 95% CI 0.32 – 3.36).(106) However, a significant reduction in risk was evident on reviewing seven non-randomised studies (n=74744; RR 0.45; 95% CI 0.40 – 0.50). In contrast, a Cochrane review of "hands-off" versus "hands-on" showed no effect on the incidence of OASI, however important to note that there was difficulty in achieving comparative analysis due to considerable heterogeneity of technique and methodology.(7, 106-108)

Interventional studies since the guideline publication have reported success in significantly reducing OASI rates through the introduction of programmes promoting MPP. Of note, Laine et al. reported a reduction in OASI from 4.03% (285 of 7,069) to 1.17 % (42 of 3,577) ($p<0.001$). This was attributed to the use of "hands-on" technique during the second stage of labour.(109) Moreover, lack of ability to visualise the perineum, e.g. due to the maternal birthing position, was also

considered as a risk factor for OASI due to hindered access for the clinician to undertake such perineal protective measures.(77)

The aforementioned RCOG guideline, published since the NICE guideline, now promotes "perineal protection at crowning" in the prevention of OASI.(37) In the UK however, there has been a trend towards a preference for "hands-off". 72% of midwives qualified less than five years prefer this technique over MPP; this even in the presence of known OASI risk factors (primiparity, macrosomia and previous OASI). It was hypothesised that this may be contributing to the increasing rates of OASI as newly qualified midwives are less comfortable to undertake MPP despite evidence promoting its benefit.(110)

1.3.6.2 Warm compress during the second stage of labour

Application of a warm compress (swab / gauze / cloth soaked in warm water and wrung out) to the perineum, continuously from when the vertex is visible until delivery, to promote blood supply to and improve elasticity of the perineal tissues. It has been recognised by the RCOG to reduce the risk of OASI. A review of two studies comparing the use of compresses versus "hands-off", showed a significant effect of the intervention in halving the risk of sustaining an OASI (n=1525; RR 0.48, 95% CI) 0.28 to 0.84).(111, 112)

1.3.6.3 Perineal massage

Perineal massage has been advocated from 34-weeks' gestation for the preservation of perineal integrity during childbirth through increasing tissue elasticity and improving perineal blood flow. Carried out by the woman or her partner, it involves placing their thumbs on the posterior vaginal wall whilst resting the forefingers on the buttocks. In a 'U' shaped movement, the tissues are massaged as the thumbs move from the six o'clock position laterally and superiorly to the three and nine o'clock positions and back to the original position again. This rhythmic motion is repeated for up to ten minutes, every other day. It is generally well tolerated and women's assessment of its effect on birth preparation and delivery is positive.(113) Objectively, it is associated with a nine percent overall reduction in perineal trauma requiring suturing (n=2480; RR 0.91; 95% CI 0.86 – 0.96) with a number needed to treat to benefit (NNT) 15. This effect was greater in primiparous women. Although the need for episiotomy was also reduced, no difference was reported in the incidence of OASI.(114)

Perineal massage can also be performed during the second stage, using two lubricated fingers at the posterior fourchette in a stretching or sweeping motion during each uterine contraction. Data regarding its use for prevention of OASI is inconclusive. Although underpowered, an RCT showed fewer OASIs in the massage arm of the trial (12 [1.7%] versus 23 [3.6%]; absolute risk 2.11, RR 0.45,

95% CI 0.23–0.93). No differences were seen when comparing less severe degrees of trauma, including episiotomy.(115) A recent Cochrane review of trials evaluating massage versus "hands-off" or care as usual revealed a significantly reduced risk of OASI in the massage group (n=2147; RR 0.52, 95% CI 0.29 to 0.94).(108) The RCOG guideline makes mention of the research outcomes but neither encourages or discourages the use of perineal massage.(37)

1.3.6.4 Episiotomy in the Prevention of Primary OASI

The aim of an episiotomy is to increase the vaginal outlet size in order to decrease the perineal tension. Midline episiotomy is a known risk factor for sustaining OASIs, as the episiotomy incision can extend beyond desired length and involve the anal sphincters.(116) The evidence addressing the use of MLE and associated risk of OASIs are far more unclear. Some studies have failed to show any effect in MLE protecting against OASI, even when compared with midline episiotomy (RR 0.92, 95% CI 0.72 – 1.18).(117) Whereas, others have shown MLE to be an independent risk factor for OASIs, although this is thought to be due to inappropriate technique where the MLE was angled closer to the midline (26 versus 37 degrees, p = 0.01).(118) Although the current NICE guideline(17) recommends the episiotomy to cut at a 45 – 60^{o} angle, studies have shown that perineal distension during crowning makes the angle difficult to estimate. Incisions result in a far more acute suture angle, and an increased risk of OASIs.(119-121) At a suture angle of 25^{o}, the absolute risk of OASI is 10%. However, with every 6^{o} the episiotomy is away from the midline, the risk reduces by 50%. At a 45^{o} suture angle, the risk reduces to 0.5%.(122, 123) This protective effect diminishes greatly if the angle is nearly horizontal (90^{o}) leading to a nine-fold increase in risk of OASI.(123) Tincello et al.(124) and Andrews et al.(125) have found only a minority of clinicians (0 – 19% of midwives and 22 – 30% of doctors) were able to accurately perform MLE resulting in the correct incision and suture angles. Anal sphincter disruption has been observed with a suture angle of 30^{o} versus 38^{o}.(122) As a MLE consistently cut at a 60^{o} angle results in a 43^{o} suture angle, the RCOG recommends that to prevent OASI the cut should be 60^{o} from the midline. (37, 120). The length and depth are also known to influence the risk of OASI.(122, 123, 126)

A recent systematic review of 16 studies addressing the risk of OASI after episiotomy concluded that the use of MLE in the nulliparous population was protective (RR 0.67 95% CI 0.49 – 0.92).(13) Moreover, MLE has been shown to be protective against OASI regardless of delivery mode, although more markedly so in operative vaginal delivery. Forceps without episiotomy increases the rate of OASI nearly four-fold (6.1% with versus 22.7% without). Vacuum extraction without episiotomy almost triples the risk (aOR, 2.99; 95% CI, 2.86–3.12; p < 0.0001) (36, 127). This evidence supports other previous studies suggesting the same.(73, 128, 129) Conversely, studies have shown MLE to contribute to the risk of OASI in the multiparous population, however this observation is at risk of

potential bias as many current indications for MLE are also risk factors for OASI, thereby contributing to the overall incidence of OASI. When adjusted for known risk factors for OASI such as maternal age, birth weight, mode of delivery, MLE was associated with a 12% lower incidence (aOR 0.88, 95% CI 0.80 – 0.98).(130, 131)

A Cochrane review of the restrictive (by indication only) use of episiotomy versus routine use, concluded that using selective episiotomy in unassisted vaginal birth could potentially result in 30% fewer cases of severe perineal trauma (RR 0.70, 95% CI 0.52 to 0.94).(132) Additionally, a large cross-sectional study showed women giving birth without MLE to be 1.4-times the risk of sustaining OASI (95% CI 1.021 – 1.983).(50) Through gathering these research outcomes together with the observation of an overall decline in the use of MLE in unassisted delivery, one could surmise that the decrease in use could be a contributor to the increased OASI rates in the same time period.(36, 133)

1.3.6.5 Episiotomy in the Prevention of Recurrent OASI (rOASI)

Regarding future deliveries after previous OASI, the RCOG guideline states: *"The role of prophylactic episiotomy in subsequent pregnancies is not known and therefore an episiotomy should only be performed if clinically indicated."* Furthermore, the NICE intrapartum care guideline advises: *"Do not offer episiotomy routinely at vaginal birth after previous third- or fourth-degree trauma."(17)*

The use of prophylactic episiotomy in prevention of rOASI is not clear. Although research has shown the potential protective effect of MLE against OASI at first delivery (see section 1.3.6.4 and 1.6.1), no definitive conclusions have been made regarding the use of MLE against recurrent injury. Therefore, one of the areas that this thesis will focus on is determining whether the use of MLE is effective in prevention of rOASI. See 'Thesis Aims' section 1.9 and Chapter 4

1.3.6.6 Limitations of research addressing prevention of OASI

The majority of research into the prevention of childbirth related perineal trauma has been through observational studies (e.g. cohort or case-control). However, a limitation of these studies is that the measures being analysed are rarely used in isolation and subsequently are affected by other confounding factors. For example, the use of episiotomy in primiparous women, with large babies requiring operative vaginal delivery. Therefore, analysis of single interventions is likely to be subject to bias despite efforts to adjust for associated factors influencing risk. RCTs would be the best method for establishing what measures are effective in the reduction of perineal trauma. However, due to relative infrequency of severe trauma and the ad hoc nature in which interventions are carried out, based on the accoucheur's previous experience as well as clinical indication, evaluation

of such measures in this way can be difficult. Furthermore, intervention type and technique not only vary between countries and birthing units, but between individual practitioners also.

1.3.6.7 Evidence-based interventional programmes to prevent OASI

If used randomly, single measures are unlikely to have any real impact on reduction in the incidence of perineal trauma. However, a significant reduction in occurrence has been seen on implementation of standardised protocols that have been adopted by the entire maternity multi-professional team.(134) For instance, Laine et al.'s Finnish perineum protection study resulted in a 50% reduction in the incidence of OASI (4.0% to 1.9%), seen regardless of parity, delivery mode or infant birth weight. More recently, Mohiudin et al.'s recent, relatively small (n=2566), UK-based study focused on implementation of the three RCOG suggested preventative measures of antenatal perineal massage, MPP and 60-degree (using the EPISCISSORS-60) resulted in, most noticeably, 73% reduction of OASI at operative vaginal delivery.(109, 133)

In the UK, recognising the Scandinavian success in markedly reducing the incidence of OASI,(109) the RCOG and Royal College of Midwives worked collaboratively to increase the awareness of OASI incidence and risk, by developing tools to improve prevention and management of OASI for the entire multi-professional maternity care team. They established the 'OASI Care Bundle'; a small set of evidence-based interventions which, when used in unison, aim to improve the care women receive and result in significantly better outcomes i.e. reduced incidence of OASI.(135) The four elements include communication with mothers to ensure they are aware of the care bundle, use of episiotomy when required, MPP whenever possible and thorough perineal and thorough perineal and rectal examination after all vaginal deliveries. The care bundle was instigated at 16 NHS Trusts (four Trusts in four regions of the UK, with a "Champion" at each Trust), ran for and 30 months and significantly raised the profile for OASI prevention.

The results are currently in press, but with permission from the lead author through personal communication, they have been made available.

Although not as marked as Laine's study, the OASI rate significantly decreased from 3.3% pre-intervention to 3.0% (aOR 0.79, p=0.03). No change was seen in rates of OASI at OVD, but at NVD rates declined from 2.6% to 2.2%, (aOR 0.66, p<0.001). The study revealed that women wanted to be more informed, and despite having this additional knowledge of childbirth related trauma an increase in CS was not observed.

The reasons why the study may not have quite reached the same success are multifactorial. In the Scandinavian countries there has been a longstanding, raised awareness of and training in perineal

protection, with a greater emphasis and multidisciplinary training of MPP and the use of MLE. This is engrained throughout out training and in every day clinical practice. This UK study revealed significant training gaps and deskilling of midwives as well as a reluctance in performing episiotomies and “hands-on” perineal protection. Resistance was seen in those comfortable with their own well-established practices – clinicians felt their autonomy was being challenged. Furthermore, due to fear of scaring the patients, clinicians went against the protocol and made their own judgement about what they thought patients would want to know rather than providing the specified antenatal patient information.

To enable change to take place, extensive education of the whole obstetric team was required at each site facilitated by the “Champion”. This was a tall order, as in many cases it was expected to take place in addition to their own, ongoing clinical duties. However, the negative points aside, this study did result in a step in the right direction regarding the incidence of OASI, the interventions did raise awareness and improvements in obstetric team cohesion were observed.

1.3.7 Treatment of OASIs

Patients who have sustained an OASI should have the following strategies implemented. The use of broad-spectrum antibiotics is recommended to reduce the risk of fistula formation and AI associated with infection. The current recommendation is also for stool softeners and bulking agents in the immediate term (three to ten days) after sphincter repair, to help encourage women to avoid constipation and straining which could disrupt the repair. Women are also advised that physiotherapy focused on pelvic floor muscle (PFM) retraining may be beneficial in the prevention of long-term symptoms of AI.(37, 136-138)

In addition to ensuring women are fully debriefed in the early postnatal period concerning the extent of their injury and how to seek help in the event of symptom progression, it is also important they are aware that they will be followed up in a perineal clinic. Here, anorectal physiology investigations (anorectal manometry and endoanal ultrasound) will be used to help aid decisions regarding symptom management and mode of delivery with subsequent pregnancies.(37) See 1.3.8 for more information.

1.3.7.1 Repair techniques

To optimise long-term outcomes of OASI repair, it is imperative that a systematic, thorough assessment and repair are performed.(139) Sultan et al. realised the anatomical and physiological importance of recognition and separate repair of the IAS from the EAS, due to their distinct functions (see 1.1.2).(140)

There are two main techniques for the repair of the EAS; 'end-to-end' whereby the torn edges are approximated and 'overlap' by which the damaged ends are placed one on top of the other and sutured to create an overlapping. An early Cochrane review of three RCTs (n=279) suggested that when repairing complete thickness EAS injuries (e.g. complete 3b or 3c tears), overlap repair appeared to be associated with a lower risk of faecal urgency and AI. However the experience of the surgeon was not addressed; so recommending one method over the other was considered inappropriate.(141) More recently a Cochrane review of six RCTs (n=588), showed no difference in the incidence of perineal pain, dyspareunia or flatus incontinence when comparing the two repair techniques. The overlap technique was associated with a lower incidence of faecal urgency (n=52, RR 0.12; 95% CI 0.02 – 0.86) and a lower risk of deterioration of AI over 12 months (n=41, RR 0.25; 95% CI 0.09 – 0.79). However, there was no difference in QoL and follow-up at 36 months revealed no difference in flatus or faecal incontinence when comparing the techniques.(142)

Due to the risk of exerting undue tension on the tissues, the recommendation is that partial thickness EAS injuries (e.g. 3a or <100% 3b tears) should be sutured using an 'end-to-end'

technique, and the overlap technique should only be used for full thickness injuries (e.g. complete 3b or 3c tears).(37, 140) Women should be advised that a year after an EAS repair, 60 – 80% will be asymptomatic.(37, 143)

The IAS is a smooth muscle, which is less fibrous than the striated EAS, so is at greater risk of tearing under tension. Therefore, to minimise risk of tearing when repaired, the 'end-to-end' technique is recommended.(140) Anorectal mucosa (damaged in a 4th-degree tear) should be repaired by approximation using interrupted sutures with the knots tied in the anal lumen.(144)

1.3.7.2 Outcomes of primary repair

Completing a meta-analysis of literature regarding the outcomes of primary repairs (first repair immediately after an OASI is sustained) is near impossible due the heterogeneity of study design and both quantitative and qualitative data collection. Sultan and Thakar went some way in achieving this by evaluating 35 studies, with 1 to 30 months follow-up, concerning the prevalence of flatal and faecal incontinence following primary repair. 15 – 61% (35 studies, mean 39%) had persistent flatus incontinence and 2 – 29% (25 studies, mean 14%) had persistent faecal (liquids, solids +/- flatus). Furthermore, faecal urgency can affect 6 – 28% of women. Surprisingly 34 – 91% did have persistent sonographic sphincter defects despite primary repair.(145) It is possible, however, that some of the residual symptoms may in part be due to undiagnosed, co-existing pudendal neuropathy. Additionally, some studies have shown a relationship between the grade of injury sustained and the prevalence of long-term symptoms following primary repair; odds of developing symptoms increase with each grade.(146, 147)

1.3.8 Investigations of anorectal function

The effectiveness of a repair can be assessed using anorectal physiology testing – the integrity of the anal sphincter complex through endoanal ultrasound (EAUS), and the resultant functionality using anorectal manometry (ARM).

The importance of these physiological tests is not only in the preservation of anal sphincter function but also in prevention of unnecessary caesarean sections.

1.3.8.1 Anorectal Manometry

ARM is a well-established, generally well accepted, technology providing an objective assessment of anal sphincter pressures to determine sensory or muscular defects, as well as functional weakness of the IAS and EAS. Data can be from one point ('conventional anal manometry') using a water-perfused system, or through a more detailed, and increasingly more commonly used, high-resolution solid-state methodology ('high-resolution manometry'). The latter can more accurately characterise the sphincter functionality.(148)

The investigation consists of pressure readings recorded by sensors on a narrow-tipped balloon catheter produced by the muscles during various states. For instance, at rest (mainly generated by the IAS, maximal 61 – 163 mmHg), during voluntary squeeze (mainly by EAS, average 50 – 181 mmHg), involuntary anal squeeze pressure simulated by coughing (to assess the EAS reflex), during distension (to examine the RAIR) and simulated defecation ('push'). The results give a picture of recto-anal co-ordination and functionality.(149, 150) An example of how some of these states might be recorded can be seen in Figure 6.

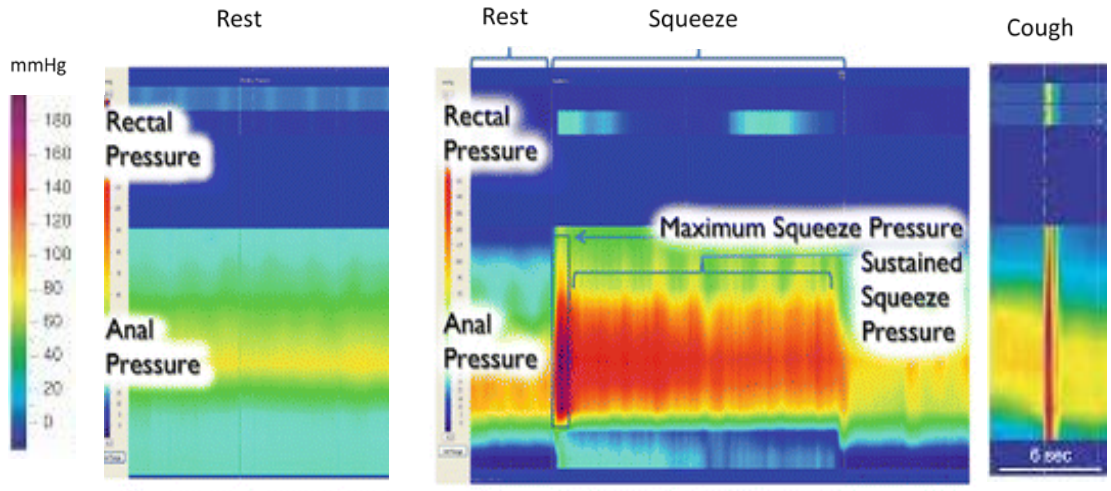

Figure 6: An example of normal anorectal manometry
Representative colour contour display with a pressure of 140 mmHg depicted red and 0 mmHg as blue (pressure scale to the extreme left). Within the rectum, pressure is low (blue). The figure shows a normal anal canal pressure reading result at rest, on sustained squeeze and on coughing. (150)
(Permission to reproduce granted by Publisher (Springer, New York) (151)

Interpretation of findings can be difficult due to the wide variability and crossover of manometric measurements in health and disease, as well as biases owing to vast inter-operative variation in technique and protocol.

Normal ranges in ARM are based on the average person (including both male and female), but due to the relaxant effect of the changes to the hormonal profile of pregnant or postnatal women these may be reduced. Currently there is a paucity of evidence regarding squeeze pressures in both the antenatal and postnatal periods, so the use of ARM as a diagnostic tool to identify abnormal bowel function in these populations remains subjective. Only one study has provided potential reference values for resting pressures in an antenatal population. However, the results did not allow for potential impact of a previous pregnancy and delivery, and may be subject to ethnicity related bias, as all participants were primigravid and of South Asian ethnicity.(152) Furthermore, the interpretation of results is reliant on, and potentially biased by, the clinician's experience.

Despite these limitations, the RCOG suggests its use where facilities are available to aid decision-making regarding subsequent delivery after an OASI (GTG no. 29).(37) However, a recent UK study of 104 hospitals revealed that less than half had follow-up clinics dedicated to those having sustained perineal trauma, or routinely used physiological testing (both ARM and EAUS).(153) This highlights that even with a consensus on markers of functionality, the availability of such facilities in aiding decision-making remains somewhat of a postcode lottery.

1.3.8.2 Endoanal Ultrasound

Considered the cornerstone of anal imaging and gold standard for evaluating anal sphincter pathology, EAUS is a simple, replicable and well-tolerated technology which has significantly increased our understanding of structural defects to the IAS and EAS.(148) Visualisation of sphincter defects is achieved through reflection of ultrasonic waves from the tissues. The level of reflection, or echogenicity, is dependent upon the density of the tissue; hyper- (high reflectivity/density, appears white) or hypoechoic (low reflectivity/density appears black).

EAUS can distinguish between six distinct anatomical layers (see also Figure 7):

1. Hyperechoic: interface with the hard cone of the ultrasound probe
2. Hypoechoic: anal mucosa
3. Hyperechoic: sub-epithelial tissues
4. Hypoechoic: internal anal sphincter (IAS)
5. Hyperechoic: longitudinal muscle
6. Mixed echogenicity: external anal sphincter (EAS)

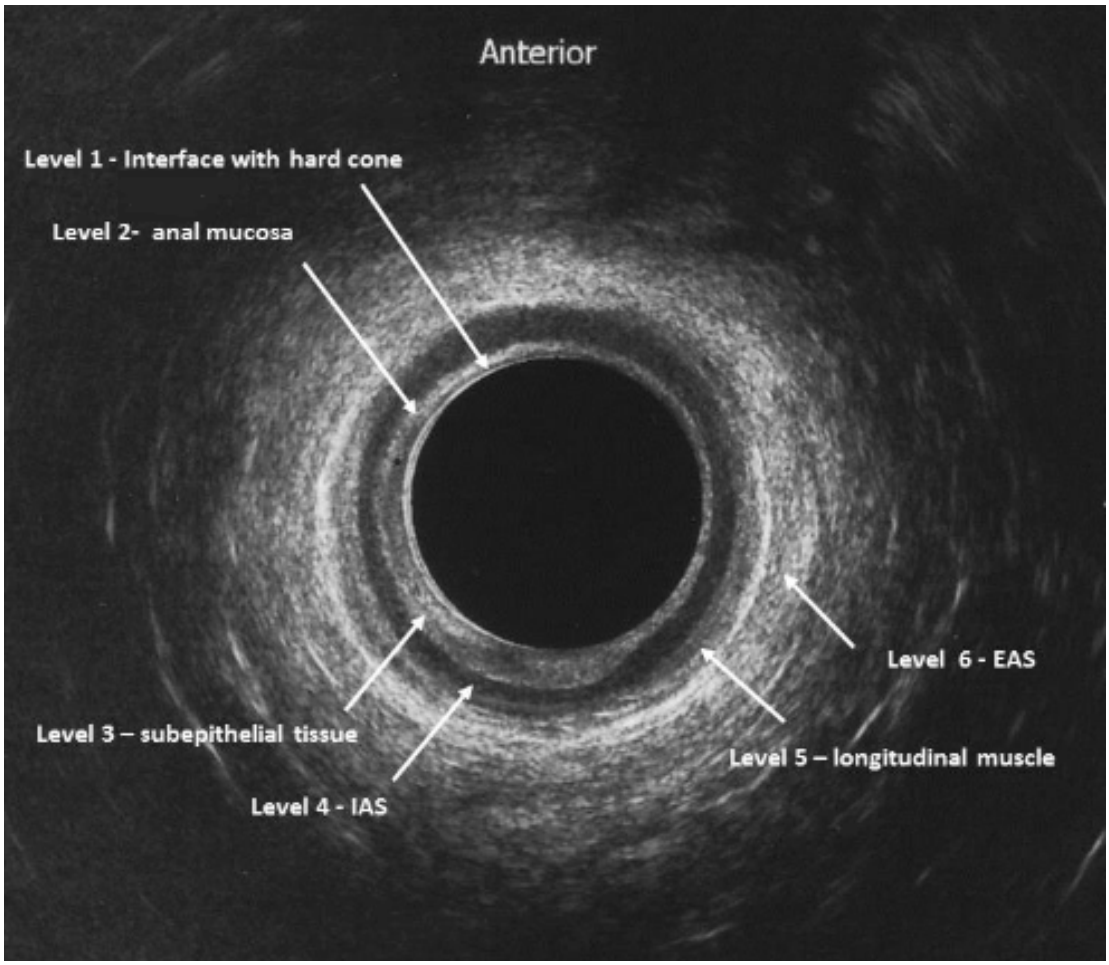

Figure 7: EAUS - six distinguishable anatomical layers

(Permission to reproduce kindly given by Dr S Webb, University of Birmingham.)

Although it has been said that EAUS has radically altered the understanding of the pathogensis of faecal incontience, it of course operator dependent.

Abnormalities to the sphicters can be seen through a cross-section view of the canal and are described according to a clock face (e.g. defect between 12 o'clock and 2 o'clock). Presence of a defect to the sphincter complex in symptomatic patients can help guide clinicians regarding mode of subsequent delivery. When performed by experienced operators, this investigation has both high sensitivity and specificity for the detection of defects.(154) However, false positive findings have been described; in a study where EAUS detected sphincter defects in a control population who had only ever delivered via caesarean section.(46) Furthermore, the clinical relevance of finding a defect in the absence of symptoms (an 'occult' injury) can be a challenge to interpret (see also 1.3.2.1) .

1.3.9 Changes in anorectal physiology associated with an OASI

EAS

EAS is a striated muscle under voluntary control and damage to the structure is associated with reduced voluntary squeeze pressures and symptoms of faecal urgency (see Figure 8). A defect or excessive scarring is demonstrated by a hypoechoic area which can be partial or full thickness (see Figure 9).

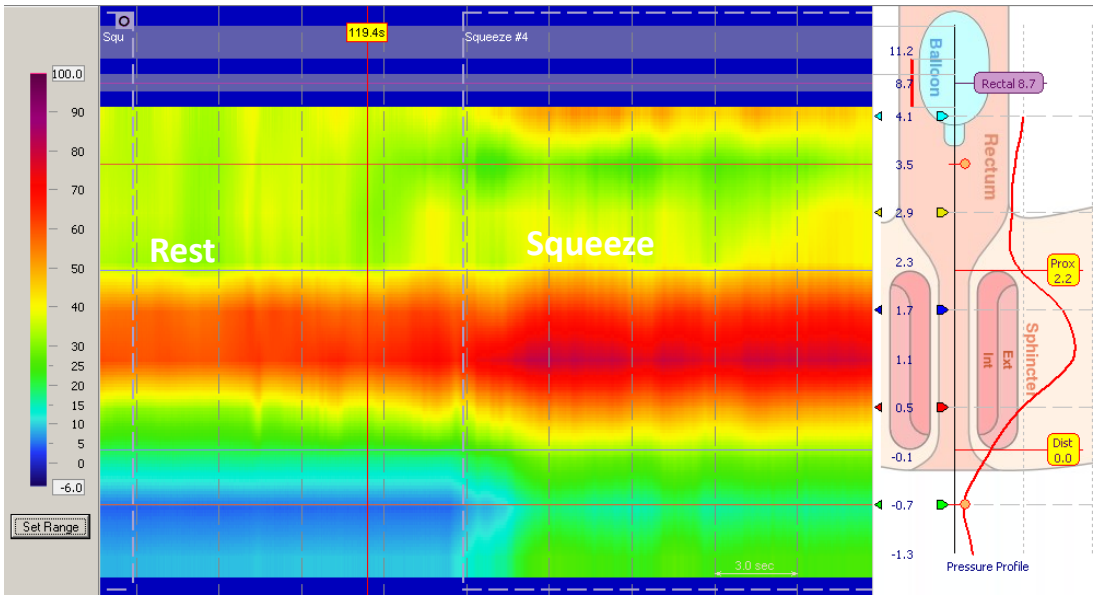

Figure 8: Anorectal manometry changes associated with an EAS defect. Failure to produce an effective squeeze pressure in a patient with an EAS defect and symptoms of urge incontinence. (With thanks to Miss K. Nugent)

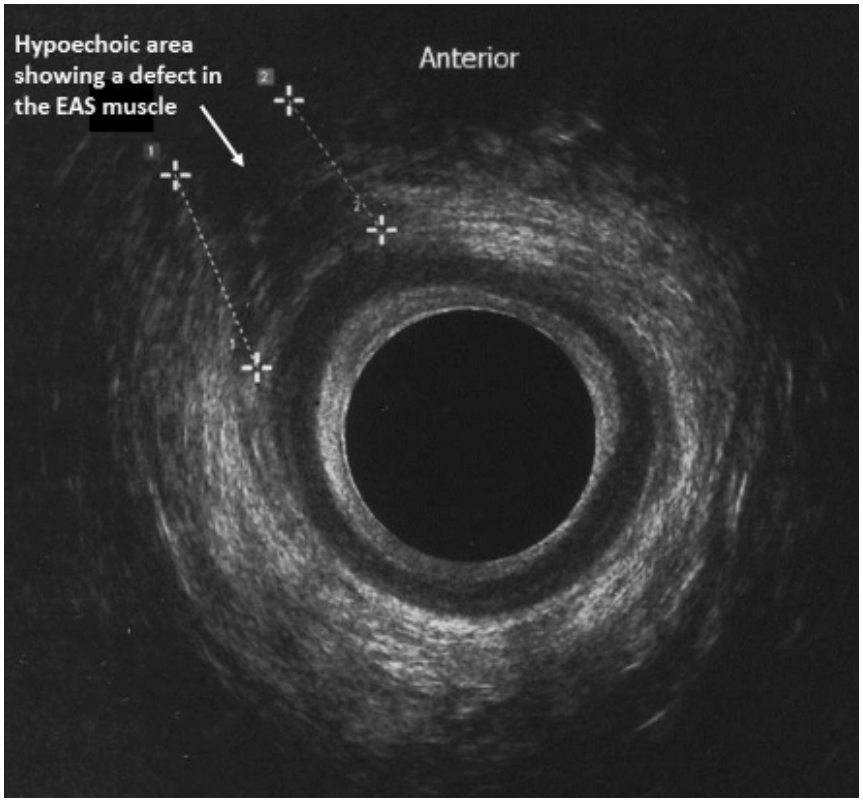

Figure 9: EAUS changes associated with an EAS defect. (With thanks to Dr S. Webb)

IAS

IAS is an involuntary, smooth muscle, and is responsible for most of the anal sphincter resting tone. Therefore, weak anal resting pressures can indicate damage to the IAS causing symptoms of passive soiling and flatal incontinence (see Figure 10). A defect is demonstrated by a hyperechoic area in the vicinity of the muscle damage and sometimes a thickening where the damaged ends retract (see Figure 11)

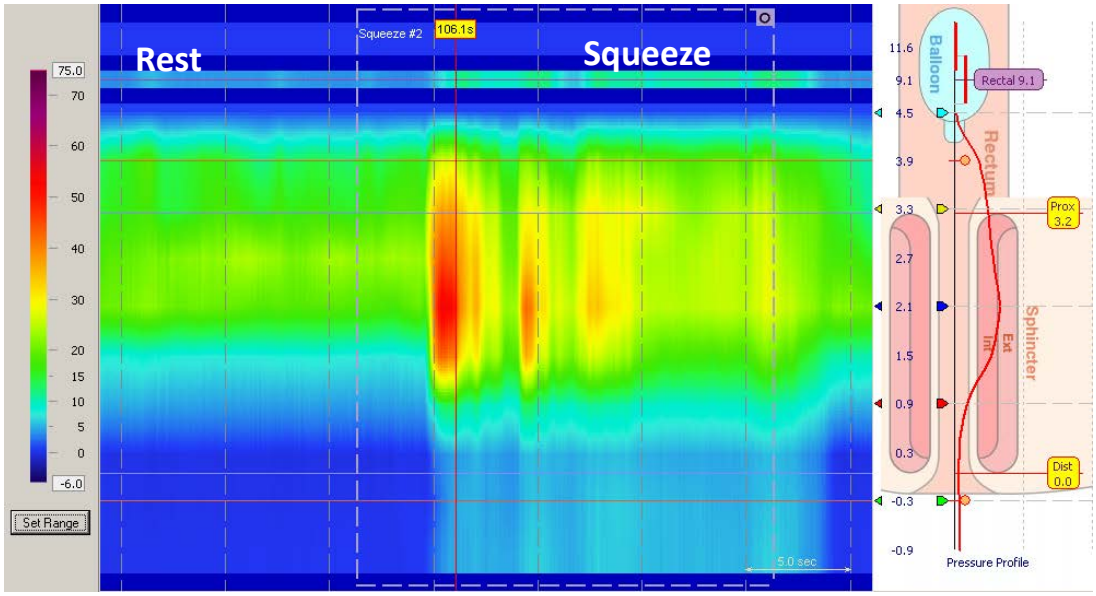

Figure 10: Anorectal manometry changes associated with an IAS defect. Poor resting tone and ineffective squeeze pressures in a patient with passive incontinence and urge incontinence (double sphincter defect). (With thanks to Miss K. Nugent)

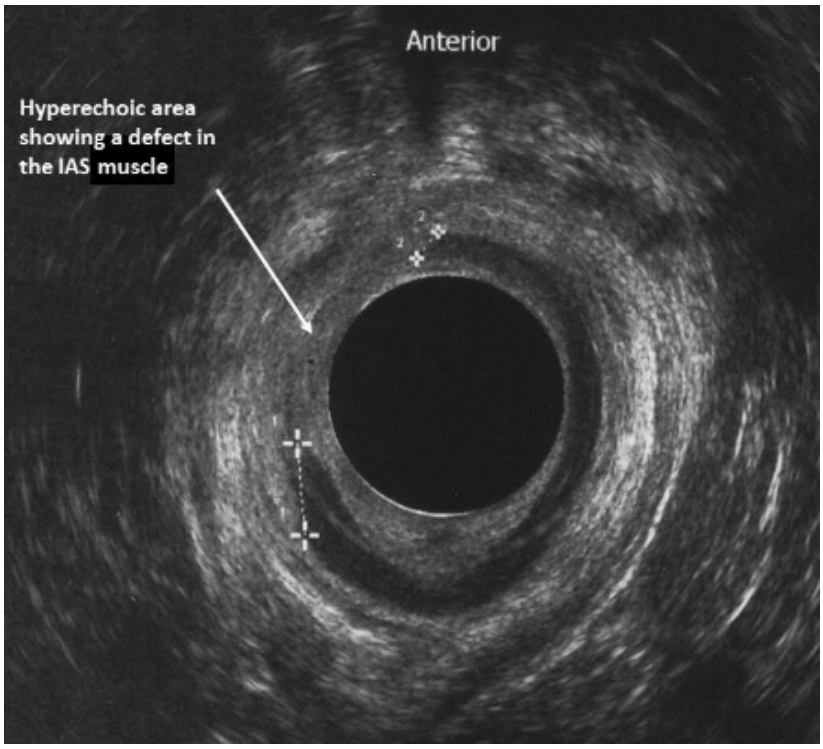

Figure 11: EAUS changes associated with an IAS defect. (With thanks to Dr S. Webb).

1.4 Symptoms of Pelvic Floor Dysfunction (PFD)

About a quarter of women are affected by PFD, with a lifetime risk of surgery for this problem 10-20%.(155) Direct and indirect mechanical and neurological trauma to pelvic floor structures at the time of vaginal childbirth are the main contributors in the development of symptoms of pelvic floor dysfunction (PFD). Trauma is incurred through the stretching, and occasional tearing, of the perineal, levator ani and anal sphincter muscles, the endopelvic fascia and the nerves supplying the perineum and pelvic organs.(156)

However, the presence of an intact perineum at vaginal childbirth or delivering via caesarean section are not indicative of an in absence of pelvic floor damage.(157) Sigurdardottir et al. found reduction in PFM strength and endurance ($p<0.001$), when comparing primiparous vaginal squeeze pressures (hectopascal, hPa) at 22 -26 weeks gestation with 6 – 12 weeks postpartum. Reduction in PFM strength was seen regardless of mode of delivery, although CS resulted in a significantly smaller reduction when compared with NVD (20.1 vs. 5.2 hPa, $p=0.028$) and more so OVD (31.4 vs. 5.2 hPa, $p=0.003$).(158) The aetiology for PFD is multi-factorial; other factors in addition to childbirth influence the incidence. These include genetic background, nutrition, medical co-morbidities and hormonal changes associated with pregnancy.(159-161) Age and parity further potentiate symptoms of PFD.(162, 163)

PFD incorporates a spectrum of conditions affecting the pelvic organs including; anal and urinary incontinence, pelvic organ prolapse and sexual dysfunction. Disclosure of symptoms to medical professionals is often difficult and complex as symptoms of PFD can be embarrassingly debilitating, not only impacting women physically but with additional negative consequences on psychological and social wellbeing. Unsurprisingly, the symptoms are commonly underreported and therefore under-recognised. To gauge the effect that the symptoms have on QoL, and hence the necessity for treatment, clinicians often use validated questionnaires (see 1.4.4 and Chapter 1).

1.4.1 Anal Incontinence

Anal incontinence (AI) is defined by the International Urognaecological Association (IUGA) and International Continence Society (ICS) as ‘the involuntary loss of faeces or flatus’(164), and it occurs due to disruption in the mechanism maintaining continence (see 1.1.3).

Direct anatomical damage obviously increases the risk of AI but is not the only causative factor, as AI affects women with less severe perineal trauma not directly affecting the sphincter muscles.(165) Denervation injuries to the pudendal nerve, and subsequent prolonged nerve latencies, have also been associated with AI.(166, 167) This nerve is particularly vulnerable to compression by the fetal

head as it curves round the ischial spine and enters the tight fibrous sheath of the Alcock's canal.(168) This may be potentiated by infant macrosomia, prolonged second stage and operative vaginal delivery – all independent risk factors for AI.(26, 169)

A pooled meta-analysis revealed OASI to be directly associated with AI (OR 2.66 (95% CI 1.77-3.98), p=0.002),(170) with a prevalence of defecatory symptoms two to three times greater when compared to women without anal sphincter injuries (47 – 61% vs. 13 – 22%).(26, 143, 171) A large Dutch follow-up study showed a worsening in prevalence of symptoms over time regardless of initial injury; 38% and 61% reported in the OASI cohort and 16% and 22% in the control comparison group, at fifteen and twenty-five year post index delivery, respectively.(172) The long-term probability of AI and faecal urgency following an OASI is reported to be as high as 53 – 80%.(163, 173) Furthermore, the severity of OASI determines the long-term prevalence of AI. Those with a 4th-degree OASI are more likely to have worse symptoms of AI (58.8% vs. 41.0%, aOR 2.14, 95% CI 1.52 – 3.02, p<0.001), FI (30.6% vs. 14.6%, aOR 2.49, 95% CI 1.73-3.56, p<0.001) and QoL due to AI (41.2% vs. 27.6%, aOR 1.59, 95% CI 1.12-2.25, p=0.009).(174) It is unsurprising that those with a 4th-degree OASI are there more likely to have a subsequent CS (50.6% vs. 22.35, P<0.001). (174) Other studies have supported this finding, concluding that integrity of the IAS has the most influential role in maintaining continence and resultant QoL.(27, 28, 175) Furthermore, QoL with regard to the bothersome effect of AI was significantly worse in those with OASIs compared with a control cohort (adjusted for compounding factors; aOR 2.87 (95% CI 1.11-7.38), p=0.03).(176) Although those having sustained an OASI are more likely suffer long-term AI and the resultant negative impact on QoL, these are not dependent on the injury as women delivery via NVD, but without OASI, and elective/pre-labour CS are also susceptible to these issues (EPIQ Anal incontinence score ≥22.8 (indication of increased severity of symptoms) 19% of OASI cohort versus 10% NVD and 9% CS control comparisons, p=0.011).(165, 173)

AI symptoms do still persist despite immediate primary repair of OASI by clinicians with adequate training, thus highlighting primary prevention as the strongest preventative measure against the development of AI.(175, 177, 178)

The impact of a repeat OASI on long-term symptoms of AI is explored in section 1.6.2.2.

1.4.2 Urinary Incontinence

Urinary incontinence (UI) is defined as 'the complaint of the involuntary loss of urine'.(179) Although unclear, the mechanism by which women develop UI in pregnancy and childbirth is likely to be multifactorial. It may be as a result of pudendal nerve damage, shortening and reduction of

the close pressures of the urethra, changes to tensile properties of the connective tissues supporting the bladder neck or injury to the levator ani muscles.(168)

The EPINCONT study compared the prevalence of UI in nulliparous women, with women who had a vaginal delivery (VD) or CS. Women delivering vaginally were at highest risk of UI; 2.3- and 1.7-times the nulliparous and CS cohorts, respectively (21.0% vs. 10.1% and 15.9%, age-adjusted OR 2.3 (95% CI 2.0 – 2.6) and 1.7 (1.2 – 1.9), respectively). Those delivering by CS were at a 1.5-fold risk of UI when compared to the nulliparous population (10.1% vs. 15.9%, age-adjusted OR 1.5, 95% CI 1.3 – 2.1), which suggests that the pregnancy itself predisposes toward developing UI. This potential 'protective' effect of CS against UI in comparison with VD dissipated with age, there being no association between incidence of UI and mode of delivery beyond 50 years of age.(180) Furthermore, in a 12-year longitudinal cohort study, Mac-Arthur et al. found women who delivered exclusively by CS to be less than half as likely to develop UI as those that exclusively had VD (OR 0.42 (95% CI 0.33 – 0.54). No difference was seen when comparing those delivering exclusively by VD with those with a combination of VD and CS (OR 1.01 (95% CI 0.78 – 1.30). Persistent UI was associated with advance maternal age at first birth, greater parity and increased body mass index.(181) Boyles et al. suggested that the risk of developing UI is associated with the actual delivery as CS after labour and/or pushing was not associated with increased risk of postpartum UI in comparison with those having an elective CS.(182) Furthermore, a recent systematic review and meta-analysis of the long-term risk and benefits associated with CS concluded that CS reduced the risk of UI by 44% when compared with vaginal birth (OR 0.56, 95% CI 0.47-0.66, $p<0.001$).(183)

Studies reviewing a possible association between UI and OASIs showed no relationship in later life, but in the immediate postnatal period UI was more common in women with an OASI.(143) This may however be compounded by other risk factors, such as operative vaginal delivery and prolonged second stage. Longer-term studies showed no difference in UI comparing control and OASI cohorts.(184)

1.4.3 Pelvic Organ Prolapse

Pelvic organ prolapse (POP) is a common condition, present in approximately 12% of the female population and carries a 19% lifetime risk of requiring surgical management.(155, 185)

Direct levator avulsion or neuronal denervation injuries, secondary to the combined effect of fetal head descent and maternal expulsive forces at active second stage and crowning, enlarge the levator hiatus and predispose women to developing POP.(168, 186) Around half of the parous population have a degree of levator ani avulsion; 15% are symptomatic.(187) Pregnancy is an independent risk factor for POP as the hormonal and mechanical effects of pregnancy on the gravid

uterus contribute to change in the pelvic organ support. Other factors, including age and collagen integrity, also predispose POP, and around 2% of nulliparous are symptomatic of POP.(187)

A recent meta-analyses have revealed that forceps delivery is a strong risk factor for levator ani avulsion when compared with vacuum extraction (OR 4.57, 95% CI (3.21-6.51, p<0.001) and more so NVD (OR 6.94, 95% CI 4.93-9.78, p<0.001). Although not statistically significant, an avulsion is 1.3-fold more likely following a vacuum extraction compared with a NVD (95% CI 1.00-1.72, p=0.051).(188) CS is protective against POP (OR 0.29, 95% CI 0.47-0.66, p<0.001).(183)

1.4.4 The Use of Symptom Scores and Questionnaires in Evaluating the Impact of Symptoms of PFD

Symptoms of PFD can be distressing and embarrassing to talk about. As such, eliciting information during a clinical consultation can be difficult and can result in non-disclosure. Self-completed questionnaires have been shown to be an effective means of obtaining sensitive information. One study showed a 10.7% increase in disclosure of symptoms of AI by questionnaire compared with direct questioning by a clinician (26.0% vs. 15.3%).(189)

Disease processes affecting the pelvic floor present a continuum rather than discrete set of symptoms, and the clinician is required to bring objectivity to otherwise subjective symptoms. Furthermore, it is both useful and important for the clinician to have a gauge on the impact such symptoms may have on QoL. Scoring systems and the completion of self-directed questionnaires can be an effective way of providing an objective measure of disease severity. Although unfortunately commonly inversely related, a questionnaire's longevity in clinical practice is subject to two factors – simplicity and accuracy. A balance is required, so that a questionnaire can be easy to use but also provide enough meaningful information to be useful.(190)

A valid questionnaire, with good psychometric properties, is one that clearly links questionnaire items to the construct it intends on assessing ('construct validity'). Otherwise, it may lead to wrong interpretation, bias, and in the clinical setting potentially unsafe information. It is therefore of great importance that the validation process ensures the data gained from the questionnaire not only adequately meets its objectives, but does so regardless of who responds, when they respond and to whom they respond.(191, 192) There are a number of stages in the validation process, including; face validity (readability, clarity, layout, feasibility), content validity (review of relevance by experts with knowledge of the construct being assessed) and construct validity (to ensure sufficient variation between items to justify their usefulness in addressing the objective). A questionnaire is also required to undergo scrutiny regarding its reliability – the ability to create reproducible, stable and consistent results. This is achieved through assessing stability (via 'test retest' – same results

by the same person at different times), internal consistency (via the 'split half method' – homogeneity between subparts of what is being measured) and equivalence ('inter-rater reliability' – two observers simultaneously study the same phenomenon/ agreement between raters).(193)

The following is an explanation of the symptoms scores and QoL questionnaires that were used to evaluated symptoms of PFD in the study "Pelvic Floor Symptoms Questionnaire Study" (Chapter 6

Cleveland Clinic Incontinence Score (CCIS)

The Cleveland Clinic Incontinence Score (CCIS), also known as the Wexner Scale, was developed by Jorge and Wexner in 1993. Although never formally validated, this simple score is useful in the assessment of type and severity (frequency) of AI. It permits an objective comparison of levels of incontinence in different people groups. Although not an official QoL tool, it does consider the extent to which symptoms alter a person's life and has achieved global popularity due to being both simple to use and accurate in the information it provides. For these reasons we too decided to include it in our study. The authors advocate its use alongside a more detailed questionnaire to develop on the general overview this score provides.(194)

Fecal Incontinence Quality of Life Scale (FIQL)

Fecal Incontinence QoL Scale (FIQL), is a QoL measure is specifically designed to take into account the overall impact a condition has on all aspects of life and to assess the effectiveness of treatment for FI. The 29-itemed QoL score is composed of four scales: lifestyle (10-items), coping/behaviour (9-items), depression/self-perception (7-items) and embarrassment (3-items), which overall give an indication of wellbeing regarding the possible imposition caused by FI. Demonstrating stability over time, these scales are both reliable and valid. Used globally, it has successfully been translated into 11 languages.(195)

In a comprehensive review of the scientific appropriateness and robustness of questionnaires assessing symptoms of AI, Avery et al. did not find any which met the 'Grade A (Highly Recommended)' classification using the International Consultation on Incontinence Committee standardised recommendation grades. To achieve this, a questionnaire should demonstrate validity, reliability and responsiveness. Three met 'Grade B (recommended)' status including; FIQL, Manchester Health Questionnaire (MHQ) and Birmingham Bowel and Urinary Symptoms Questionnaire (BBUSQ-22).(196-198) Although the MHQ was designed specifically for female patient, we decided to use the FIQL in our study as this is the tool used by clinicians at University Hospitals Southampton NHS Foundation Trust (UHS NHS FT). Furthermore, a recent review of responsiveness and interpretability of incontinence severity scores and FIQL concluded that, although none of the available instruments in the assessment of QoL in FI attain the greatest level

of psychometric soundness, the CCIS is most suitable for assessment of severity and FIQL for evaluating quality of life.(199)

International Consultant on Incontinence Questionnaire – Urinary Incontinence (ICIQ-UI)

ICIQ-UI is one of 19 questionnaires created by an organisation (The International Consultation on Incontinence Questionnaire (ICIQ)) with the goal of producing universally applicable questionnaires in both clinical and research settings. The purpose of the brief yet robust ICIQ-UI is to explore the symptoms and impact of urinary incontinence. It has now been translated into 45 languages. The questionnaire is specific to, but not exclusively concerning, complications secondary to pregnancy and childbirth. We decided to include this questionnaire in our study, as although it deviates from the focus on symptoms relating to damage to the anal sphincters muscles, we thought it would be interesting to assess whether symptoms experienced by those suffering an OASI exclusively impacted those muscles or whether an overall impact on pelvic floor is observed.(200)

Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire –12 (PISQ-12)

PISQ-12 evaluates sexual function in women with UI and/or POP.(201) It is reliable, validated shortened version of PISQ-31, which was created after recognition that there were no condition-specific, reliable, validated tools available to evaluate the impact of therapies treating diseases gynaecological diseases on sexual function.(202) Specific areas addressed by the questionnaire are the impact of gynaecological conditions on their behaviour, physical condition and their partner.

Although not specific to OASI, we saw the importance of including this questionnaire in our study when recognising the possible and probable impact of an anal sphincter injury on sexual wellbeing (see also 1.5.1). This especially so considering these injuries occur relatively early on in a woman's sexual journey and they may wish to have further children.

1.5 Other impacts of perineal trauma on health and wellbeing

In addition to symptoms of PFD, there are a whole host of other symptoms or problems which may result from sustaining significant perineal trauma.

1.5.1 Sexual Function After Delivery

Postpartum sexual dysfunction is a multifaceted condition concerning many aspects of sexuality, such as sexual desire, arousal, orgasm and dyspareunia (pain during sexual intercourse). Its prevalence ranges between 22 and 50% of all women, but only 15% of women report the problem to their doctor.(203, 204)

Women who sustain an OASI resume sexual intercourse later (average 9.3 vs. 7.1 weeks postpartum) and on resuming, have less frequent sexual activity than those with less severe perineal trauma.(172, 205) Women sustaining an OASI are more than five times more likely to postpone first intercourse after delivery than those with an intact perineum (aOR 5.52, 95% CI 1.59 – 19.165).(206) Dyspareunia is reported more frequently in those with an OASI than those without (29% vs. 13%, p=0.01); a difference which is still observed 15 years after delivery.(14, 172) Furthermore, OASI is the only significant predictor for dyspareunia at one year postpartum (aOR 3.57, 95% CI 1.39 – 9.19).(206) AI during sexual intercourse is, unsurprisingly, more prevalent (13% vs. 1% of controls, p=0.005).(172)

Perineal pain

Persistent perineal pain and/or dyspareunia are the result of excessive scar tissue formation or poor alignment of tissues, which may require reconstructive surgery.(172) A UK-based prospective cohort study revealed that 92% of women experience perineal pain on the first day postpartum, but in nearly 90% this will have resolved by two months.(207) Although few studies have assessed the effect of anal sphincter injuries on postpartum discomfort, the general consensus is that those following an OASI more frequently suffer from postpartum perineal pain than those with intact perineum, episiotomy or less severe spontaneous trauma. This was observed in the immediate-term (1-10 days) and mid-term (2-3 months) postnatal periods.(14, 207, 208)

1.5.2 Psychological aspects

Perineal trauma related to childbirth can have a negative impact on self-identity and confidence, leading to strains on relationships and the increased potential for postnatal depression.(209) Unexpected injury at childbirth and the associated complications can subsequently result in a more stressful postpartum period, lead to isolation and also the feeling of being devalued.(210) Due to

the fear of rejection or being perceived as not coping or fulfilling their role as a mother or partner, women often are too embarrassed to make even those close to them aware of their struggles.(211) This highlights the importance of midwives and doctors in remaining supportive and vigilant in ensuring that these potentially unspoken about feelings are discussed so the right steps are made to aid psychological recovery and the regaining of self-confidence.

Body image

Body image has an important relationship with both physical and psychology aspects of wellbeing, impacting levels of self-esteem and depression, as well as sexual function and QoL relating to other medical conditions. Sustaining perineal trauma can also influence dissatisfaction in body image. However, this is a complicated subject as several factors interplay to give an overall view of self, not just the resultant physical effect of the trauma.

In a qualitative study of 422 women having sustained an OASI, more than half had perceived a change in body image. Lower self-esteem and change in personality were reported in 18.9% and 17.7%, respectively. A third felt less attractive. Interestingly, the perceived change was strongly associated AI (OR 1.97, 95% CI 1.16-3.36, p=0.013) and forceps delivery (OR 2.59, 95% CI 1.23-5.43, p=0.012), therefore relating more to genital anatomy due to the delivery, rather than their overall view of body image. However, the results may be skewed as participants were recruited for the study from a dedicated perineal clinic attended by those more likely to have been suffering with physical and psychosocial problems than the approximate 30% non-attenders.(212)

Fear of subsequent delivery

It is unsurprising that women who experience severe perineal trauma or suffer the associated complications can feel anxious or frightened, leading them to delay or even prevent subsequent future pregnancies.(53, 209, 212) Fear of recurrence of injury, or the circumstances in which the injury was incurred, may lead to the decision for an elective caesarean section (ElLSCS) in the absence of any pathophysiological indication.(213)

Women end up in a mental conflict between fear of repeat trauma, with the associated physical and psychological effects, and the need for empowerment and fulfilment which comes with a further delivery.(211) This is why provision of comprehensive, comprehendible information in the early postnatal period to ‘debrief’ the women is of utmost importance to help alleviate fears and to aid women in regaining control and empowerment.

1.5.3 Financial and legal implications

The psychological and physical impact of perineal trauma can last well beyond the early postpartum period. Prolonged healing, as well as symptoms secondary to perineal trauma and resultant complications of childbirth, can have significant personal financial implications. This could be due loss of earnings secondary to delays in returning to work, time out to attend hospital appointments, or job losses due to the inability to return to work as the ability to complete every day duties are compromised. Women may have to stop work altogether due to constraints of the symptoms they experience.(214)

Currently occurrence of OASI is not considered 'substandard care' as it is a recognised known complication of vaginal childbirth. The NICE CG190 states that *"If genital trauma is identified after birth, offer further systematic assessment, including a rectal examination."*.(17) Failure to thoroughly examine, identify an injury or carry out an adequate repair, leading to potential resultant incontinence or fistula formation, is considered 'substandard care'.(37) In the previous decade there were 441 claims of negligence in England arising out of obstetric perineal trauma. This was the fourth highest number of claims in obstetrics; estimated to cost £31.2 million. Misdiagnosis of perineal trauma related to 85% of the cases, which demonstrates the importance carrying out and documenting rectal examination following vaginal delivery.(215, 216)

Depending on the extent of the injury and effectiveness of the primary repair, an OASI can also have a serious financial impact on the NHS regarding the ongoing patient journey, including diagnostics, follow-up appointments, physiotherapy, and ongoing medical and surgical treatments. However, hidden beneath the financial burden is the greater impact on QoL i.e. lifelong suffering of the individuals and their families.

1.6 Subsequent Delivery following previous OASI

1.6.1 The Risk of Recurrence of OASI

The RCOG guideline on the management of OASIs quotes a recurrence rate of 5 – 7%.(37) The NICE guideline on Intrapartum Care (written 2007, revised 2014 and 2017) statement 1.13.16, advises clinicians to inform women that the "*risk of repeat severe perineal trauma is not increased in a subsequent birth"*, however this was based on a comparison with primpara rather than other multiparous women.(17)

A recent global systematic review and meta-analysis revealed a rOASI of 6.8% (2.0 – 19.3%), with OVD (forceps OR 3.12; 95% CI 2.42 – 4.01 and vacuum extraction OR 2.44; 95% CI 1.83 – 3.25), previous 4th-degree tear (OR 1.7; 95% CI 1.24 – 2.36) and birth weight of successive infant >4Kg (OR 2.29; 95% CI 2.06 – 2.54) identified as risk factors for recurrence.(217) Birth weight >5Kg carried an even greater risk of recurrence (aOR 7.9; 95% CI 4.7 – 13.3).(218) Edozien et al. additionally found Asian ethnicity (aOR 1.59 compared with White women; 95% CI 1.48–1.71) and shoulder dystocia (aOR 2.92; 95% CI 2.59–3.28) to be associated with an increased risk of rOASI.(53) Jangö et al. also found, in addition to the above factors, shoulder dystocia, previous OVD and a longer delivery interval between first and subsequent birth to be associated with an increased risk of rOASI. Furthermore, those who had a fourth-degree tear at initial vaginal delivery were not only more likely to have a subsequent elective CS, but also a rOASI if they had a subsequent VD (50.6% vs. 22.3% ($p<0.001$). A greater proportion of those who had an initial fourth-degree tear had a rOASI compared with those with a previous third-degree tear (6.8% vs. 10.7%, but $p=0.09$).(174, 219) Chapter 4 will develop on these findings.

The use of elective episiotomy in the prevention of rOASI is a little less clear. The aforementioned meta-analysis showed no association, however there was significant heterogeneity of the data pooling (I^2=89%) and results were therefore subject to significant confounding bias such as the episiotomy technique used.(217) One recent UK-based cohort study has shown a potential protective effect of MLE against rOASI (aOR 0.66; 95% CI 0.58–0.75), whereas a Danish found no association between recurrence of injury and the use of MLE.(53, 97)

The NICE guideline on Intrapartum Care also states in point 1.13.18 *"Do not offer episiotomy routinely at vaginal birth after previous third- or fourth-degree trauma."* Furthermore, the RCOG's GTG no. 29 "The Management of Third- and Fourth-Degree Perineal Tears" recognises a paucity of evidence as *"There are no studies to suggest that prophylactic episiotomy in the subsequent delivery would prevent [a rOASI]."*(37) It would therefore be of interest to address this area of uncertainty. See 'Thesis Aims' 1.9, Chapter 4 and Chapter 5 .0

1.6.2 The Impact of Subsequent Delivery

1.6.2.1 Subsequent VD vs. no subsequent birth – Symptoms of AI

The cumulative effect of subsequent vaginal delivery on pudendal-nerve damage, and resultant symptoms of PFD and deterioration in anorectal manometry, is well recognised.(220-222) This phenomenon is seen regardless of whether an OASI was sustained at index delivery. Poen et al. found subsequent delivery after an OASI increased risk of AI by 17% when comparing anorectal function with a control population without subsequent delivery (56% vs. 34%, RR 1.6 (95% CI 1.1-2.5), p=0.025).(222) Furthermore, deterioration is related to severity of the initial injury.(146, 223) Surprisingly, even asymptomatic women who have signs of damage on anorectal physiology (manometry squeeze increments less than 20mmHg and EAUS defect greater than one quadrant) are at significantly greater risk of developing symptoms after a subsequent vaginal delivery.(220)

A recent meta-analysis demonstrated no significant difference in reported AI when comparing those who had a subsequent delivery after an OASI with those who did not (n=562; OR 1.25, 95% CI 0.73 – 2.15). However these data were significantly confounded by study sample size, quality and statistical heterogeneity, leading to the conclusion that in the absence of higher quality evidence the current RCOG recommendations for subsequent delivery (see 1.7) should not be changed.(224)

1.6.2.2 Subsequent rOASI vs. no recurrence - Symptoms of AI

Jangö performed a postal questionnaire of 1490 women who had two vaginal deliveries between 1997-2005, all of which had an OASI at the first delivery. Comparisons of long-term (more than five years after subsequent delivery) symptoms were made between those with a rOASI and those without a recurrence. Those with a rOASI had greater prevalence of long-term AI (50.0% vs. 37.9%, p=0.02). The same was seen for symptoms of faecal urgency (41.5% vs. 26.6%, p=0.002), as well as an increased risk of urgency in those without AI before the subsequent pregnancy (aOR 2.58, 95% CI 1.52-4.37, p<0.001). After adjusting for possible confounding factors, including whether AI was present prior to subsequent pregnancy, Jangö et al. found that long-term the risk of flatal and faecal incontinence was increased in patients with a rOASI compared with those without a recurrence (aOR 1.68, 95% CI 1.05-2.70, p=0.03 and aOR 1.98, 95% CI 1.13-3.47, p=0.03, respectively). These findings therefore indicate women should be informed that a recurrence increases the risk of AI-related symptoms, which should be weighed against the potential maternal and fetal risks associated with CS.(219)

1.6.2.3 Subsequent vaginal birth vs. ElLSCS – Symptoms of AI

Accurate information is necessary to appropriately counsel women regarding long-term outcomes and the mode of subsequent delivery. Unfortunately, only low-level evidence is available to aid development of guidelines due to the limitations associated with retrospective study designs and the unfeasibility of random allocation of either vaginal delivery or ElLSCS at subsequent delivery. Furthermore, assigning a delivery mode would need to be irrespective of persistent symptoms of AI in order to provide information purely assessing the effect or not of both options.

Although ElLSCS protects against rOASI, it is uncertain how the subsequent delivery affects the risk of long-term AI. Meta-analysis of previous studies has not shown ElLSCS to be protective against de novo AI or worsening of symptoms after subsequent delivery in women with previous OASI (n=195; OR 0.61, 95% CI 0.20 – 1.90). However, this analysis too was subject to significant statistical heterogeneity and poor small size.(224)

Jangö et al., in a population-based cohort study via a postal questionnaire survey, compared symptoms of AI in those having a subsequent NVD versus those with a CS. Although the incidence of AI prior to subsequent delivery after an OASI was lower in the NVD cohort compared with the CS cohort (29.8% vs. 53.2%, respectively), a greater deterioration of symptoms was observed in those having a subsequent NVD compared with those having a subsequent CS (9.5% vs. 3.0%, respectively). However, when adjusting for important maternal and obstetric characteristics, a subsequent CS did not significantly lower the risk of long-term AI (aOR 0.77, 95% CI 0.57-1.05, p=0.09) or faecal incontinence (aOR 1.04, 95% CI 0.76-1.43, p=0.79). Unsurprisingly, women with persistent symptoms prior to the second pregnancy had increased risk of long-term anal (aOR 64.70; 95% CI 42.85 – 97.68, p<0.001) and faecal (aOR 13.76; 95% CI 10.03 – 18.88, p<0.001) incontinence. They concluded that although a subsequent NVD is associated with higher risk of deterioration in symptoms, the most important predictors of long-term AI was the injury at the initial delivery.(225)

It is however also important to recognise that although CS may result in less severe deterioration in symptoms in those with previous OASI, there are conditions for which a CS will not protect again the deterioration (such as, Irritable Bowel Syndrome and constipation with overflow). Clinicians therefore need to be clear on the symptom aetiology by ensuring they have adequate information from the patient history, examination and relevant physiological testing to aid differentiation between these conditions as the cause for symptoms versus the resultant effect of an OASI.

1.6.2.4 Subsequent vaginal birth vs. ElLSCS – QoL

Very few studies have successfully investigated the impact of subsequent birth after an OASI on QoL. Scheer et al. found significant impact on QoL regarding incontinence impact (p=0.012), emotions (p=0.003) and symptom severity measures (p=0.032) for women who had a recommended ElLSCS compared with women who had recommended subsequent vaginal delivery. However, this was not adjusted for indication for which the ElLSCS was recommended; most probably due to substantial compromise in anal function.(226)

1.6.2.5 The need for further research

It would be interesting to establish both the objective (quantitative) and subjective (personal) impact that sustaining an OASI has on QoL. It would also be useful to expand upon and add to previous research attempting to establish whether a subsequent delivery, and the mode of that subsequent delivery, further potentiates symptoms of PFD. See 'Thesis Aims' 1.9 and Chapter 1

1.7 Current Guidelines

1.7.1 RCOG guidance on management of subsequent deliveries

Management of subsequent delivery following an OASI remains contentious due to the lack of both subjective and objective evidence regarding outcomes and QoL due to an understandable lack of RCTs. The current guideline recommends that if a *"woman is symptomatic or shows abnormally low anorectal manometric pressures and/or endoanal ultrasonographic defects, an elective caesarean section may be considered"* due to the risk of impaired continence after a subsequent vaginal birth.(37, 220) In the absence an obvious defect on EAUS, asymptomatic women can be allowed a vaginal delivery by an experienced accoucheur.(144)

Women should be counselled antenatally on the increased of risk developing de novo AI and of sustaining a recurrent OASI, which, in that absence of recommendation for ElLSCS, may be reason enough for women to choose ElLSCS.(220) This decision may also in part be influenced by the counselling clinician, as 22% of UK obstetricians and 14% of trainees would recommend an ElLSCS following previous OASI.(136) It is also important to take into account the circumstance by which the injury was incurred, as the psychological impact of that experience will also influence decision making regardless of symptoms or anorectal physiology.

It is imperative that the counselling by clinicians regarding the mode of subsequent delivery is both accurate and clearly documented, especially in view of the potential impact of birth trauma on QoL and resultant clinical negligence claims. A clearer understanding of the maternal, intrapartum and neonatal factors which contribute to the risk of sustaining a rOASI will facilitate accurate provision of information enabling women and caregivers together to make informed decisions regarding future pregnancies and mode of delivery.

1.7.2 Local guidelines

The management of an OASI

In addition to antibiotics, stool softeners, analgesia, the UHS NHS FT 'Perineal Repair Guideline'(227) recommends that following an OASI women are *"given a detailed explanation of what happened*", advised that *"60 – 80% are asymptomatic at 12 months following delivery"* and provided with sign-posting information regarding *"how to seek help in the event of experiencing impaired continence".* Where possible, before discharge patients are also seen by, and given the contact details of, a specialist women's health physiotherapist. Research carried out by Urogynaecologists affiliated with Princess Anne Hospital (UHS NHS FT) revealed the vast majority

of those sustaining a 3a tear to be asymptomatic six months after repair.(228) As a result of this research, and in an effort to streamline resources, those sustaining a 3a tear are reviewed in the community by their GP during their routine six-week postnatal check and are referred back if symptomatic. Those with 3b, 3c or fourth-degree tears have an EAUS at five months postpartum and are reviewed with the results of that scan a month later (six months postpartum). The same referral process is applied to those following a recurrent OASI.

The management of subsequent deliveries

In local guidelines,(227) abnormalities in EAUS and AM are quantified as a defect greater than 30-degrees or greater than one hour on a clockface, and an incremental mean squeeze pressure of less than 20mmHg, respectively. Decision-making regarding subsequent delivery is based on these findings and an individual's symptomatology. The guidelines outline four situations to aid in this decision:

1. If intact sphincters, normal function and asymptomatic – reassurance that repeat VD is unlikely to cause significant deterioration in function.
2. If mild or moderately symptomatic – then EAUS and AM is performed. A CS is recommended if an abnormality is detected as a repeat VD may deteriorate symptoms.
3. If severely symptomatic with abnormalities on EAUS and/or AM, a VD is unlikely to impact her prognosis so a VD can be supported. Referral to colorectal surgeons for possible secondary sphincter repair will be needed once her family is complete.
4. If symptomatic but no abnormalities detected on EAUS and/or AM, in absence of clear evidence regarding worsening of symptoms at subsequent VD, a woman can decide how she wishes to deliver.

This fourth point differs from the RCOG's guidance as the policy makers saw the importance of offering choice to women where, in the absence of any robust data or inability to perform for RCTs, there is lack of clarity as to the impact of a further delivery on symptomatic women with normal test results.

Regarding the use of MLE in the prevention of a rOASI at subsequent VD, the guideline states "*An episiotomy can be used at maternal request if there is a history of previous OASI or if the accoucheur feels a sphincter injury is imminent*.".

1.8 Benefits and Limitations of Database Research

For every research method there are both benefits and limitations. It is important for the researcher to recognise them, in the hope to gain from the benefits whilst curbing the limitations where possible. Several of the aims of this thesis (see 1.9) will be answered through analysis of data collected from NHS Trust maternity databases.

Here are some of the pros and cons of researching by this method.

1.8.1 Benefits of Database Research

Access to a lot of information – A major benefit of database research is the inclusion and processing of information regarding vast populations. Consequently, an increased population size boosts the statistical power, and makes results worthy of publication and wider application with the potential to influence current practice and improve patient outcomes.

Increased productivity – Once compilation of a dataset is complete, having been translated into binary and/or numeral data, this can be transferred to the required analytical programmes to facilitate statistical analysis. Although compilation of the database can be laborious (see point below), once the data is available, the analysis and subsequent answers to the research questions can then be comparably more straightforward to attain.

Data sharing and anonymity – Expansion of datasets to incorporate information for additional sources, e.g. expansion of studies to additional Trusts to corroborate or refute findings, can be done efficiently and whilst maintaining patient confidentiality.

Gaining additional, unforeseen information from a data set – The process of data collection and subsequent analysis can open the researcher up to other opportunities or avenues of investigation, beyond their initial hypothesis or objectives, which may not have been realised before the data was made available. To expand the analysis to accommodate these additional themes can be achieved with relative ease, as the dataset is already available to undergo any necessary statistical analysis.

1.8.2 Limitations of Database Research

Data entry is laborious – To a certain extent, some of the information regarding patient data can be readily derived by database custodians via electronic data extrapolation to set criteria. This can then be repurposed in a formatted spreadsheet ready for analysis. However, data extrapolation only goes so far and not all the data fields can be extracted by this method. Thus, then ensues the time-consuming task of manual data collection from individual records to ensure data entry of all

required information is complete. It can also be somewhat disheartening for the research when in retrospect other data points, which could have been beneficial to the study, have unintentionally been overlooked.

Not all the required information is available – Unfortunately, a researcher is limited by what is recorded on a database. Therefore, when fields are left blank by the clinician completing the patient record, this can result in the study populations being much reduced in comparison to the total number of records available to analyse. Consequentially, this can potentially hinder the usability and credibility of the results. This can happen when using a single database, but also when merging data from other Trusts, as there is variability between different centres' databases.

Subject to human error – Throughout the data collecting process, the information can be subject to inaccuracy and error. From the outset, unbeknown to the researcher, the information could have been entered into the database incorrectly. Furthermore, at data entry data fields can be, intentionally or not, missed entirely and left incomplete. The data is also subject to inaccuracies during the subsequent manual extrapolation of data by the researcher. Methods to help prevent this limitation, such as double data entry or two-pass verification, unfortunately lead to the prolonging of the already arduous task.

1.9 Thesis Aims

The overarching aim of this thesis was to evaluate the risk factors associated with sustaining perineal trauma at childbirth, the subsequent birthing outcomes and the effect of perineal trauma on symptoms of pelvic floor dysfunction. This was achieved by addressing the following objectives:

- To explore what maternal, intrapartum and neonatal factors make sustaining an OASI more likely at normal vaginal delivery in the primiparous population (Chapter 2)
- To assess whether women having VBAC delivery are at increased risk of sustaining an OASI compared to i) multipara who have had a previous vaginal delivery and ii) primiparous women (Chapter 3)
- To evaluate whether specific baseline characteristics and urgency of caesarean at first delivery affect subsequent VBAC outcomes, especially with regard to sustaining an OASI (Chapter 3)
- To investigate subsequent delivery outcomes in women having sustained a previous OASI and establish whether women with a history of OASIS are at higher risk of rOASI than:
    - i) initial primiparous risk
    - ii) other multipara without history of OASI (Chapter 4)
- To explore whether there are any factors which increase the risk of rOASI (Chapter 4)
- To explore factors which influence the risk of rOASI, namely the use of episiotomy (Chapter 5 – an expansion of the previous chapter's findings)
- To assess both the quantitative and subjective personal effect (via free text comments) an OASI has on QoL and symptoms of pelvic floor dysfunction (PFD) (Chapter 1)
- To determine whether having a subsequent delivery impacts upon symptoms of PFD in women who have previously sustained an OASI (Chapter 1)
- To determine whether the mode of delivery at subsequent delivery impacts symptoms of PFD in women who have previously sustained an OASI (Chapter 1)

Chapter 2 Risk Factors for OASI in the Primiparous Population

2.1 Objective

The aim of this study was to explore which maternal, intrapartum and neonatal factors make sustaining an OASI more likely at normal vaginal delivery in the primiparous population

2.2 Methods

2.2.1 Study Design

Data from the University Hospital Southampton NHS Foundation Trust (UHS NHS FT) maternity database (via researcher contact with the Clinical Manager HICSS Maternity Information System) was analysed via retrospective analysis of prospectively collected data.

The sample included all primiparous women sustaining an OASI from January 2004 to December 2015, during a singleton, term (birth at ≥37 week's gestation), cephalic, non-operative vaginal delivery at the University of Southampton NHS Foundation Trust. Comparisons were made with a control group of primiparous women, delivering between January 2014 and December 2015, who had a documented 'intact perineum' with otherwise identical birthing conditions. The study group cohort was 756 and the control group 212. We were unable to match population sizes as we only had authorisation from the database custodians to uses the 2014 – 2015 control data.

As operative vaginal deliveries (OVD) are known to be associated with a higher risk of OASI, those sustaining an OASI at OVD (n=513) were excluded to control for this potential bias.

The following information was included in the data collection:

- Total number of singleton, cephalic, term vaginal deliveries
- From the above number:
    - The total number of primiparous women
    - The total number of OASIs* (to calculate the overall Trust's OASI rate)
- From the total number of OASIs, we extracted only the primiparous women** (from which the primiparous OASI rate was calculated)
- From that final group**, we excluded all operative deliveries (forceps and vacuum extraction) and for each individual case (using a combination of manual and electronic extraction) the following information was sought:
    - Maternal demographics - age, ethnicity, level of education
    - Intrapartum and neonatal factors regarding:

- whether the delivery was post-dates (>40 weeks gestation)
- whether the labour was induced
- the use of epidural anaesthesia
- whether the delivery was in water ('water birth')
- the length of the second stage of labour (minutes)
- the fetal head position (whether occiputo-posterior or not)
- the birth weight (grams)

The same information was extrapolated for the control population.

2.2.2 Statistical Analysis

Women who had multiple, pre-term, non-cephalic or operative deliveries were excluded from the analysis. Data on third- and fourth-degree OASIS were combined. Univariate analysis was carried out comparing maternal, intrapartum and neonatal factors between women sustaining an OASI and the control population. Operative vaginal deliveries (OVD) were excluded from the analysis. Continuous data were analysed using the Mann-Whitney U test, as the Kolmogorov-Smirnov test determined the distribution to be non-parametric. Categorical data was analysed with the Chi-Square test. Binary logistic regression (BLR) was used to calculate the independent odds ratio (OR) for OASI, including factors reaching statistical significance ($p<0.05$). Analysis was carried out using IBM SPSS v.24.

2.2.3 Ethical considerations

As this research was carried out for the maternity department as an audit, and there was no direct patient contact, ethics approval was not required. Only anonymised data were used, so informed consent was not required.

2.3 Results

During the twelve-year period there were 68606 births, of which 52412 were singleton, term, cephalic, vaginal deliveries. 41.2% (21605/52412) of that number were to primiparous women. The overall prevalence of OASI was 3.5% (1841/52412). Just over two thirds (68.9%) of all OASIs were sustained by primiparous women at a rate of 5.9% (1269/21605), which was 3.1-fold greater than the Trust's contemporaneous multiparous rate (5.9% vs. 1.9% (572/30807), difference 4.0% (95% CI 3.7, 4.3)). These figures included all modes of vaginal delivery.

Table 1 shows the univariate analysis of maternal, intrapartum and neonatal factors comparing those sustaining an OASI (n=756) at normal vaginal delivery (NVD) with the control sample (n=212). Women sustaining an OASI were significantly older (median age 28 vs. 24, p<0.001) and had achieved a higher level of education (43.8% graduates from University vs. 24.4%, p<0.001). Significant differences were seen in the frequency of OASI among women of non-Caucasian ethnicity; namely there were 4.9-fold more Asian women sustaining an OASI (14.6% vs. 3.0%p<0.001). Those suffering OASIS had significantly heavier babies (median weight (g) 3500 vs. 3245 p <0.001) with a 3.6-fold greater proportion weighing > 4 kg (10.7% vs. 3.3%, p = 0.001). They were more likely to deliver post-term (57.8% vs.44.3%, p<0.001) and have a longer second stage of labour (median time (min) 62 vs. 35, p <0.001). Epidural anaesthesia was associated with a reduced incidence of OASI (5.6% vs. 13.7% (control), p <0.001), as was giving birth in water (8.9% vs. 15.6%, p=0.005). No significant differences were seen when analysing whether the labour was induced or whether the fetal head was malpresented (whether occiput-posterior (OP) or not).

		Women sustaining an OASI (n=756)	Control group (n=212)	p-value
Age	Median	28 (15 – 45)	24 (15 – 40)	**p<0.001[a]**
	By age category:			
	<20	36 (4.8%)	43 (20.3%)	
	20-25	147 (19.4%)	75 (35.4%)	
	25-30	263 (34.8%)	58 (23.4%)	
	30-35	242 (32.0%)	29 (13.7%)	
	35-40	59 (7.8%)	6 (2.8%)	
	>40	9 (1.2%)	1 (0.5%)	
Ethnicity (OASIS n=734, Control n=203)	**Caucasian**	**609 (83.0%)**	**194 (95.6%)**	**p<0.001[b]**
	Asian	**107 (14.6%)**	**6 (3.0%)**	
	Black	**18 (2.5%)**	**3 (1.5%)**	
Education (OASIS n=750, Control n=209)	Higher (Graduate)	321 (43.8%)	51 (24.4%)	**p<0.001[b]**
	Lower	429 (57.2%)	158 (75.6%)	
Gestation (>40 weeks)		**437 (57.8%)**	**94 (44.3%)**	**p<0.001[b]**
Induction of labour		113 (14.9%)	37 (17.5%)	p=0.373[b]
Epidural anaesthesia		**42 (5.6%)**	**29 (13.7%)**	**p<0.001[b]**
Length of 2nd stage (mins)	Median	62 (2 – 375)	35 (2 – 192)	**p<0.001[a]**
Head position (if OP) (OASIS n=81 (2014-15 only), Control n=211)		**1 (1.2%)**	**6 (2.8%)**	p=0.421[b]
Waterbirth		67 (8.9%)	33 (15.6%)	**p=0.005[b]**
Birth weight (g)	Median	3500 (2260 – 4800)	3245 (2020 – 4450)	**p<0.001[a]**
	% over 4Kg	81 (10.7%)	7 (3.3%)	**p=0.001[b]**

[a] Mann-Whitney U Test, [b] Chi-square Test, p≤0.05 (p values in bold type met statistical significance)

Table 1: Univariate analysis comparing those sustaining an OASI with the control population

The factors remaining independently associated with the risk of OASI after BLR are shown in Table 2. Infantile macrosomia and giving birth post-term were associated with a 3.2- and 1.8-fold increased risk of sustaining a sphincter injury, respectively. When adjusting ethnicity to only include Caucasian and Asian women, those sustaining an OASI were 6.5-times more likely to be of Asian ethnicity (OR 6.553, 95% CI 2.773-15.483, p<0.001). Epidural anaesthesia was associated with a 67% reduction in OASI.

Table 2: Factors independently associated with the risk of OASI at primiparous NVD

	OR	95% CI	p-value
Maternal age (years)	1.147	1.107 – 1.188	p<0.001
Ethnicity	3.592	1.966 – 6.563	p<0.001
If baby >4Kg (%)	3.201	1.390 – 7.367	p=0.006
Gestation (>40 weeks)	1.832	1.295 – 2.592	p=0.001
Epidural anaesthesia	0.326	0.171 – 0.624	p=0.001
Length of 2nd stage (mins)	1.009	1.004 – 1.014	p<0.001

OASI group n=729, Control group n=200

2.4 Discussion

2.4.1 Main Findings

This study aimed to assess what maternal, intrapartum and neonatal factors influence the risk of OASI in the primiparous population during non-operative vaginal childbirth. This was achieved by using a control comparison of primiparous women with a documented 'intact perineum'.

Although the Trust's overall OASI rate was slightly higher than the national average (3.5% vs. 2.9%), the primiparous OASI rate was very similar (5.9% vs. 6.1%).(8) In agreement with previous studies, we found advancing maternal age and Asian ethnicity to be associated with an increased risk of sustaining an OASI.(31, 33, 49, 52)

In line with previous studies we also found women having an OASI to have larger babies, with a greater proportion over four kilograms.(31, 33, 52) We also discovered a disparity in the proportion of women delivering post-term when comparing those sustaining an OASI with the control population, which would also be associated with increased infant size. Prolonged second stage, or rather the resultant effect of prolonged tension on the perineal tissues, increased the risk of sustaining an OASI, even in the absence of OVD.(31, 52)

We expected women delivering a baby in the OP position to be at greater risk of OASI due to the presenting part having a larger diameter, but no significant difference was seen.(40, 73) Previous

studies have shown an increased risk of OASI in induction of labour or augmentation with Oxytocin but, when excluding operative vaginal deliveries, we found no significant difference.(79) The use of epidural was associated with a decreased risk of sustaining an OASI, as was giving birth in water.

2.4.2 Strengths and Limitations

One of the strengths of this study is that we controlled for the risk potentiating effect of operative vaginal delivery by excluding women having either forceps or vacuum extractions. This also removed any potential bias when analysing factors known to be affected by or associated with OVD e.g. prolonged second stage, episiotomy or epidural anaesthesia. Previous studies have used vaginal spontaneous delivery as the reference in logistic regression when analysing the effect of OVD but have then included all modes of delivery in the analysis of other factors. Additionally, other studies have made comparisons between those sustaining an OASI and those sustaining all other degrees of perineal trauma (including intact perineum, first- and second-degree and episiotomy), whereas our study only included those with an 'intact perineum'.(8, 31, 33, 52) This allows for a cleaner 'all versus nothing' analysis, so removing the potential for bias and the inclusion of undiagnosed OASIs into the control group.

A significant limitation of this data-based study was that, because of being limited to only analysing the variables recorded in the birth records, we were unable to review specific intrapartum practices and their effect on outcomes. For instance, whether any techniques or measures known to protect the perineum and reduce the risk of OASI were implemented e.g. manual perineal protection or application of a warm compress during the second stage.(37) Limitations of time and the process of manual extraction of data meant that even some data which would have been useful to corroborate or refute the findings of previous studies not able to be included, such as maternal weight and height.(64, 65) The analysis of the above confounders would have resulted in more robust, applicable evidence but this was unfortunately beyond this study's remit. See also section 1.8.2.

A further limitation of this study was that the number of patients in the control comparison cohort did not match the number of patients in the subject cohort due to unforeseen barriers enforced by the custodians of the database. For more information see sections 6.2.6 and 7.1.

2.4.3 Interpretation

A possible explanation for the increased risk of OASI with advancing maternal age is a decrease both in elasticity of connective tissues due to loss of function and strength of connective tissues with increasing age.(33, 51) Previous studies have shown those of higher economic status to be

associated with an increased risk of perineal trauma.(68, 69) Often economic status and academic success go hand-in-hand, as educational achievements give way to better employment and financial prospects. Our analysis of academic success revealed that those with higher educational achievements (University graduates) were of increased risk of OASI. This is likely a reflection of risk associated with increased maternal age as a result of their pursuit for their educational achievements prior to entering motherhood. The most likely explanation for the increased risk of OASI in women of Asian ethnicity is ethnic variation in perineal body length, where Asian women tend to have shorter perineal bodies.(55)

We expected our study to agree with previous research revealing women delivering an OP baby to be at greater risk of OASI due to the larger diameter of the presenting part, but no significant difference was seen.(72, 73) As these studies did not adjust for delivery mode, this could possibly be due to a combined effect of head malpresentation and use of instrument increasing the pressure on the perineal tissues rather than malpresentation alone. However, it is worth noting that the information available regarding this variable was limited to just 2 years' worth of data and hence the population may not have been sufficient to provide any meaningful conclusions. Previous studies have also shown an increased risk of OASIS in induction of labour or augmentation with oxytocin, but when excluding OVD we found no association.(79) Therefore, the injury sustained is more likely to be due to the need for an OVD rather than the initial induction or augmentation processes.

Epidural has been associated with increased rate of OASI but this has not previously been adjusted for the mode of vaginal birth.(82, 83, 229) We expected that epidural anaesthesia would potentiate the risk of OASI due to the association of regional anaesthesia with the prolonging of the second stage and resultant need for an OVD; both known as risk factors for OASIs. Our study showed epidural at NVD to be protective against OASIs. This could be due to better visualisation and support of the perineum by the accoucheur due to maternal immobility, and effective analgesia leading to better control and ability of the mother to follow instruction regarding pushing at crowning.

We also found giving birth in water to be protective against OASI. Although water birth has been shown to be associated with an increased incidence of intact perinea and reduction in significant perineal trauma, other studies have shown waterbirth (and more so immersion in first stage of labour) to potentiate the risk of OASI.(84, 87, 91) We expected to come to the same conclusion, as water birth inhibits the accoucheur from being able to visualise the perineum, or perform perineal protective measures such as manual perineal protection or application of a warm compress to the perineum during second stage, we expected to conclude that water birth is a risk factor for sustaining an OASI.(37, 77) An explanation the apparent protective effect of water birth could be due to reduced perineal tension and improved elasticity of, and blood supply to, the perineal tissues

due to immersion in warm water.(89) However, it is worth noting that the data collection may have been subject to errors as there were difficulties in differentiating between the use of water immersion for pain relief in the first stage of labour versus actual delivery in water. Therefore, water birth may have been over-reported in the lower risk control population (who were more likely to benefit from the use of water), which brings in to question the credibility of these findings.

2.5 Conclusion

This research is novel as we controlled for bias associated with OVD by focusing purely on primiparous women achieving a NVD. Additionally, we used a control population with documented 'intact' perinea. The findings support previous research in recognising increased maternal age, Asian ethnicity, prolonged second stage, post-term delivery and infantile macrosomia as risk factors for OASI. This study showed a potential protective effect of the use of regional anaesthesia.

Chapter 3 Risk factors for OASI at VBAC

3.1 Objectives

- To assess whether women having VBAC delivery are at increased risk of sustaining an OASI
- To evaluate whether specific baseline characteristics and urgency of caesarean at first delivery affect subsequent vaginal birthing outcomes, especially regarding sustaining an OASI

3.2 Methods

3.2.1 Study Design

The objectives were achieved through the retrospective analysis of prospectively collected data from the UHS NHS FT maternity database (via researcher contact with the Clinical Manager HICSS Maternity Information System). Only anonymised data were used, so informed consent was not required. The study was granted full ethical approval by NHS HRA; reference no. 15/NW/0782.

Data extrapolated from the maternity database for the purpose of this research, ran from January 2004 to December 2014. The sample selected included secundiparous women documented to have had a previous Caesarean delivery, who subsequently achieved a singleton, cephalic, term (birth at ≥37 weeks gestation), vaginal delivery.

The following information was included in the data collection:

- Total number of vaginal births during the study period
    - Of those, the number of singleton, cephalic, term vaginal deliveries*****
    - From the above number*****, the total number of OASIs
- Total number of VBAC deliveries
    - Of those, the number of secundiparous (with no previous vaginal delivery) women who had singleton, cephalic, term vaginal deliveries******
    - Of those, the total number of women sustaining an OASI at first VBAC

From the above group******, the following was extracted for each individual case:

- Maternal demographics – age (at VBAC) and ethnicity

- Information about the VBAC delivery:
    - Birth weight, delivery mode (NVD / forceps / vacuum extraction), use of episiotomy, whether the labour was induced or post-term, the use of regional anaesthesia, whether the fetus was in a persistent occipitoposterior position or there was shoulder dystocia, the length of the active second stage of labour and the degree of perineal trauma
- Information about initial Caesarean delivery:
    - Birth weight, gestation, category of CS (whether urgent or not), whether it took place whilst in labour, whether it followed induction of labour, cervical dilatation at decision to deliver via CS, whether the presentation was non-cephalic

Category of CS was classified using the National Institute for Health and Care Excellence (NICE) ' Caesarean section' clinical guideline number 132 (see Table 3).(230) For the purposes of this study, an 'urgent' or 'emergency' CS was defined as a category 1 or 2, where there is maternal or fetal compromise.

Table 3: Category of caesarean section

Urgency	Category	Definition
Maternal or fetal compromise	**1**	immediate threat to the life of the woman or fetus
	2	maternal or fetal compromise which is not immediately life-threatening
No maternal or fetal compromise	**3**	no maternal or fetal compromise but needs early delivery
	4	delivery timed to suit woman or staff

3.2.2 Statistical analysis

Women who were delivered by repeat CS, breech delivery or who delivered pre-term were excluded from analysis. We calculated the rate of OASI and all perineal trauma among the included women. Maternal and neonatal factors were compared between those women who suffered an OASI and those who did not, in univariate analysis. Factors reaching statistical significance in this analysis ($p \leq 0.05$) were entered into binary logistic regression to calculate the adjusted, independent odds ratio (OR) of OASIS. We performed a secondary regression, including all factors of borderline significance ($p < 0.2$).

The data were analysed using IBM SPSS v.22. The Kolmogorov-Smirnov test was used to determine the distribution of continuous data; parametric data were analysed using Independent Samples t-test and non-parametric data by the Mann-Whitney U test. Categorical data were analysed using Chi-Square test. For comparisons between continuous and categorical data, parametrically distributed data were analysed using the One-Way ANOVA and non-parametric data by the Kruskall-Wallis Test. Statistical significance was defined as a p-value ≤0.05. In all analyses, data on third- and fourth-degree OASI were combined.

3.2.3 Ethical considerations

Permission to undertake this research was granted by our sponsor, UHS NHS FT, under registration no. RHM O&G0234. The study was granted ethical approval by the HRA NW-Preston Research Ethics Committee under reference no. 15/NW/0782. Patient contact was not required as this was a retrospective database study with no direct patient contact.

3.3 Results

During the eleven-year period there were 2736 successful, singleton VBAC deliveries. The approximated VBAC success rate for the study period was estimated by the custodians of the maternity database to be approximately 70%. After excluding all those whom did not fit the inclusion criteria (see Figure 12 below), the study population was 1375. Of that number, 86.6% sustained perineal trauma (either spontaneous or facilitated) at VBAC. The prevalence of OASI was 8.1%; of which the vast majority had either 3a or 3b tears (41.1% and 45.5%, respectively) (see Table 4).

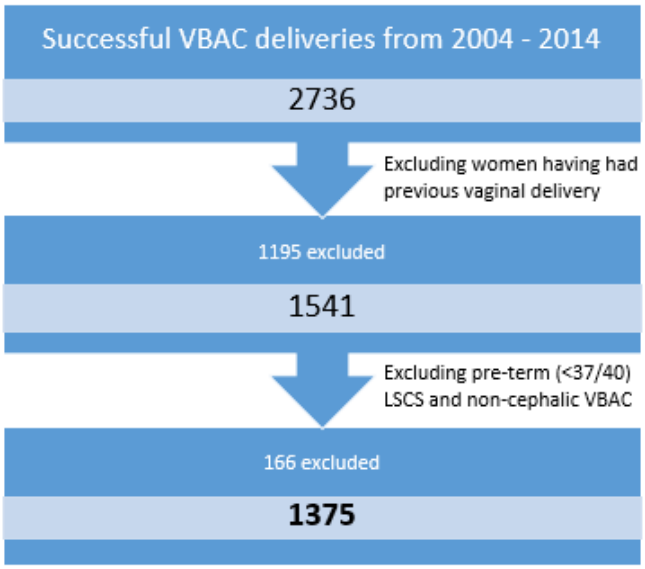

Figure 12: Schematic representing the VBAC study population

Table 4: Classification and distribution of OASI at VBAC

Type of OASI [11]	**Count**	**Percentage of all OASIs**
3a – < 50% of EAS involved	46	41.1%
3b – ≥ 50% of EAS involved	51	45.5%
3c – EAS and IAS involvement	11	9.8%
4th – 3c + rectal mucosa	4	3.6%
Total	**112**	

EAS = external anal sphincter, IAS = internal anal sphincter

The hospital's contemporaneous birthing outcomes revealed an overall OASI rate of 3.1 %, including a multiparous OASI rate of 1.2 % and a primiparous OASI rate of 5.8 %. In comparison to the primiparous OASI rate, secundiparous women at VBAC were at a 1.4 -fold greater risk (8.1% vs. 5.8 % ($p<0.05$, difference 2.4%, 95% CI 1.1, 3.6)). Secundiparous women were at significantly greater risk than other multiparous women with prior vaginal deliveries ($p<0.05$, difference 7.0, 95% CI 6.4, 7.6), representing a 6.8–fold increase.

Two thirds of the sample not sustaining an OASI had no spontaneous trauma. Of those however, 77.5% had an episiotomy. The overall episiotomy rate was 50.8%, which is 2.3-times greater than the Trust's rate for the concurrent period (50.8% vs. 22.3%). The next common birthing outcome was a 2nd degree tear, equating to 28.6% of the population. 3.9% sustained a 1st degree tear (see Table 5).

Table 5: Birthing outcomes of those not sustaining an OASI at VBAC

Perineal Condition	**Count**	**Percentage of all births** (n=1375)	**Percentage that had episiotomy**
No spontaneous trauma	816 (64.6%)	59.3%	632 (77.5%)
1st	54 (4.3%)	3.9%	3 (5.6%)
2nd	393 (31.1%)	28.6%	23 (5.9%)
Total	**1263**		

Univariate analyses are shown in Table 6, Table 7 and Table 8, to identify factors associated with OASIs in this cohort. Women sustaining an OASI at VBAC were significantly older than those who did not (median age 32.0 vs. 30.7, $p=0.011$); 68.7% of the women sustaining an OASI at VBAC were over the age of 30 vs. 57.3% of the non-OASI population, and analysis using a One-Way ANOVA statistical tool showed a significant difference in the distribution. We identified large differences in the frequency of OASI among women of non-Caucasian ethnicity (1.5-fold more Asian and 2.7-fold fewer Black women) although these did not reach statistical significance ($p=0.189$). See Table 6.

Table 6: Maternal demographics of women achieving a VBAC

		VBAC with OASI	VBAC, no OASI	p-value
Age		(n=112)	(n=1263)	
	Median	32.3 (21.0 – 43.6)	31.0 (17.3 – 45.9)	**p=0.011** [a]
	By age category:			
	<20	0 (0.0%)	13 (1.0%)	p=0.002[b]
	20-25	9 (8.0%)	199 (15.8%)	
	25-30	26 (23.2%)	324 (25.7%)	
	30-35	52 (46.4%)	456 (36.1%)	
	35-40	22 (19.6%)	232 (18.4%)	
	>40	3 (2.7%)	38 (3.0%)	
Ethnicity		(n=111)	(n=1231)	
	Caucasian	95 (85.5%)	1090 (88.5%)	**p=0.189**[c]
	Asian	15 (13.5%)	111 (9.0%)	
	Black	1 (0.9%)	30 (2.4%)	

[a] Mann-Whitney U Test (non-parametric data), [b] One way AVOVA, [c] Chi-square,
p≤0.05 (p values in bold type) – used in the binary logistic regression

Those with an OASI had significantly heavier babies (mean weight 3642g vs. 3466g, p<0.001), with a significantly greater proportion weighing greater than four kilograms (p=0.001, 24.1% vs. 13.1%). A One-Way ANOVA analysis revealed statistical significance when comparing the birth weight means across all the different subcategories of OASIS (p=0.002). See Table 7.

Operative vaginal delivery at VBAC was 2.4-fold more likely than the Trust's approximated instrumentation rate (45.0% vs. 18.9%). While there was no difference in whether the VBAC deliveries were instrumented (45.5% vs. 45.0%, p=0.918), the women sustaining an OASI at VBAC had significantly more forceps deliveries (80.4% vs. 66.5% of all the instrumental deliveries, p=0.043). Furthermore, these women were 1.4-fold more likely to require an operative vaginal delivery if the previous CS was urgent (50.0% vs. 36.5% of those not sustaining an OASI at VBAC, p=0.084).

Women without an OASI were significantly more likely to have had an episiotomy (52.2% vs. 37.5% of those with OASIS, p=0.003). This difference was seen regardless of the type of delivery; normal vaginal delivery with episiotomy (21.1% vs. 9.8% of those sustaining an OASI, p=0.035) and operative vaginal delivery with episiotomy (overall; 89.8% vs. just 70.6% of those sustaining an OASI, p<0.001, forceps; 95.8% vs. 82.9%, p=0.001, vacuum extraction; 77.9% vs. 20.0%, p<0.001).

There were no significant differences when analysing the fetal head position (whether occiput posterior (OP) or not, p=0.744), length of second stage of labour (active second stage (p=0.845) and total second stage (p=0.744)), the use of regional anaesthesia during second stage (p=0.145) or

whether the VBAC was post-term (p=0.326) or induced (p=0.839). Although the difference was not significant, those sustaining an OASI were 2.5-fold more likely to have delivered a baby with shoulder dystocia than those without an OASI (4.5% vs. 1.8%, p=0.058).

Table 7: Information regarding the VBAC delivery

		VBAC with OASI (n=112)	**VBAC, no OASI** (n=1263)	**p-value**
Birth weight (g)	Mean	3642.2 (±488.26)	3465.6 (±470.27)	p<0.001 [a]
	% over 4Kg	27 (24.1%)	166 (13.1%)	**p=0.001**[b]
Operative vaginal delivery (OVD)	As a percentage of all deliveries	51 (45.5%)	568 (45.0%)	p=0.918[b]
	Comparison of OVD type - Forceps - Ventouse	 41 (80.4%) 10 (19.6%)	 378 (66.5%) 190 (33.5%)	 p=0.043[b]
Episiotomy	Overall rate	42 (37.5%)	657 (52.2%)	**p=0.003**[b]
	OVD episiotomy rate	n=51 36 (70.6%)	n=568 510 (89.8%)	 p<0.001[b]
	- Forceps - Ventouse	34 (82.9%) 2 (20.0%)	362 (95.8%) 148 (77.9%)	p=0.001[b] p<0.001[b]
	NVD episiotomy rate	n= 61 6 (9.8%)	n=695 147 (21.2%)	 p=0.035[b]
Gestation (Post-term (>40 weeks))		69 (61.6%)	717 (56.8%)	p=0.326[b]
Induction of labour		20 (17.9%)	216 (17.1%)	p=0.839[b]
Use of regional anaesthesia		37 (33.0%)	506 (36.8%)	**p=0.145**[b]
Head position (if OP)		4 (3.6%)	38 (3.0%)	p=0.744[b]
Shoulder Dystocia		5 (4.5%)	23 (1.8%)	**p=0.058**[b]
Length of 2nd stage (mins)	Median - Active - Total	 45 (4 – 148) 50 (6 – 213)	 49 (1 – 211) 60 (1 – 554)	 p=0.845[c] p=0.995[c]

[a]Independent t-test (parametric), [b]Chi-square, [c]Mann-Whitney U Test (non-parametric data),
p≤0.05 (p values in bold type) – used in the binary logistic regression

When comparing those that sustained an OASI at VBAC with those that did not, there was no difference in whether the initial CS was post-term (>40 weeks gestation, p=0.546), whether the CS followed an induction of labour (p=0.920), nor in overall cervical dilation at time of CS decision (p=0.336) or whether fully dilated at CS decision (9.8% in those sustaining OASIS at VBAC vs. 11.6% in those that did not, p=0.624). See Table 8.

Table 8: Information regarding initial caesarean delivery

		VBAC with OASI (n=112)	VBAC, no OASI (n=1263)	p-value
Gestation Post-term (>40 weeks)		52 (46.4%)	624 (49.4%)	p=0.546[a]
Birth weight at LSCS (g)	Mean	3557 (±543.53)	3450 (±527.50)	**p=0.04[b]**
	% over 4Kg	22 (19.6%)	178 (14.2%)	p=0.120[a]
LSCS in labour		91 (81.3%)	980 (77.6%)	p=0.371[a]
Induction of labour		31 (27.7%)	344 (27.2%)	p=0.920[a]
Cervical dilatation (cm) (at time of CS decision)	Median	6 (0 -10) (n=82)	5 (0 -10) (n=936)	p=0.336[c]
	10cm dilated	8 (9.8%)	108 (11.5%)	p=0.624[a]
Non-cephalic presentation		22 (19.6%)	325 (25.7%)	p=0.155[a]
Category of LSCS^	Overall comparison			p=0.007[a]
	Category 1	7 (8.0%)	74 (7.8%)	
	Category 2	39 (44.3%)	259 (27.1%)	
	Category 3	29 (33.0%)	419 (43.9%)	
	Category 4	13 (14.7%)	202 (21.2%)	
	Urgent CS (1+2)	46 (52.3%)	333 (34.9%)	**p=0.001[a]**

[a]Chi-square, [b] Independent t-test (parametric)[c] Mann-Whitney U Test (non-parametric data),
p≤0.05 (p values in bold type) – used in the binary logistic regression
(^Initial caesarean data not available for all births; for 78.6% (88/112) OASI at VBAC, 75.5% (954/1263) no OASI)

78.0% (1071/1375) of all VBAC deliveries had an initial CS in labour. Of those sustaining an OASI at VBAC, 81.3% (91/112) were in labour at the initial CS and those with no OASI at VBAC, 77.6% (980/1263) were in labour at the initial CS. The OASI rate of those who had an initial CS whilst in labour was 8.5% (91/1071) compared with 6.9% (21/304) of those that were not in labour at initial CS (p=0.371). Although there was no difference if at initial CS there was a non-cephalic presentation, those presenting this way were 1.3-fold less likely to have an OASI at VBAC (19.6% of those with an OASI vs. 25.7% of those not sustaining an OASI, p=0.155). Those that had an OASI had significantly heavier babies at the initial CS (mean weight 3557g vs. 3450g, p=0.04), but no difference was seen in the proportion of those that had a birth weight greater than four kilograms (p=0.120). There was a significant difference when comparing the overall categories of CS (p=0.007); moreover those sustaining an OASI were 1.5-fold more likely to have an urgent CS (category 1 or 2; see Table 3) (52.3% of those sustaining an OASI at subsequent delivery vs. 34.9% whom did not, p=0.001).

The factors which remained independently associated with the risk of an OASI after binary logistic regression are shown in Table 9. These included the age of the mother, birth weight at VBAC, whether an episiotomy was performed and whether the initial CS was an emergency (category 1 or 2). The same factors were seen when including all statistically significant outcomes (i.e. p≤0.05) vs. those that had a significance of p<0.2. Regression analysis including birth weight as a continuous variable gave an increase OR of 1.001 (95% CI, 1.000-1.001. p=0.001) per gram of increased birth weight. To aid interpretation, results presented in the table show birth weight dichotomised into '>4Kg or not'. The analysis of odds ratios revealed that episiotomy at VBAC more than halved the risk of OASIS, whereas an emergency CS at initial delivery more than doubled the risk.

Table 9: Factors independently associated with OASI at VBAC

	VBAC with OASI (n=112)	**VBAC, no OASI (n=1263)**	**OR**	**95% CI**	**p-value**
Maternal age (yrs)	32.3 (21.0-43.6)	31.0 (17.3-45.9)	1.054	1.008-1.102	0.020
If baby >4Kg (%)	27 (24.1%)	166 (13.1%)	2.146	1.091-3.426	0.006
Episiotomy (%)	42 (37.5%)	657 (52.2%)	0.511	0.321-0.813	0.005
Emergency CS (%)	46* (52.3%)	333* (34.9%)	2.054	1.313-3.213	0.002
(*Initial caesarean data not available for all births; for 78.6% (88/112) OASI at VBAC, 75.5% (954/1263) no OASI)					

3.4 Discussion

3.4.1 Main Findings

This study aimed to assess whether women having VBAC are at increased risk of sustaining an OASI, and whether specific baseline characteristics and indication for initial CS affect subsequent birthing outcomes. Data was collected manually by inspecting approximately 1400 electronic maternity records, incorporating all VBAC deliveries between January 2004 and December 2014 within the University of Southampton NHS Foundation Trust.

The main finding was that a VBAC delivery does significantly increase the likelihood of sustaining an OASI; this more so than at primiparous vaginal birth, which is in line with previous findings.(47, 104, 105) As with other OASI studies, we found an association of an increased risk of an OASI with fetal macrosomia and increased maternal age.(231) We also found episiotomy to be strongly protective against OASI at VBAC. This research has revealed that a previous emergency caesarean is associated with significantly increased risk of OASI at VBAC.

3.4.2 Strengths and Limitations

This study's strength lies in the fact that the available information was collected manually by inspecting and extrapolating from the electronic documentation of every woman undergoing secundiparous VBAC during the study period. This removed any potential inaccuracies associated with incomplete or incorrect coding of electronically devised datasets found, which other studies have encountered.(8, 102) However, the information concerning the initial CS was missing in some cases due to the birth taking place prior to the electronic documentation, or at a different Trust.

We decided not to include the Category 3 CS as 'Emergency' as the majority (85.3%) of documented cases were due to failure to progress of the first stage, non-cephalic presentation or maternal infirmity i.e. reasons not related to the pelvic outlet or pressure on the perineum. It would have been interesting to analyse the CS category decision making in more detail, but due to incomplete and unreliable documentation this was not possible. The VBAC success rate (as a percentage of total VBAC deliveries including repeat unplanned caesareans) was only predicted value as information regarding whether VBAC was attempted (and failed resulting in subsequent unplanned caesarean) was not reliably recorded on the maternity database. (See also section 1.8.2.) As such we were unable to establish the VBAC failure rate. It would be useful to have this information to analyse the reason for repeat CS and to see whether this correlates with the indication for the initial CS. Furthermore, as with the previous chapter (see section 2.4.2) we were unfortunately able to include information regarding the maternal BMI and height in our analysis.

3.4.3 Interpretation

Although it could be reasonable to assume the risk of OASI in a woman undergoing VBAC delivery is similar to a nulliparous patient (as neither would have previously delivered vaginally), we found the rate of OASI to be higher. Previous studies have found that although more likely to attempt VBAC, a history of emergency CS, namely arrested dilation or descent¸ is a negative predictors of a successful VBAC.(103, 232) Our research, which in agreement with these studies, supports the speculation of a relative cephalopelvic disproportion and risk of such, being carried over from previous delivery.(33, 47, 105) Although the indications for the initial CS was not known, it is worth noting that the cohort sustaining OASI not only had larger subsequent babies compared with their first babies, but also in comparison to those not sustaining an OASI at VBAC. This again would support the speculation of an obstructive cause for initial caesarean and, coupled with potentially more propulsive multiparous contractions, a greater impact on the perineum and resultant heightened risk of OASI.(103)

The overall episiotomy rate was far greater than the national rate of 20.2%; more so in the cohort not sustaining an OASI.(8) This therefore is suggestive of episiotomy being protective against OASI at VBAC. A systematic review revealed a 40 – 50% risk reduction of OASI, when compared with spontaneous tears, through relieving the pressure on the central posterior perineum via episiotomy.(55) Our regression model showed the same outcome. We also found significantly fewer patients sustained an OASI if an episiotomy was performed, regardless of whether the delivery was instrumented or not. We found that 6.8 episiotomies would need to be performed to prevent one OASI (NNT = 1/ARR = 1/ (0.375-0.522) = -6.8). Like Hehir et al., we found forceps delivery to cause a greater increase in risk of OASI than vacuum extraction, especially when no episiotomy is performed.(103) This is perhaps unsurprising due to the additional force exerted on the perineum to aid the delivery of the fetal head .

It was rather surprising to discover that how relatively infrequently episiotomy was performed at operative deliveries in the OASI cohort (70.6%); more so that episiotomy was performed at only 20.0% of the ventouse deliveries. Despite the small number of patients included in this subgroup this does highlight an area that requires addressing, especially as it is well recognised that nulliparous women are at greater risk of OASI and especially at OVD. It would be prudent to include the VBAC population in any recommendations regarding the use of episiotomy in nulliparous women, especially during operative delivery.

Previous studies have shown a negative correlation between perineal length and risk of OASI. Additionally, Asian women have been found to be at increased risk of severe perineal trauma, however the causation has been disputed i.e. whether this is due to anatomical differences in perineal length or other factors such as differences in pelvic shape or tissue composition.(54-57) An earlier study found an element of protection against sphincter tears in Black women, but not of statistical significance.(105) Although we had no documentation of anatomical variations, our study supported these findings as Asian women were at an increased risk of sustaining an OASI at VBAC.

Groban's prediction model for successful VBAC, is a widely used, useful tool, which has since been validated across different cultures and ethnicities. However, their measure of "success" only goes as far as the infant being delivered vaginally – with no interest in the impact of the delivery on the perineum.(232) There is real value to our study as it is the first VBAC study focusing on perineal trauma to have reviewed potential exacerbating factors associated with the initial caesarean birth, namely the association between urgency of initial delivery and increased likelihood of severe perineal trauma at subsequent delivery. It would be useful to substantiate these findings with an expansion of this work, and a view to creating a prediction tool for impact of VBAC on the perineum.

3.5 Conclusion

This study has shown that secudiparous VBAC delivery is associated with a significantly increased risk of OASI, operative vaginal delivery and episiotomy, especially if the initial CS was an emergency. The current patient pathway for VBAC delivery makes no reference to these risks, highlighting the need for improvements in counselling and provision of information to enable patients to make informed choices regarding their subsequent delivery.(37) This is however likely to have a negative impact on the already increasing CS rate. Currently, the only basis of whether a VBAC delivery is "successful" is if the infant is born vaginally. More consideration needs to be made to the potential impact of VBAC delivery on the perineum and the resultant effects this may have on long term physical, social and psychological well-being of patients.

Chapter 4 Subsequent delivery after previous OASIS

4.1 Objectives

Primary Objectives

- To investigate subsequent delivery outcomes in women having sustained a previous OASI
- To explore whether there are any factors influencing the risk of a recurrent OASI (rOASI)

Secondary Objectives

- To establish whether women with a history of an OASI are at higher risk of sustaining a further OASI at subsequent delivery than:
    - The primiparous population
    - Other multiparous women but without previous OASI
- To investigate what factors influence Obstetric decision-making regarding mode of subsequent delivery in women with a history of OASI

4.2 Methods

4.2.1 Study Design

The same cohort of primiparous women sustaining an OASI was used as an earlier chapter (see Chapter 2), but only including those with a recorded subsequent singleton, term, cephalic vaginal delivery. Unlike the previous chapter, all modes of vaginal delivery, at both index and subsequent delivery, were included.

The following information was extracted (through a combination of manual and electronic data retrieval):

- Additional information regarding the index delivery:
    - Whether the vaginal delivery was operative (OVD e.g. forceps or vacuum extraction)
    - The grade of OASI at the index delivery
- Information regarding the subsequent delivery:
    - Whether the delivery was post-dates (>40 weeks gestation)
    - Whether the labour was induced
    - The use of epidural anaesthesia
    - The length of the second stage of labour (minutes)

- The mode of vaginal delivery (OVD or normal vaginal delivery (NVD))
- Whether the delivery was in water ('water birth')
- The degree of perineal trauma sustained (including rOASI grade if applicable)
- Whether an episiotomy was performed
- The fetal head position (whether occiputo-posterior or not)
- The birth weight (grams)

To address the second of the secondary objectives a brief online questionnaire was devised and circulated to clinicians via an emailed link (see Appendix C). This included:

- an assessment of what factors influence their decision-making e.g. results of investigations, their own knowledge of associated risk factors, patient choice, patient ethnicity
- an assessment of their knowledge of the incidence of rOASI, factors that increase the risk of a rOASI and the risk of long-term anal incontinence associated with a recurrence

4.2.2 Statistical Analysis

Univariate analysis compared those sustaining a rOASI with those that did not, to determine what factors influence the risk of sustaining a rOASI. Depending on distribution, continuous data was analysed using Independent Samples T-test or Mann Whitney U. Chi-Square test was used to analyse categorical data. The binary logistic regression (BLR) tool was used to establish which factors remained independently associated with the risk of recurrent injury.

4.2.3 Ethical considerations

As this research was carried out for the maternity department as an audit, and there was no direct patient contact, ethics approval was not required. Only anonymised data were used, so informed consent was not required.

4.3 Results

49.6% of the 1269 primiparous women with an OASI had a further delivery at the Trust, of which 79.3% had a further vaginal delivery (see Figure 14). The most common perineal injury at subsequent vaginal delivery after previous OASI was a second-degree tear (59.8%). Just over a fifth of the population (109/495) had no further spontaneous trauma, however 60.6% (66/109) of these women had an episiotomy (see Figure 13).

The overall episiotomy rate at subsequent vaginal delivery after OASIS was 13.7% (68/495), which is far lower than national rate of 20.2%.(8) Of those who had an episiotomy, 97.1% (66/68) had an

otherwise intact perineum, and only 4.7% (2/43) of those with rOASI had an episiotomy. None of the women sustaining a first- or second-degree tear had an episiotomy.

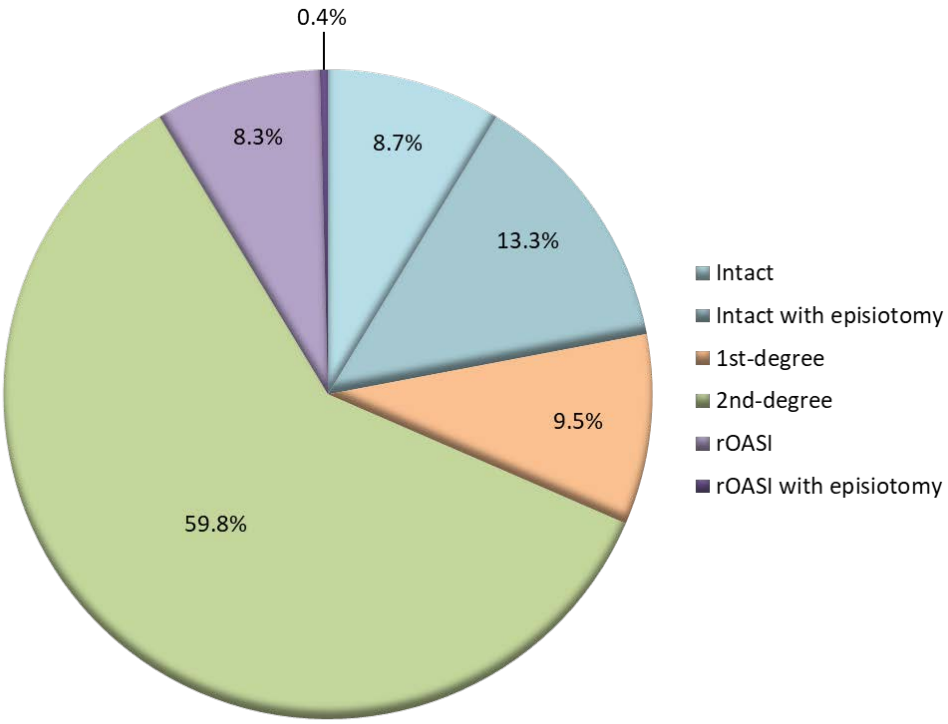

Figure 13: Percentage distribution of perineal outcomes at subsequent delivery after previous OASI

The rOASI rate was 8.7% (43/495), which is 1.5-times the primiparous rate and 4.6-times the prevalence in multiparous women without a previous OASI (difference 6.8% (95% CI 5.6, 8.1), $p<0.05$). The vast majority of OASIs at index and subsequent vaginal delivery were 3a and 3b (combined percentages at first and subsequent delivery of 87.4% and 83.7%, respectively), however the proportion of more severe tears (3c- and fourth-degree) was higher at subsequent delivery (see Table 10). Those sustaining a fourth-degree tear at initial delivery were 1.8-times more likely to sustain a rOASI than those with a previous third-degree tear (15.4% (2/13) vs. 8.4% (41/482)).

Table 10: Percentage distribution of the grades of OASI at both index and subsequent delivery

Type of OASI	**Index OASI**		**rOASI**	
	Count	% of all OASIs	Count	% of all OASIs
3a – < 50% of EAS involved	595	46.9%	21	48.8%
3b – ≥ 50% of EAS involved	515	40.5%	16	34.9%
3c – EAS and IAS involvement	109	8.5%	6	11.6%
4th – 3c + rectal mucosa	49	3.9%	2	4.7%
Total	**1269**		**43**	

EAS = external anal sphincter, IAS = internal anal sphincter

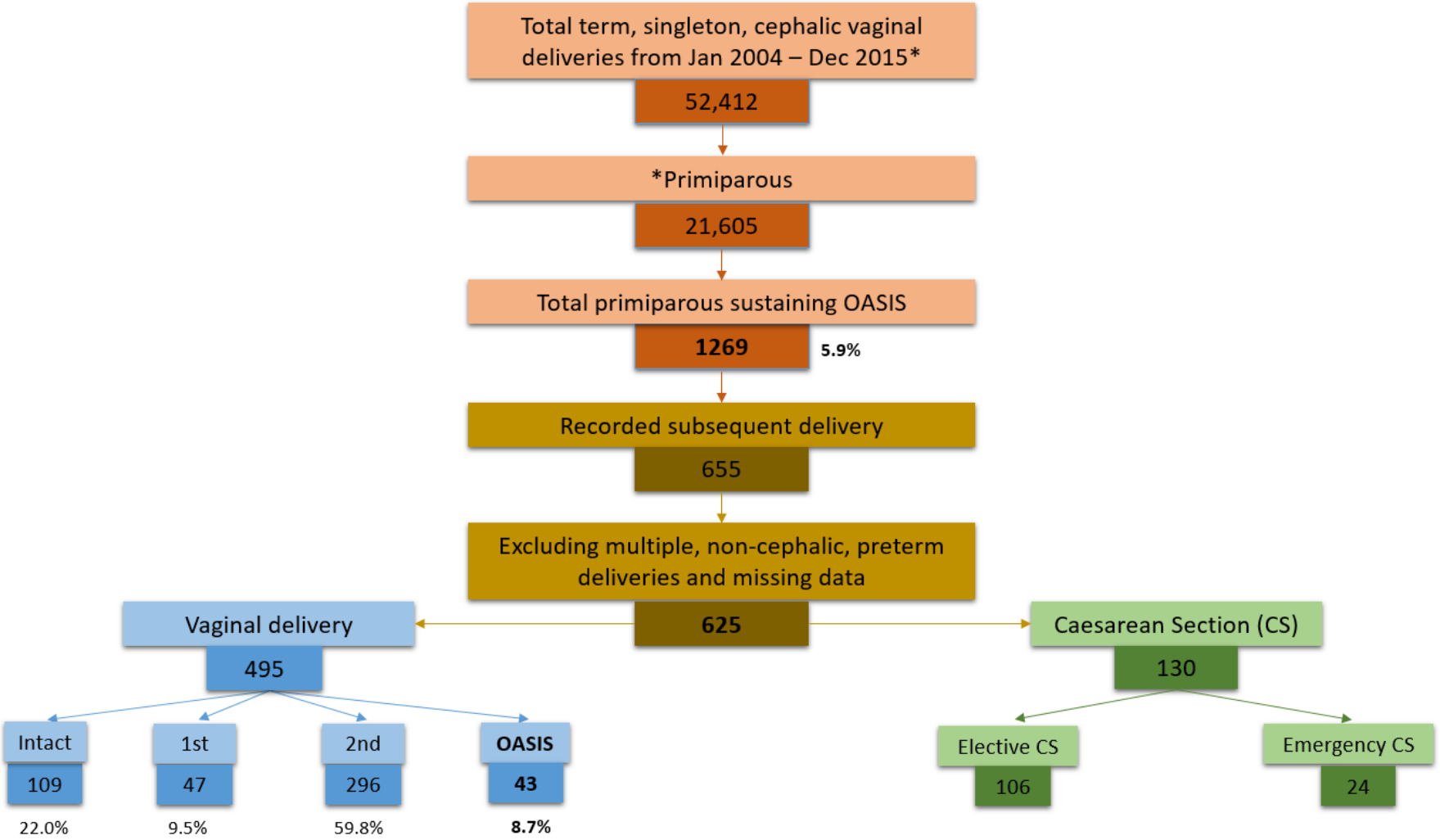

Figure 14: Delivery outcomes after previous primiparous OASI

Table 12 shows univariate analysis comparing those that sustained rOASI (n=43) with those who did not (n=452). No differences were seen when comparing the maternal demographics.

No significant differences were seen when analysing the length of second stage or mode of delivery at either delivery, or whether the subsequent delivery was post-term or induced. Although not statistically significant, the use of epidural anaesthesia was more common in those not sustaining a rOASI; more so when adjusting for OVD. Those sustaining rOASI were 4.2-fold less likely to have delivered in water, but this was not statistically significant.

Women sustaining rOASI had a greater proportion of more severe sphincter damage at the initial delivery, however this difference was not statistically significant (p=0.088). Those without rOASI were over three-times more likely to have had an episiotomy. Moreover, those with rOASI had significantly fewer episiotomies during normal (non-operative) deliveries than those without recurrent injury (0.0% vs. 10.5%, p=0.029).

Women suffering a rOASI had significantly heavier babies at both index (3661.6 vs. 3507.8, p=0.031) and subsequent delivery (37.64 vs. 3575.0, p=0.016). They also had a significantly greater proportion of babies weighing more than four kilograms at subsequent delivery (32.6% vs. 16.6%, p=0.009).

Factors remaining independently associated with the risk of rOASI after BLR are detailed in the table below. A rOASI is 1.7-times more likely if a more severe form of OASI was sustained initially. Having a subsequent baby weighing more than four kilograms increases the risk of rOASI 2.7-fold. The analysis suggests that episiotomy is protective against rOASI, by reducing the risk by approximately 75%, however this finding is inconclusive as the BLR did not meet statistical significance.

Table 11: Factors independently associated with the risk of a recurrence

	OR	**95% CI**	**p-value**
Grade of initial OASI	1.725	1.184 – 2.512	p=0.004
If baby >4Kg at subsequent delivery (%)	2.670	1.322 – 5.393	p=0.006
Use of episiotomy at subsequent delivery (%)	0.253	0.059 – 1.086	p=0.064

Table 12: Comparison of those sustaining a rOASI at subsequent delivery with those who did not

		rOASI (n=43)	**No rOASI** (n=452)	**p-value**
Age	**Index delivery** Median	28 (17 – 40)	28 (16 – 40)	p=0.886 [a]
	Subsequent delivery Median	31 (21 – 41)	31 (18 – 45)	p=0.679 [a]
Ethnicity (rOASI n=42, no rOASI n=445)	Caucasian Asian Black	32 (76.2%) 9 (21.4%) 1 (2.4%)	379 (85.2%) 60 (13.4%) 6 (1.3%)	p=0.307 [b]
Gestation (Post-term (>40 weeks))		27 (62.8%)	258 (57.1%)	p=0.469 [b]
Induction of labour		8 (18.6%)	72 (15.9%)	p=0.649 [b]
Use of regional anaesthesia	Overall rate	1 (2.3%)	39 (8.6%)	p=0.147 [b]
	Epidural in NVD	0/41 (0.0%)	31/430 (7.2%)	p=0.075 [b]
Length of 2nd stage (mins)	**Index delivery** Median	70 (11 – 264)	71 (4 – 380)	p=0.291 [a]
	Subsequent delivery Median	18 (1 – 185)	17 (1 – 255)	p=0.499 [a]
Operative delivery (% of deliveries)	**Index delivery**	17 (39.5%)	159 (35.2%)	p=0.950 [b]
	Subsequent delivery	2 (4.7%)	22 (4.9%)	p=0.568 [b]
Waterbirth (NVD only included)		1/41 (2.4%)	22/430 (10.0%)	p=0.447 [b]
Grade of OASI at index delivery	Overall comparison			p=0.088 [b]
	3a 3b 3c 4th	16 (37.2%) 19 (44.2%) 6 (14.0%) 2 (4.7%)	254 (56.2%) 153 (33.8%) 34 (7.5%) 11 (2.4%)	
Episiotomy	Overall rate	2 (4.7%) (2/43)	66 (14.6%)	p=0.070 [b]
	Episiotomy in NVD	0/41 (0.0%)	45/430 (10.5%)	**p=0.029** [b]
Birth weight (g)	**Index delivery**			
	Mean	3661.6	3507.8	**p=0.031** [c]
	% over 4Kg	8 (18.6%)	57 (12.6%)	p=0.266 [b]
	Subsequent delivery			
	Mean	3764.0	3575.0	**p=0.016** [c]
	% over 4Kg	14 (32.6%)	75 (16.6%)	**p=0.009** [b]

[a] Mann-Whitney U Test (non-parametric data), [b] Chi-square, [c] Independent t-test (parametric).
Significance level **p≤0.05** (in bold type)

4.4 Discussion

4.4.1 Main findings

This study fulfilled its aims in investigating the subsequent outcomes in women having sustained a previous OASI as well as exploring any influencing factors for rOASI. The findings of this study oppose the NICE guideline on Intrapartum Care regarding risk of recurrence, as we found women were at increased risk of rOASI compared with both primipara and multipara without a history of OASI.(17) Furthermore, we found the rate of rOASI to be greater than what is currently quoted in the RCOG guidance (8.7% vs. 5 – 7% quoted)**.**(37) This study also revealed a potential protective effect of mediolateral episiotomy (MLE) against rOASI at subsequent vaginal birth after previous sphincter injury.

4.4.2 Strengths and Limitations

Although one of this study's strengths is that the data was collected manually, which removes inaccuracies due to incorrect or incomplete coding, but this can also be a downfall as data collection in this manner is open to human error. Time and manpower were lacking to enable techniques to limit potential data entry errors, such as double data entry. For the same reasons, and also due to also recognition only in hindsight after data collection was complete, variables which would have been useful to develop on previous research and publications were not included e.g. time interval between index and subsequent delivery, incidence of shoulder dystocia and maternal BMI. (See also section 1.8.2.) Although data entry was a mammoth task, the same size was relatively small and so the credibility of some of the results are questionable. Therefore, expansion of this study would be useful to substantiate or refute the findings (see Chapter 5

4.4.3 Interpretation

This research provides new information about the proportion of the other less severe forms of perineal trauma (e.g. those with no spontaneous trauma, first- or second-degree perineal trauma) at vaginal birth following an OASI. It also highlights some factors which make sustaining a recurrent injury more likely.

When comparing women who sustained rOASI with those who did not, similar trends of risk relating to ethnicity were seen in this study that were previously observed in this thesis and other publications.(53) Although not statistically significant, a greater incidence of repeat trauma was observed amongst those of Asian ethnicity (21.4% vs. 13.4%). This is in line with other studies that

have shown ethnic variation in perineal length, pelvic anatomy and tissue composition, and resultant differences in predisposition to birth trauma. It is therefore unsurprising that this risk factor is carried over to any subsequent delivery.(53-57)

Interestingly, unlike previous studies, we found no difference in rate of rOASI regarding whether the subsequent delivery was an OVD. This was surprising considering how strong a risk factor for OASI OVD is the primiparous population.(97, 217)

A greater proportion of those sustaining a fourth-degree tear at index delivery had a recurrence (15.4% of those with previous fourth-degree vs. 8.4% of those having previously sustained a 3a – 3c), which is in line with prior research (6.8% vs. 10.7%).(174, 219) We used BLR to determine which factors were independently associated with sustaining a repeat injury. This revealed that a worse degree of tear at the index delivery was associated with an almost two-fold increased risk of sustaining a rOASI. This correlates almost identically with a recent meta-analysis of risk factors associated with rOASIs (our analysis: OR 1.7, 95% CI 1.18-2.51, p=0.004) vs. (Jha et al.'s analysis: OR 1.7; 95% CI 1.24-2.36, p<0.05)). Furthermore, BLR revealed that if successive infant weighed >4kg, this was associated with a far greater risk of recurrent injury (OR 2.67, 1.32-5.39, p=0.006) which, again is in line with the same study (OR 2.29; 95% CI 2.06-2.54).(217)

Due to lack of evidence regarding any potential protective effect, the current guidelines do not recommend routine/prophylactic episiotomy at subsequent delivery after previous OASI.(17, 37) Our findings support those of another UK-based cohort study, that MLE protects against rOASI (Edozien et al.'s analysis: aOR 0.66, 95% CI 0.58-0.75, p<0.001 vs. our analysis: OR 0.25, 95% CI 0.059-1.086, p=0.064).(53) Although calculations would suggest ten episiotomies would be required at subsequent vaginal delivery to prevent one rOASI (NNT = 1/ATT = 1/(0.047-0.146) = -10.1), it would be naïve not to take into consideration the potential impact, healing and long-term effects of this intervention. This would need to be balanced with the effect, or not, of potential trauma or recurrence on symptoms of anal incontinence. Furthermore, although lack of episiotomy was highlighted to be a factor associated with a higher proportion of repeat injuries, this finding through BLR was not statistically significant (p>0.05). It would therefore be useful to expand this study to refute or corroborate this finding (see Chapter 5).

The RCOG's guidance on how to manage subsequent deliveries after an OASI quotes a recurrence rate of 5-7% and recommends women are, where possible, reviewed in a dedicated perineal clinic with results of endoanal sonography and anal manometry to aid decision-making. If a woman is symptomatic or has defect on physiological testing, an elective CS can be considered (see 1.7.1).(37)

A brief survey of Obstetricians (n=8) at Princess Anne Hospital (UHS NHS FT) (see Appendix C for the survey questions), and a review of their Trust specific guidelines (see also 1.7.2), revealed that

clinicians counsel women with a history of OASI antenatally regarding risk of recurrence, worsening of symptoms (regardless of mode of delivery but more so with VD) and the risk/benefit of an ElLSCS. Regarding complex cases, advice is sought at a specialist joint clinic of Urogynaecologists and Colorectal surgeons. Emphasis is more on results of EAUS, as all women should be reviewed at six-months postpartum at perineal clinic with the results of this investigation. Only those who remain symptomatic are referred only for AM via the joint specialist clinic.

Obstetric decision-making regarding the mode of subsequent delivery is based on several factors held at differing levels of importance. The survey asked clinicians to score their level of agreement (0 = completely disagree, 10 = completely agree) to different factors which may influence their decision-making. The decision to recommend a subsequent elective LSCS was most strongly influenced by the results of EAUS (level of agreement; median 10 (range 8-10)), patient choice (median 9 (range 3-10)) and own knowledge of risk factors associated with rOASI (median 8 (range 6-10)). Interestingly, very little or no regard was made to the patients' ethnicity (median 3 (range 0-7)) despite a well-established population of South Asian women in Southampton and the knowledge (by 75.0% of the clinicians) that Asian ethnicity is a risk factor for rOASI.

All were aware that the risk of rOASI is greater than primary OASI in multipara without a history of OASI and 37.5% thought the risk of recurrence was the same as the primiparous risk. Half were aware that the risk of a recurrence at subsequent delivery is worse than risk of injury at the index delivery. However, the median rate of recurrence quoted by the participants was six (range 5-10), which, although is in line with the guidelines, is considerably less than the rate of rOASI in this study. See Appendix D for the raw data.

4.5 Conclusion

The aim of this study was to investigate the delivery outcomes at subsequent delivery after previous OASI. We established that women with a history of an OASI are at greater risk of sustaining a rOASI that the primiparous population as well as the multiparous with previous vaginal birth but not sustaining an OASI. There are also positive correlations between severity of initial injury and the birth weight of the subsequent offspring, and risk of recurrence. This study revealed a potential protective effect of the use of mediolateral episiotomy in the prevention of rOASI. A study expansion to involve data from other NHS Trusts is required to corroborate or disprove these findings (see Chapter 5).

Chapter 5 Perineal trauma in subsequent delivery after previous OASI: A Multi-Centre Study

5.1 Objective

The main purpose of this chapter was to corroborate the findings of the previous chapter by increasing the cohort size to include patients from three additional NHS Trusts. The primary objective was to investigate the grade of perineal trauma at subsequent delivery after an OASI and explore what maternal, intrapartum and neonatal factors influence the risk of rOASI, specifically the use of MLE. Our secondary outcome measure was to explore what factors influence the likelihood of subsequently delivering by ElLSCS.

5.2 Methods

5.2.1 Study Design

The study was a retrospective population-based cohort study. The objective was addressed through analysis of prospectively collected data from maternity databases and paper records, from the following National Health Service (NHS) Trusts in the UK; University of Southampton NHS Foundation Trust, Croydon Health Services NHS Trust, Poole Hospital NHS Foundation Trust and University Hospitals of Leicester NHS Trust.

The sample included all primiparous women sustaining an OASI during a singleton, term, cephalic, vaginal delivery who had a subsequent delivery, between January 2004 and December 2015. Women who had had multiple, pre-term or non-cephalic deliveries at initial or subsequent delivery were excluded from the analysis.

Information was collected regarding demographic (maternal age at initial and subsequent delivery, and ethnicity), intrapartum (mode of delivery at both index and subsequent delivery, whether the subsequent delivery was post-term or whether an episiotomy was performed) and neonatal (birth weight at initial and subsequent deliveries) factors, as well as the degree of perineal trauma sustained. Sultan's classification of OASIs as in the current RCOG Green-top Guideline was used, and all degrees of perineal trauma involving the anal sphincter muscles were combined into one variable.(37)

5.2.2 Statistical analysis

Univariate analysis was carried out to compare maternal, intrapartum and neonatal factors at initial and subsequent delivery between women sustaining a repeat OASI at subsequent delivery with those who did not. Analysis was carried out using IBM SPSS v.24. The Kolmogorov-Smirnov test was used to determine the distribution of continuous data; parametric data were analysed using Independent Samples t-test and non-parametric data, the Mann-Whitney U test. Chi-Square test was used to analyse categorical data. Binary logistic regression (BLR) was used to calculate the adjusted, independent odds ratio (OR) for the risk of an OASI a subsequent delivery, including factors reaching statistical significance ($p \leq 0.05$). Further univariate analysis explored the subsequent deliveries in women suffering OASIS at first delivery, comparing those with a further vaginal delivery with those having an ElLSCS.

5.2.3 Ethical considerations

As the study involved transfer of data between NHS sites, it was deemed appropriate to gain ethical approval. Permission to undertake this research was granted by our sponsor, UHS NHS FT, under registration no. RHM O&G0235. The study was granted ethical approval by the HRA SC-Hampshire B Research Ethics Committee under reference no. 16/SC/0126 on 24th February 2016. Patient contact was not required as this was a retrospective database study with no direct patient contact. See Appendix A for ethics approval documents.

5.3 Results

During the twelve-year period, there were 209,584 singleton, term, cephalic vaginal deliveries of which 40.9% were primiparous women. The overall prevalence of OASIs was 3.1%. 77.3% of all OASIs were sustained by primiparous women at a rate of 5.8%, which is significantly greater than both the multiparous and overall rates of OASIS, 1.2% (difference 4.6%, $p<0.05$; 95% CI 4.5, 4.8) and 3.1% (difference 2.7%, $p<0.05$; 95% CI 2.6, 2.9), respectively. 48.1% of the primiparous women sustaining OASIS had a further recorded delivery. Having excluded all multiple, preterm and non-cephalic deliveries, as well as incomplete records, the study population was 2272. 77.9% (n=1769) had a subsequent vaginal delivery; of which 95.3% were by normal vaginal delivery (NVD), 2.5% had vacuum extraction and 2.1% delivered by forceps. The OASI recurrence rate was 10.2%. The most common perineal injury after previous OASIS was a second-degree tear (59.4% of births). See Figure 15 and Table 13 for overall delivery and perineal outcomes.

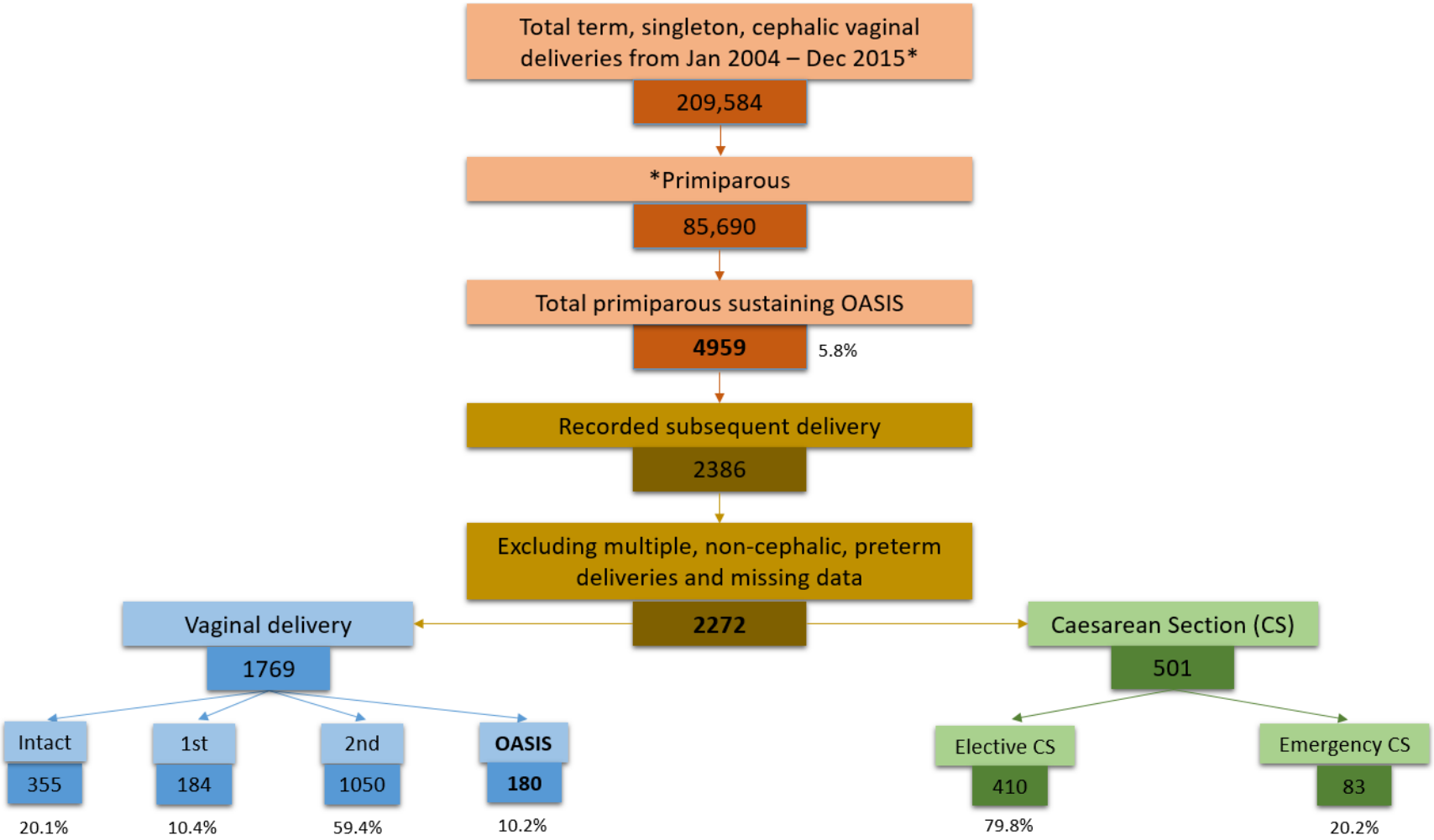

Figure 15: Delivery outcomes at subsequent delivery after previous primiparous OASI

Table 13: Perineal condition and incidence of episiotomy at subsequent vaginal delivery

Perineal Condition	Count	Percentage that had episiotomy	
No spontaneous trauma	354 (20.0%)	213 (60.2%)	
1st	185 (10.5%)	9 (4.9%)	268 (16.9%)
2nd	1050 (59.4%)	46 (4.4%)	
OASI	180 (10.2%)		8 (4.4%)
Total	**1769**		

Univariate analyses are shown in Table 14 comparing maternal, neonatal and intrapartum factors concerning the risk, or not, of sustaining repeat OASIS at subsequent vaginal delivery. We identified differences in the frequency of recurrence of OASI relating to ethnicity; although not statistically significant, Asian women (of South Asian decent e.g. Indian, Pakistani, Bengali) were more likely to sustain a repeat tear than both Caucasian and Black women (12.6% (53/422) vs. 9.6% (105/1092) and 9.1% (7/77), respectively; p=0.225). Those sustaining rOASI were significantly older at both the index and subsequent delivery (28 vs. 27yrs, p=0.013 and 31 vs. 30, p=0.010) and had significantly heavier babies at subsequent delivery (3625 vs. 3502.5, p=0.001), with a greater proportion over four kilograms (25.0% vs. 14.3%, p<0.001). Women with rOASI were more likely to have had a more severe degree of anal sphincter injury at their first delivery. No difference was seen when analysing the mode of delivery or whether the subsequent delivery was post-term.

The overall MLE rate at subsequent delivery was 15.6% (276/1769) and was carried out in 81.9% of OVDs (92.1% (35/38) forceps, 73.3% (33/45) vacuum extraction) and 12.3% (208/1687) of NVDs. Four out of 15 (26.7%) women having an operative vaginal delivery (OVD) without an episiotomy had a repeat sphincter injury compared with 2.9% (2/68) of those with a MLE. MLE was protective against OASIS; p<0.001 (difference 12.4%, 95% CI 6.8, 18.0). This was regardless of delivery mode (NVD p<0.001 (13.4% of repeat OASIS without MLE versus 3.4% of repeat OASIS with MLE, 95% CI 4.5, 15.0), forceps p=0.02 (difference 30.5%, 95% CI 4.1, 56.8) or vacuum extraction p=0.02 (difference 22.0%, 95% CI 3.2, 40.8)). 77.2% of those with MLE sustained no spontaneous perineal trauma. Only 4.4% of women with recurrent OASI had a MLE; 2.9% (8/276) of those with MLE had recurrent OASIS. The number of MLE required to prevent one OASI is eight (NNT = 1/ARR = 1/(0.169-0.044)) when including all modes of VD; ten if the delivery was a NVD (NNT = 1/(0.134-0.034)) and two if the subsequent delivery was an OVD (NNT = 1/(0.857-0.333))

Table 14: Comparison of those sustaining a rOASI at subsequent delivery with those who did not

		rOASI (n=180)	No rOASI (n=1589)	p-value
Ethnicity (n=1591: 165 rOASI, 1589 no rOASI)	Caucasian	105 (63.9%)	987 (69.2%)	p=0.225[a]
	Asian	53 (32.1%)	360 (25.9%)	
	Black	7 (4.2%)	70 (4.9%)	
Age	**Index delivery**			
	Median (years)	28 (15 – 40)	27 (15 – 48)	**p=0.013**[b]
	Subsequent delivery			
	Median (years)	31 (18 – 41)	30 (17 – 50)	**p=0.010**[b]
Birth weight (g)	**Index delivery**			
	Mean (g)	3459.5 (±468.01)	3420.8 (±455.61)	p=0.296[c]
	% over 4Kg	19 (10.6%)	174 (11.0%)	p=0.872[a]
	Subsequent delivery			
	Median (g)	3625 (2512 – 5440)	3502.5 (2030 – 6480)	p=0.001[b]
	% over 4Kg	45 (25.0%)	228 (14.3%)	**p<0.001**[a]
^ Degree of OASIS at 1st delivery (n=902: 104 rOASI, 798 no rOASI)	Overall comparison			**p=0.006**[a]
	3a – < 50% of EAS involved	37 (35.6%)	428 (53.6%)	
	3b – ≥ 50% of EAS involved	50 (48.1%)	268 (33.6%)	
	3c – EAS and IAS involvement	10 (9.6%)	53 (6.6%)	
	4th – 3c + anorectal mucosa	7 (6.1%)	49 (6.1%)	
Operative VD (% of all deliveries)	**Index delivery**	51 (28.3%)	464 (29.2%)	p=0.808[a]
	Subsequent delivery	6 (3.3%)	77 (4.8%)	p=0.363[a]
Gestation	Post-term (>40 weeks)	99 (55.0%)	762 (48.0%)	p=0.073[a]
Episiotomy	Overall rate	8 (4.4%)	268 (16.9%)	**p<0.001**[a]
	NVD	6 (3.4%)	202 (13.4%)	**p<0.001**[a]
	Forceps delivery	1 (50.0%)	34 (94.4%)	**p=0.023**[a]
	Vacuum extraction	1 (25.0%)	32 (78.0%)	**p=0.022**[a]

[a] Chi-square, [b] Mann-Whitney U Test (non-parametric data), [c] Independent t-test (parametric)
(^ Data loss as the majority of OASI were recorded as either a 3rd- or 4th-degree tear, without use of the 3a/3b/3c subclassification. Data included in the analysis only refers to records where the subcategories of 3rd-degree tear were used.)

The factors which remained independently associated with the risk of OASIS after binary logistic regression (BLR) are shown in Table 15. These included the age of the mother at subsequent delivery, proportion of babies weighing over four kilograms at subsequent delivery, degree or severity of OASIS at initial delivery and whether an episiotomy was performed at subsequent delivery. The analysis of odds ratios revealed that episiotomy at subsequent delivery decreased the risk of repeat OASIS by 80%, whereas birth weight greater than four kilograms increased the risk of repeat OASI by 2.5-fold.

Table 15: Factors independently associated with rOASI

	OR	95% CI	p-value
Age of mother at subsequent delivery (years)	1.05	1.004 – 1.097	0.032
Birth weight >4Kg at subsequent delivery (%)	2.51	1.534 – 4.122	<0.001
Degree of OASIS at initial delivery (%)	1.57	1.240 -1.989	0.001
Episiotomy at subsequent delivery (%)	0.21	0.080 – 0.524	<0.001

The caesarean section (LSCS) rate at subsequent birth was 22.1%, of which 79.8% were elective. The analyses in **Error! Reference source not found.** compare the women having a further VD with those having an ElLSCS. Those having an emergency LSCS were excluded from the analysis as the indication for LSCS was unknown. An assumption was made that the indication for ElLSCS was most likely due to either symptoms of sphincter injury or abnormal anorectal physiology test results.

Significant variation was seen when comparing the mode of subsequent delivery across the categories of ethnicity. Caucasian women were 2.2-times and 4.5-times more likely to have had an ElLSCS than Asian and Black women respectively (22.2% vs. 10.2% and 4.9% as proportion of women from each ethnic category). Women having an ElLSCS were significantly older at both initial and subsequent delivery. They also had heavier babies at first delivery (3577 vs. 3450, p<0.001), with a significantly greater proportion weighing over four kilograms (17.7% vs. 10.9%, P<0.001). Women having ElLSCS had a worse grade of OASIS at initial delivery and were 1.5-times more likely to have had an operative vaginal delivery, than those having repeat vaginal delivery.

When taking into account the factors highlighted in the regression model (see Table 15 above) which would have affected the risk of subsequent OASI if those having a CS instead had had a further VD, 33.1% (169/510) would have been classified as ‘high risk’ of a rOASI (when quantifying ‘age of mother at subsequent delivery’ as >35 years old, subsequent birth weight as >4kg and degree of previous OASI as a fourth-degree tear). This would have risen to 39.8% (203/510) if being of Asian ethnicity was included. Of the 83 who had a subsequent EmLSCS (excluded from the analyses below), 37.3% (31/83) would be classified ‘high risk’ based on the same criteria and this would have risen to 56.6% (47/83) if those of Asian ethnicity were included.

Table 16: Comparison of women with subsequent VD vs. EILSCS

		Subsequent VD delivery	Subsequent ELLSCS delivery	p-value
Ethnicity (n=1963: 1598 VD, 365 EILSCS)	Caucasian Asian Black	1098 (68.7%) 423 (26.5%) 77 (4.8%)	313 (85.8%) 48 (13.2%) 4 (1.1%)	**p<0.001**[a]
Age	**Index delivery** Median	28 (15 – 48)	29 (15 – 42)	**p<0.001**[b]
	Subsequent delivery Median	30 (17 – 50)	32 (16 – 46)	**P<0.001**[b]
Birth weight (g)	**Index delivery** Mean % over 4Kg	3450.2 (±454.14) 193 (10.9%)	3577.5 (±455.61) 73 (17.7%)	**p<0.001**[c] **p<0.001**[a]
	Subsequent delivery Median % over 4Kg	3520 (2030 - 6480) 273 (15.4%)	3480 (2000 – 4820) 47 (11.4%)	**p=0.001**[b] **p=0.042**[a]
Mode of delivery at 1st delivery	Operative VD	517 (29.1%)	176 (42.7%)	**p<0.001**[a]
^ Degree of OASIS at 1st delivery (n=1112: 910 VD, 202 EILSCS)	Overall comparison 3a 3b 3c 4th	 468 (51.4%) 318 (34.9%) 65 (7.1%) 59 (6.5%)	 54 (26.7%) 88 (43.6%) 21 (10.4%) 39 (19.3%)	**p<0.001**[a]

[a] Chi-square, [b] Mann-Whitney U Test (non-parametric data), [c] Independent t-test (parametric)
(^ Data loss as the majority of OASI were recorded as either a 3rd- or 4th-degree tear, without use of the 3a/3b/3c subclassification. Data included in the analysis only refers to records where the subcategories of 3rd-degree tear were used.)

5.4 Discussion

5.4.1 Main findings

This study aimed to substantiate the findings of the previous chapter by assessing whether there are any key factors influencing the risk of women sustaining a rOASIS. Data regarding women who sustained an OASI and had a subsequent birth between January 2004 and December 2015 was collected, combined and analysed from four NHS Trusts' maternity databases.

Our primary finding was that women with a history of previous OASI had a greater risk of rOASI than both primiparous and other multiparous women without previous OASI. This confirms the outcomes of the previous chapter, and further refutes the current guidance. (53, 217)

Recurrence was more likely with increased maternal age if the subsequent infant had a birth weight greater than four kilograms and a more severe degree of OASI at index delivery. MLE was shown to be protective against rOASI regardless of the delivery mode. This study provides new information regarding those who elected to have a subsequent LSCS. This cohort were more likely to be older

at both index and subsequent delivery than those having a further VD were more likely to be Caucasian, to have had an OVD at index delivery and to have sustained a more severe degree of OASI.

5.4.2 Strength and Limitations

This study's strength lies in the fact that data collection was achieved through manual, prospective examination of electronic- and paper-based birthing records of 2272 women having sustained an OASI over a 12-year period. Data collection in this manner removes potential inaccuracies associated with incomplete or incorrect electronic coding, which has been highlighted as a limitation of previous large database studies.(8, 36, 53) However, one potential limitation of our study was that the process of identification of those meeting the inclusion criteria was electronic, and hence at risk of being subject to incorrect coding. Data was also extracted from four different Trust-based maternity databases. We believe that we have largely overcome any potential coding inaccuracies by manual prospective collection of data concerning the subsequent delivery and retrospective review of the electronically extracted data of the index delivery. However, this method was still subject to human error and strategies to reduce this (e.g. two-pass verification) were not performed. Approximately 1% of collated data were incomplete and excluded from analysis, and an entire year's data were excluded from one site due to errors in coding associated with a changeover of the maternity database that year. Furthermore, there was considerable data loss regarding the subcategory of OASIs sustained at the index deliveries, as the vast majority of cases were recorded as either a third- or fourth-degree tear (without the use of the 3a/3b/3c subclassification of third-degree tears). Only the records using the third-degree tear subclassification were included in the analysis.

For further explanation regarding the limitations of database research, refer to section 1.8.2.

A further limitation was that individual cases were subject to bias in clinical decision making as the data encompasses the practice of many different clinicians, at four individual sites over a 12-year timeframe. However, we believe it safe to assume practitioners were working in accordance with nationally recognised guidelines, hence validating the merging of the datasets. Unfortunately, we do not know whether the angle at which the MLE were performed was to the recommended 60^{o} as the patients were not examined. However, given the fact that it has been established that an episiotomy cut at a 60^{o} angle is protective, the impact of ensuring a 60^{o} angle can only enhance its beneficial effect. We are also aware that the extent to which OASI preventative measures, such as manual perineal protection, are used may vary between the different sites. Additionally, the indication for EILSCS was unknown, hence the analysis was based on the assumption that the reason

for ElLSCS over VD was due to the resultant effect of the OASI sustained at index delivery. It would have been of interest to also compare the rates of induction of labour, length of second stage and birthing position, but this was not within the scope of this study.

5.4.3 Interpretation

This research both supports and substantiates the findings of the previous chapter regarding increased risk of repeat OASI, associated risk factors for a rOASI (Asian ethnicity, grade of initial OASI and weight of the successive infant) and the proportion of the other less severe forms of perineal trauma.

In agreement with earlier studies exploring the risk of OASIS in the primiparous population, we found both macrosomia and increased maternal age carried through to the subsequent delivery as positive predictors of rOASI.(36, 231) We also found that women with a more severe degree of OASIS at initial delivery were at increased risk of a rOASI. No association was seen between mode of delivery, or gestation at initial and subsequent vaginal delivery, and risk of a recurrence.

MLE has been shown to be protective against sphincter damage at OVD, and a recent review of second stage interventions in the prevention of OASI quotes an overall 40 – 50% reduction in risk of OASI with MLE.(54, 128, 217) The use of MLE in the prevention of rOASI was less clear.(217) Although the episiotomy rate at subsequent delivery in this study was lower than the national rate of 20.2%(8), the cohort not sustaining rOASI were significantly more likely to have had a MLE regardless of delivery mode. Overall, eight episiotomies would need to be performed to prevent one OASI (inclusive of all delivery modes); ten if the delivery was non-operative and two if operative. This supports the findings of a recent large national cohort study and the national guidelines regarding the prevention of primary OASI, especially with regard to the use of MLE at OVD.(36, 37) Although the proportion of subsequent OVDs was very low (4.6% of all subsequent VD (83/1769)), it was somewhat surprising to find that 7.9% of women having a subsequent forceps delivery did not have a MLE. This practice not only would put these women at even greater risk of OASI but also goes recommendations in the national guidelines.(17, 36, 37)

The host Trust's guideline (see section 1.7.2)(227) goes some way in encouraging the use of MLE in the prevention of rOASI. Though, in reality the likelihood of this practice is somewhat improbable as there is a reliance on a) patients' awareness of the intervention ('maternal request') and b) not only the accoucheurs' recognition of when a tear is 'imminent' but also their when willingness to perform one (see also section 1.3.6.7). However, this research revealed the importance of MLE as the use of MLE after previous OASI returns the rate of OASI at subsequent delivery to the overall UK national rate of 2.9% (1.7% for multiparous women).(8) This is regardless of mode of VD.

Multivariate logistic regression has become the analytic tool of choice in retrospective studies and was useful in this study to determine the factors independently associated with the risk of OASIS.(233) Most strikingly, MLE was associated with an 80% reduction in the risk of rOASI. This is the first published study to make this conclusion and could go some way in providing the required evidence to update the current recommendations in favour of the use of prophylactic MLE in the prevention of rOASI.(37) Although, it is important to recognise that MLE is not without potential complications such as long-term symptoms of perineal pain and dyspareunia, we would agree with previous research that the morbidity has less of an impact than an OASI, and we would expect this to be even more the case in the event of a recurrence.(128)

A brief survey of Obstetricians regarding management of women sustaining an OASI and the process of decision-making concerning mode of subsequent delivery revealed some variation between the Trusts involved in this study. At the host site (UHS NHS FT), only those suffering a 3b and worse have hospital-based follow-up, and only endoanal ultrasonography is performed postnatally (see section 1.7.2). In contrast, Croydon and Leicester follow-up all who sustain an OASI, with both EAUS and anal manometry (AM). A greater reliance on the results of these investigations would therefore be expected when counselling women antenatally regarding a subsequent delivery. (However a significant limitation of the survey was that not enough responses were received to make any meaningful conclusions – n=8 for host site, n=3 all other sites combined.) Interestingly, those sustaining a rOASI at the host site are followed-up in the same was as those after primary OASI – excluding those with a 3a-tear and only referring for EAUS. This is surprisingly considering that the majority of the 10.2% rOASIs sustained would be 3a-tears, and that they are at significantly increased risk of long-term anal incontinence, faecal urgency, and subsequent negative impact on quality of life.(219)

An interesting observation was noted when analysing the delivery mode after OASI across the ethnic categories; a greater proportion of Caucasian women had a subsequent ElSCS than both Asian and Black. A possible interpretation is that women of ethnic minority groups are more likely to underreport symptoms, opt for a more natural approach and be less inclined to accept recommendations – observations seen in other areas of clinical medicine.(234) Without information regarding the indication for ElLSCS, this observation is entirely speculative.

Those having ElLSCS at subsequent birth were significantly older at both index and subsequent delivery, which correlates with the observed impact of maternal age on obstetric outcome and the increased likelihood of requiring a CS.(235) This also supports previous research regarding age-related change in perineal collagen composition, which could predispose both the initial injury, resultant symptoms and the recommendation for a subsequent ElLSCS.(229) Due to the gestation at which the ElLSCSs would have taken place, these women had significantly lighter babies than

those having a further VD. The results of this study support the notion based on linearity regarding the degree of sphincter involvement and severity of symptoms; hence worse damage resulting in the recommendation for a subsequent ElLSCS. These women had significantly heavier babies at first delivery, with a greater proportion weighing more than four kilograms, and were also 1.5-times more likely to have had an OVD; factors associated with greater severity of trauma.(53, 231)

It was somewhat surprising to realise the proportion of those having a subsequent CS who, according to our regression model, would have been classified as 'high risk' for a rOASI. This more so in those having an unplanned subsequent CS. We can only speculate that the indication for these EmLSCSs may have in some cases been due to reasons that would have made a recurrent injury more likely, e.g. in an obstructive picture (larger baby (than those electing to have a CS) and possible cephalopelvic disproportion. It is reasonable to suggest therefore that had a higher number of VD been achieved in this cohort, the rOASI rate may have been even higher and these risk of resultant symptoms of AI, faecal urgency and impact on QoL even greater.(174, 225)

5.5 Conclusion

Women with previous OASIS are at an increased risk of sustaining another OASI at subsequent delivery, further predisposing them to anal sphincter dysfunction. Increased maternal age and birth weight, and severity of tear at index delivery are positive predictors for rOASI. More liberal use of MLE could decrease the risk of recurrence by 80%. This information will be useful in aiding clinical decision-making and counselling of women who decide to have a further vaginal delivery after an OASI.

Chapter 6 Pelvic Floor Symptoms Questionnaire Study

6.1 Objectives

- To assess both the quantitative and subjective personal effect (via free text comments) an OASI has on QoL and symptoms of pelvic floor dysfunction (PFD)
- To determine whether having a subsequent delivery impacts upon symptoms of PFD in women who have previously sustained OASIS.
- To determine whether the mode of delivery (MoD) at subsequent delivery impacts symptoms of PFD in women who have previously sustained OASIS.

6.2 Methods

6.2.1 Study Design

To address the objectives participants were required to complete a 26-question, 72-item postal questionnaire on the symptoms of pelvic floor dysfunction. The first two questions provided background information and established the participant's eligibility to take part. Questions 3 – 25 formed the quantitative assessment, and question 26 the space for free text comments.

Comparison of questionnaire scores and maternal, intrapartum and neonatal factors were made between:

a) Those sustaining an OASI at initial delivery and a control population
b) Those of the OASI cohort having a further delivery and those without a further delivery
c) Those having a subsequent vaginal delivery (VD) and those having a subsequent CS (caesarean section (CS)

The subjects were invited to participate in the study by initial postal pack, which included a cover letter and Patient Information Sheet (PIS). The covering letter had a tear off response slip for participants to indicate whether they wished to participate. This was then sent back to the researcher in a prepaid postage envelope. Following a positive response the second postal pack was sent out to the participants; including a PIS (to re-familiarise themselves with the study), two identical consent forms (one for their own records, one for the research file), and the questionnaire. The completed consent form and questionnaire were then returned in a further prepaid postage envelope. Nothing further was required of the participants. See Appendix B for all participant study paperwork, including the questionnaire. On receipt of the questionnaire, the quantitative information was tabulated into an Excel spreadsheet together with extrapolated information from

the maternity database concerning maternal, intrapartum and neonatal factors relating to each of the births of those consenting to take part.

6.2.2 Participant subcategories

The participants' information was firstly grouped according to whether an OASI was sustained at initial delivery. Then those having sustained an OASI were further grouped according to whether they had a further delivery and the mode of that subsequent delivery (see Table 17 and Figure 16).

Table 17: Key of participant group subcategories

Group		
C		Control (intact perineum)
NVD		Normal VD (NVD), OASI sustained, no further delivery
OVD		Operative VD (OVD), OASI sustained, no further delivery
NVD - NVD		Subsequent NVD after previous NVD, no OASI recurrent
NVD - CS		Subsequent Caesarean Section (CS) after previous NVD with OASI sustained
OVD - NVD	*	Subsequent NVD after previous OVD, no OASI recurrent
OVD - CS		Subsequent Caesarean Section (CS) after previous OVD with OASI sustained

*OVD-NVD includes all deliveries where at least one of them was an OVD e.g. OVD-OVD, NVD-OVD

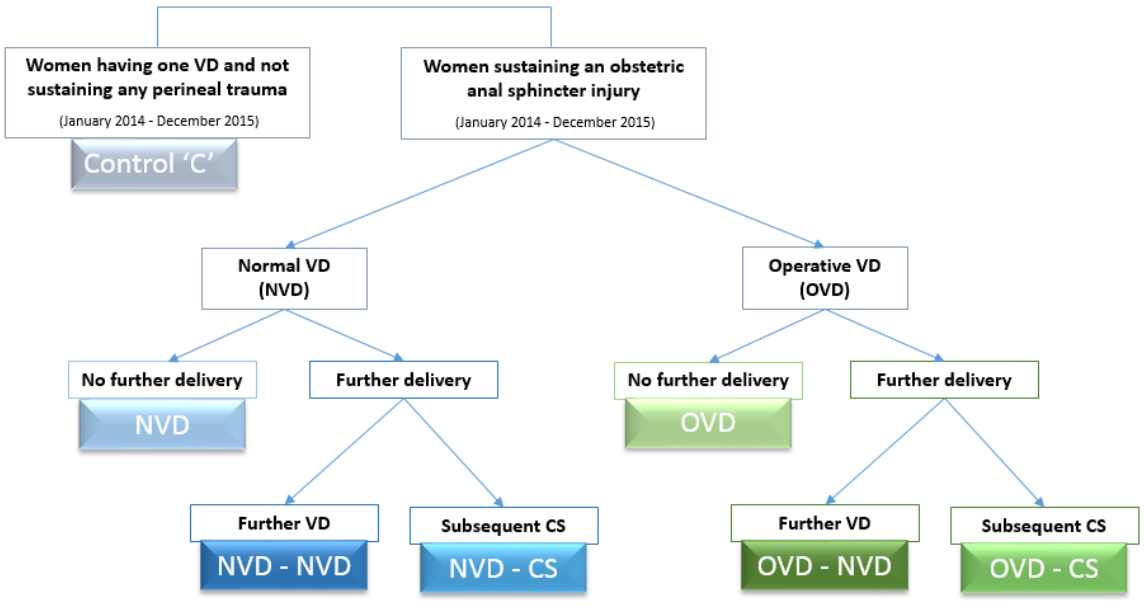

Figure 16: Subcategories of participants completing the questionnaire

The first section of the questionnaire – 'Your background information', included past medical history and current pregnancy status. These were used to ascertain the participants' eligibility to be involved in the study. The next section – 'The birth of your child(ren)', was used to determine which comparison group the participants would be grouped into. Aside from a space for free text and comments, to assess the subjective personal effect of an injury, the rest of the questionnaire comprised four widely recognised questionnaires used in clinical practice at UHS NHS FT for the assessment of different aspects of pelvic floor dysfunction (PFD):

- Anal incontinence: CCIS (Cleveland Clinic Incontinence Score) and FIQLI (Faecal Incontinence Quality of Life Instrument)
- Urinary incontinence: ICIQ-UI (International Consultant on Incontinence Questionnaire – Urinary Incontinence)
- Sexual dysfunction and pelvic organ prolapse: PISQ-12 (Pelvic Organ Prolapse/ Urinary Incontinence)

6.2.3 Participant selection

The same cohort of patients from the database study "Risk Factors for OASI in the Primiparous Population" (see Chapter 2) was used in this study.

The inclusion criteria were as follows:

- Women who sustained an OASI at a cephalic, term, singleton vaginal delivery (either NVD or OVD using forceps or vacuum extraction) from 2004 to 2015, with ≤ one subsequent delivery. (If further delivery – rOASI, preterm delivery, non-cephalic and multiple births excluded.)
- A control comparison was made with women who had one vaginal delivery which had also been cephalic, term, singleton but resulted no perineal trauma (perineum documented as 'intact' on the maternity database)
- All participants were required to be at least 18 years of age and able to comprehend English with capacity to understand the study and consent to participation

Women were excluded if they had any conditions affecting the pelvic floor which had the potential to skew the questionnaire result. These included:

- A previous diagnosis and treatment of pelvic floor dysfunction
- Currently pregnant or less than one year postpartum
- Metabolic/ neurological/ pathological condition affecting bladder function or anal sphincter tone
- A History of lower tract genitourinary malignancies or any previous pelvic radiation
- Any clinically significant systemic disease or condition that in the opinion of the Investigator would make the subject unsuitable for the study.

6.2.4 Sample size calculation

Power calculations were made based on the following studies examining anal incontinence in women who sustained an OASI at their initial delivery:

- After initial delivery only: Tin et al. found the prevalence of AI following an OASIS to be as high as 7.7 to 19.7% (solid vs. loose stool). Most studies report approximately 20% of women have AI after OASIS.(236)
- After subsequent delivery: Fynes et al. found that 42% of women (with OASIS at first delivery) develop symptoms of AI after a second vaginal delivery.(220)

Assuming similar differences in prevalence of symptoms as the above studies of PFD between the groups, a sample size of 69 subjects per group (69 women who have had an OASIS but no subsequent delivery, and 69 women who have had a subsequent vaginal delivery) was calculated. Therefore, the total number needed to reject the null hypothesis at 80% power level and at 0.05 significance level was 138. We anticipated a response rate of about 25 – 30% (which is in line with other postal questionnaires).(237) Knowing from the database that 495 women with OASIS had a subsequent vaginal delivery, we were hopeful that we would be able to recruit the desired number from our centre alone.

6.2.5 Statistical analysis

Univariate analysis, using IBM SPSS v.24, compared maternal, intrapartum and neonatal factors, and various components of the questionnaire scores between the different groups outlined in 6.2.1. Continuous data was analysed using either Mann-Whitney U or Independent Student's T Test. Chi-square was used to analyse categorical data. Statistical significance was defined as a p-value ≤0.05.

6.2.6 Gaining ethical approval

An initial unfavourable opinion was granted on 8th June 2015, following scrutiny of the proposed study (15/SC/0297) by a review panel (NRES Committee South Central – Hampshire B) comprising lay people and medical professionals not specialised either in this area of medicine or of pelvic floor dysfunction. The committee recommended amendments be made to both the methodology and the Patient Information Sheet (PIS). The committee recommended that the first contact with potential participants should be by the clinicians in their 'direct care team', and by post rather than by telephone as initially planned.

In the redevelopment of the methodology, PIS and questionnaire, we agreed with the committee in their suggestion of involving an independent patient and public involvement (PPI) review team.

Through their involvement (facilitated by a Patient and Public Involvement Officer for the National Institute for Health Research, Southampton) we gained insight into how best to make the study as clear, concise and 'patient-friendly' as possible, not only in format and wording but also in content and method of recruitment. All recommendations for alteration of the original PIS and questionnaire drafts were implemented, and the redrafted documents were then re-reviewed. The reviewers accepted all changes.

Due to the substantial changes made to the research proposal, we created a new application to the NHS Health Research Authority. This was submitted on 1st December 2015 (15/NW/0867) and was granted a favourable opinion by North West - Liverpool Central Research Ethics Committee on 5th January 2016.

In addition to the obstructions faced in achieving ethical approval to carry out the study, we also encountered significant difficulties in gaining access to the required patient information. The custodians of the maternity database were hesitant to provide the hospital numbers of those fitting the inclusion criteria for the study, as I was a research fellow from the University and not a clinical fellow. The same cohort of patients, and hence access to the same patient information, was required for all the studies so this resulted in significant setbacks and delays in the proceedings. (See also section 7.1.)

6.2.7 Questionnaire scoring

The following is an explanation of how the individual questionnaires were scored:

CCIS

CCIS is a tool used to assess the severity/frequency of five categories concerning anal incontinence. It provides a symptom score rather than an indication of QoL. The frequency is rated on a 1 (never) to 5 (always/daily) scale. The score yielded from the sum of the frequencies indicates the symptom severity, where a higher score implies a worse degree of incontinence.(194) See also 0.

FIQL

Questions two to five of section three of the questionnaire comprised the FIQL scale. The score compilation for this component of the study questionnaire was carried out as recommended.(195) The FIQL comprises four scales analysing the possible resultant effects of 'accidental bowel leakage' on lifestyle, coping/behaviour, depression/self-perception and embarrassment, using a 4-point score for each component (1 = most of the time, 4 = none of the time). Low scores indicate a lower functional status of quality of life (QoL). Table 18Table 18 outlines which questions are associated

with each of the QoL indictors. As questions two and five used scales of greater than four components, these scores were multiplied by 0.8 and 0.67, respectively, to yield a score out of four. Additionally, question two is reverse scored for the analysis. An average score was then worked out for each of the QoL indicators (by dividing the score by the number of questions in that category), which were then totalled to give an overall score out of 16. See also 0.

Table 18: FIQL subcategories of QoL indicators

FIQL (Q2-5)	
Scale 1 -Lifestyle	3a, 3b, 3c, 3d, 3e, 3g, 3h, 4b, 4l, 4m
Scale 2 - Coping/Behaviour	3f, 3i, 3j, 3k, 3m, 4c, 4h, 4j, 4n
Scale 3- Depression/Self-Perception	2, 4d, 4f, 4g, 4i, 4k, 5
Scale 4 - Embarrassment	3l, 4a, 4e

ICIQ-UI

The ICIQ-UI questionnaire comprises three scored items (questions six to eight of the study questionnaire) analysing how often, and the quantity, that they leak urine and the impact this has on QoL. The unscored self-diagnostic item (Question 9) was used to help determine the type of UI the participant is experiencing. The sum of the three scores determines the level of impact, with higher scores indicating a greater effect on QoL (best score = 0, worst score = 21).(200) See also 0.

PISQ-12

PISQ-12 is the validated short form of PISQ-31 and is used to evaluate sexual function in women with pelvic organ prolapse and/or urinary incontinence. This questionnaire was used to assess the QoL associated with sexual function as there was not a questionnaire specific to for those suffering an OASI available. Question 10 of the study questionnaire was used to determine whether the participants were sexually active. Those not sexually active completed Question 11 and 12 to establish whether abstinence was due to symptoms of PFD. The PISQ-12 score, for those sexually active, was determined by completing Questions 13 – 23 and 25. Scores were calculated by totaling the 4-point scale answer from each question. As recommended, reverse scoring was applied to the first four questions (Question 13 – 16). The highest possible score, indicating minimal impact of condition on sexual function, was 48. Further analysis to determine whether the sexual dysfunction was due to a behavioural, physical or partner-related component are detailed in Table 19.(201) See also 0.

Table 19: PISQ-12 subcategories of sexual dysfunction

PISQ-12 (Q13 – 23 + 25)	
Behaviour	Q13, 14, 15, 16
Physical	Q17, 18, 19, 23
Partner	Q20, 21, 22, 25

6.3 Results

Participants were recruited using a maternity database of 1435 women (1269 with an OASI, 166 with an intact perineum) having had primiparous, term, singleton, cephalic vaginal delivery. Between February and August 2016, a total of 675 women with a history of OASI were invited to participate. Recruitment was reverse chronological i.e. women delivering most recently (e.g. in 2015) were invited to participate first. Recruitment concluded in the NVD and OVD groups at years 2010 and 2011, respectively, as response rates decreased as time since most recent delivery increased. This was most likely due either to the women changing address or interest in the subject matter declining over time. About a third (32.7%) of those invited replied, giving permission for follow-up postal pack to be sent to them. Three-quarters of those women returned the completed questionnaire yielding a total cohort of 168, and an overall response rate of 24.9%. Ten women were excluded from the analysis. See Table 20.

Table 20: Response rates and Exclusions of the subcategories

	C	NVD	OVD	NVD - NVD	OVD - NVD	NVD - CS	OVD - CS	Total (Excl. 'C')
Total sent	166	167	146	168	91	51	52	675
1st round response	18 (10.8%)	37 (22.2%)	42 (28.8%)	66 (39.3%)	28 (30.8%)	20 (39.2%)	28 (53.8%)	221 (32.7%)
2nd round response	18 (10.8%)	26 (15.6%)	34 (23.3%)	50 (29.8%)	19 (20.9%)	16 (31.3%)	23 (44.2%)	168 (24.9%)
Exclusions	0	1 - Pregnant	2 - Pregnant	1 – IBS 1 – PFD operation	1 – Ulcerative Colitis	1 – Had 3rd child 1 – Under Neurourogynae	1 – Had 3rd child 1 – Neuronal damage	10
Final number	**18**	**25**	**32**	**48**	**18**	**14**	**21**	**158**

Tables Table 21 and Table 22 show the background maternal, neonatal and intrapartum factors per subgroup. The comparisons are made between subgroups in 6.3.1 and 6.3.3. Table 23 shows the individual questionnaire scores for each of the subcategories. Of all the subcategories, the control population had the best questionnaire scores of all the subcategories. Analysis in section 0 aimed to determine whether this was due to the sphincter injury alone or whether there were other contributing factors.

Table 21: Maternal, neonatal and intrapartum factors of those with a single delivery

Variable	**Single delivery**			
	Control n=18	**NVD** n=25	**OVD** n=32	**NVD+OVD** n=57
Ethnicity *	94.4%	100%	96.7%	98.1%
Age[a]	31 (20-37)	30 (19-42)	29 (24-41)	30 (19-42)
Birth weight[b]	3401.1	3518.2	3594.8	3561.2
% >4Kg	5.6%	12.0%	9.4%	10.5%
Length 2nd stage[a]	53 (9-192)	40 (4-135)	148 (11-362)	81 (4-362)

*as % Caucasian, a = non-parametric data so median (and range), b = parametric data so mean

Table 22: Maternal, neonatal and intrapartum factors of those with a subsequent delivery after an OASI

Variable	Subsequent delivery					
	NVD-NVD	**OVD-NVD**	**NVD-NVD + OVD-NVD**	**NVD-CS**	**OVD-CS**	**NVD-CS + OVD-CS**
Ethnicity *	97.9%	94.4%	97.0%	100%	95.2%	97.1%
Index delivery						
Age[a]	30 (22-37)	30.5 (23-38)	30 (22-38)	31 (24-33)	32 (27-38)	31 (24-38)
Birth weight[b]	3544.7	3683.4	3582.6	3589.2	3600.0	3595.7
% >4Kg	8.3%	27.8%	13.6%	21.4%	4.8%	11.4%
Length 2nd stage[a]	54 (7-375)	137.5 (11-210)	73.5 (7-375)	71 (22-155)	53 (15-220)	114 (15-220)
Subsequent delivery						
Age[a]	32 (26-38)	32 (25-40)	32 (25-40)	33.5 (27-35)	35 (28-41)	34 (27-41)
Birth weight[b]	3665.8	3541.3	3634.7	3501.8	3744.0	3647.1
% >4Kg	22.9%	16.7%	19.7%	7.1%	28.6%	20.0%

*as % Caucasian, a = non-parametric data, therefore the median (and range) are used, b = parametric data, therefore the mean is used

Table 23: Individual questionnaire scores per subcategory

			Single delivery			Subsequent delivery			
	Best	**Worst**	**Control**	**NVD**	**OVD**	**NVD-NVD**	**OVD-NVD**	**NVD-CS**	**OVD-CS**
CCIS	5	25	5 (5-12)	9 (5-9)	7 (5-18)	5.5 (5-20)	5 (5-11)	6.5 (5-12)	8 (5-17)
FIQLI	16	4	15.9 (14.8-16.0)	15.8 (12.1-16.0)	15.7 (9.3-16.0)	15.5 (9.7-16.0)	15.9 (6.6-16.0)	15.7 (9.9-16.0)	15.1 (10.2-16.0)
ICIQ-SF	0	21	1.5 (0-7)	4 (0-12)	3.5 (0-12)	4 (0-14)	3 (0-15)	3 (0-10)	3 (0-9)
PISQ-12	48	12	41 (36-44)	36 (30-44)	35 (26-44)	38.5 (25-45)	38 (24-42)	34.5 (27-42)	35.5 (27-42)

As all data was non-parametrically distributed, scores represented are medians (with the range)

6.3.1 The effect of sustaining an OASI on symptoms of PFD

To determine the effect that sustaining an OASI has on resultant symptoms of PFD, a comparison of questionnaire scores was made between a control population and three different groups of women having sustained an OASI; those delivering via NVD, OVD and those groups combined. There was no difference when comparing maternal (age and ethnicity) or neonatal (birth weight and proportion greater than four kilograms) factors. Although the OVD cohort had a longer 2nd stage of labour compared with the control cohort (p<0.001), this difference disappeared when NVD and OVD were combined (p=0.058). See Table 24. For the raw data see Table 21.

Table 24: Comparison of variables between those that sustained an OASI with a control population

Variable	Control vs. NVD	Control vs. OVD	Control vs. NVD+OVD	NVD vs. OVD
Age	p=0.720[a]	p=0.417[a]	p=0.498[a]	p=0.765 [a]
Ethnicity	p=0.252[b]	p=0.315[b]	p=0.187[b]	p=0.385 [b]
Birth weight	p=0.375[c]	p=0.121[c]	p=0.148[c]	p=0.458 [c]
% >4Kg	p=0.473[b]	p=0.633[b]	p=0.527[b]	p=0.749 [b]
Length 2nd stage	p=0.614[a]	**p<0.001**[a]	p=0.058[a]	**p<0.001**[a]

[a] Mann-Whitney U Test, [b] Chi-square, [c] Independent t-test, **p≤0.05** (p values in bold type met statistical significance)

Table 25 shows the effect that sustaining an OASI has on symptoms of PFD by making a comparison between the questionnaire scores of control cohort with those sustaining OASI at NVD, at OVD, and the total population sustaining OASI (NVD+OVD). Sustaining an OASI at OVD was associated with significantly CCIS score than the control population (p=0.020). Although conversely an OASI at NVD was not associated with worse scores (p=0.752), nor when combined with the OASI at OVD population (NVD+OVD) (p=0.108).

No difference was seen comparing individual questionnaire components of the OASI at NVD with OASI at OVD (p=0.585). Sustaining an OASI did not affect symptoms of urinary incontinence (ICIQ-SF) as there were no differences in the scores when compared with the control population.

Table 25: The effect of sustaining an OASI and the MoD on symptoms of PFD

	Control vs. NVD	Control vs. OVD	Control vs. NVD+OVD	NVD vs. OVD
CCIS	p=0.752 (5 vs. 9)	**p=0.020** (5 vs. 7)	p=0.108 (5 vs. 8)	p=0.113 (9 vs. 7)
FIQLI	p=0.249 (15.9 vs. 15.8)	p=0.098 (15.9 vs. 15.7)	p=0.114 (15.9 vs. 15.8)	p=0.563 (15.8 vs. 15.7)
ICIQ-SF	p=0.2 (1.5 vs. 4.0)	p=0.269 (1.5 vs. 3.5)	p=0.188 (1.5 vs. 4.0)	p=0.623 (4.0 vs. 3.5)
PISQ-12	**p=0.037** (41 vs. 36)	**p=0.001** (41 vs. 35)	**p=0.002** (41 vs. 36)	p=0.176 (36 vs. 35)

Mann-Whitney U Test was used for all, **p≤0.05** (p values in bold type met statistical significance)
Median scores (in brackets) follow the p-value

Although no differences were seen when comparing the overall FIQL scores, questions relating to changes in lifestyle to accommodate symptoms of faecal incontinence were significantly greater in those having sustained an OASI (see Table 26).

Table 26: Faecal Incontinence related QoL – Control vs. OASI

	Control vs. NVD	**Control vs. OVD**	**Control vs. NVD+OVD**
FIQL	p=0.249 (15.9 vs. 15.8)	p=0.098 (15.9 vs. 15.7)	p=0.114 (15.9 vs. 15.8)
Lifestyle	**p=0.047** (4.0 vs. 4.0)	**p=0.032** (4.0 vs. 4.0)	**p=0.034** (4.0 vs. 4.0)
Coping/Behaviour	p=0.319 (4.0 vs. 4.0)	p=0.061 (4.0 vs. 4.0)	p=0.103 (4.0 vs. 4.0)
Depression/Self-perception	p=0.064 (3.9 vs. 3.9)	p=0.106 (3.9 vs. 3.8)	p=0.056 (3.9 vs. 3.9)
Embarrassment	p=0.567 (4.0 vs. 4.0)	p=0.099 (4.0 vs. 4.0)	p=0.194 (4.0 vs. 4.0)

Mann-Whitney U Test was used for all, **p≤0.05** (p values in bold type met statistical significance)
Median scores (in brackets) follow the p-value

PISQ-12 scores were significantly worse in the OASI cohort regardless of MoD, but more so in those having an OVD. Significant differences in scores were seen across all three aspects of QoL examined regarding sexual health (behaviour, physical and partner), but only when comparing the control cohort to groups comprising those delivering by OVD (C vs. OVD and C vs. NVD+OVD, see Table 27).

Table 27: Assessment of QoL relating to sexual function – Control vs. OASI

	Control vs. NVD	**Control vs. OVD**	**Control vs. NVD+OVD**
PISQ-12	**p=0.037** (41 vs. 36)	**p=0.001** (41 vs. 35)	**p=0.002** (41 vs. 36)
Behaviour	p=0.108 (12 vs. 10)	**p=0.014** (12 vs. 9)	**p=0.019** (12 vs. 9)
Physical	p=0.108 (15 vs. 14)	**p=0.030** (15 vs. 14)	**p=0.030** (15 vs. 14)
Partner	p=0.115 (14 vs. 14)	**p=0.001** (14 vs. 13)	**p=0.003** (14 vs. 13)

Mann-Whitney U Test was used for all, **p≤0.05** (p values in bold type met statistical significance)
Median scores (in brackets) follow the p-value

6.3.2 The effect of subsequent delivery on symptoms of PFD

To assess the effect that having a subsequent delivery after an OASI has on symptoms of PFD, a comparison was made between those that sustained an OASI during NVD with those that had either a subsequent NVD or CS after sustaining an OASI at a previous NVD, and those that sustained an OASI during OVD with those that had either a subsequent NVD or CS after sustaining an OASI at a previous OVD. Four of the total CS cohort had an emergency CS, however it was deemed appropriate to include these women in the analysis as the indications for the CS were not related to obstructed labour (e.g. failure to progress in the first stage of labour, non-cephalic presentation and suspected fetal compromise but not during the second stage of labour).

Table 28 shows that the only difference in factors associated with the initial delivery was that those having a CS after sustaining an OASI at previous NVD had a longer 2nd stages of labour at that initial delivery. The raw data can be found in Tables Table 21 and Table 22.

Table 28: Comparison of variables between those having a subsequent delivery after an OASI with those that did not

Variable	NVD vs. NVD-NVD	NVD vs. NVD-CS	OVD vs. OVD-NVD	OVD vs. OVD-CS
Age	p=0.967[a]	p=0.874[a]	p=0.935[a]	p=0.116[a]
Ethnicity	p=0.486[b]	p=1[b]	p=0.315[b]	p=0.340[b]
Birth weight	p=0.774[c]	p=0.656[c]	p=0.502[c]	p=0.959[c]
% >4Kg	p=0.614[b]	p=0.434[b]	p=0.088[b]	p=0.534[b]
Length 2nd stage	p=0.069[a]	**p=0.020**[a]	p=0.531[a]	p=0.730[a]

[a] Mann-Whitney U Test, [b] Chi-square, [c] Independent t-test, **p≤0.05** (p values in bold type met statistical significance)

The results in Table 29Table 29 suggest that having a subsequent delivery has no effect on symptoms of PFD as no differences were seen when comparing questionnaire scores. This was regardless of the initial and subsequent MoD.

Table 29: The effect of subsequent delivery on symptoms of PFD

	NVD vs. NVD-NVD	NVD vs. NVD-CS	OVD vs. OVD-NVD	OVD vs. OVD-CS
CCIS	p=0.418 (9.0 vs. 5.5)	p=0.208 (9.0 vs. 6.5)	p=0.072 (7.0 vs. 6.5)	p=0.212 (7 vs. 8)
FIQLI	p=0.055 (15.8 vs. 15.9)	p=0.592 (15.8 vs. 15.7)	p=0.230 (15.7 vs. 15.7)	p=0.096 (15.7 vs. 15.1)
ICIQ-SF	p=0.645 (4.0 vs.4.0)	p=0.633 (4.0 vs. 3.0)	p=0.724 (3.5 vs. 3.0)	p=0.716 (3.5 vs. 3.0)
PISQ-12	p=0.309 (36.0 vs. 38.5)	p=0.083 (36.0 vs. 34.5)	p=0.081 (35.0 vs. 34.5)	p=0.957 (35.0 vs. 35.5)

Mann-Whitney U Test was used for all, **p≤0.05** (p values in bold type met statistical significance)
Median scores (in brackets) follow the p-value

6.3.3 The effect of the mode of subsequent delivery on symptoms of PFD

To assess the effect of MoD at subsequent delivery on symptoms of PFD, a comparison was made between those that either had an initial NVD or OVD and a subsequent NVD (NVD-NVD or OVD-NVD) with those that had a subsequent CS (NVD-CS or OVD-CS) . The purpose of this analysis was to attempt to establish whether having a subsequent CS protects women against progression in symptoms of PFD following an OASI.

Regardless of whether an OVD was at first, subsequent or both vaginal deliveries, all women who had two vaginal deliveries, with at least one of them an OVD, were pooled into the OVD-NVD group (e.g. also including OVD-OVD and NVD-OVD) as numbers were too small for any sub-analysis.

Table 30 shows a comparison of factors which may influence the resultant symptoms of PFD, between those that had a subsequent NVD or CS after the initial delivery when they sustained the OASI. The raw data can be found in Table 22, pg98. There was no difference in ethnicity, maternal age at first delivery, length of the second stage of the first delivery or infant birth weight at either delivery. Those having a subsequent CS were older at the subsequent delivery and had heavier babies at the initial delivery, especially if that delivery was operative.

Table 30: Comparison of variables between those having a subsequent NVD vs. subsequent CS after previous OASI

Variable	NVD-NVD vs. NVD-CS	OVD-NVD vs. OVD-CS	(NVD-NVD + OVD-NVD) vs. (NVD-CS + OVD-CS)
Ethnicity	p=0.586[b]	p=0.911[b]	p=0.961[b]
Index delivery			
Age[a]	p=0.946[a]	p=0.148[a]	p=0.097[a]
Birth weight[b]	p=0.734[c]	p=0.542[c]	p=0.883[c]
% >4Kg	p=0.173[b]	**p=0.047**[b]	**p=0.021**[b]
Length 2nd stage[a]	p=0.277[a]	p=0.568[a]	p=0.753[a]
Subsequent delivery			
Age[a]	p=0.274[a]	p=0.094[a]	**p=0.012**[a]
Birth weight[b]	p=0.797[c]	p=0.176[c]	p=0.893[c]
% >4Kg	p=0.189[b]	p=0.239[b]	p=0.970[b]

[a] Mann-Whitney U Test, [b] Chi-square, [c] Independent t-test, **p≤0.05** (p values in bold type met statistical significance)

Those having a subsequent CS had significantly worse questionnaire scores; most noticeably when comparing the combined cohort having a subsequent VD with the combined cohort having a subsequent CS (see Table 31). The difference was seen most markedly when comparing the assessment of sexual health (PISQ-12) and bowel symptoms (CCIS and FIQL) rather than bladder (ICIQ-SF) symptoms.

Tables
Table 32 and

	NVD-NVD vs. NVD-CS	OVD-NVD vs. OVD-CS	(NVD-NVD + OVD-NVD) vs. (NVD+CS + OVD-CS)
FIQL	**p=0.036** (15.9 vs. 15.7)	**p=0.018** (15.7 vs. 15.1)	**p<0.001** (15.9 vs. 15.5)
Lifestyle	**p=0.023**(4.0 vs. 4.0)	p=0.133 (4.0 vs. 4.0)	**p<0.001** (4.0 vs. 4.0)
Coping/Behaviour	**p=0.037** (4.0 vs. 4.0)	**p=0.011** (4.0 vs. 3.7)	**p<0.001** (4.0 vs. 3.9)
Depression/Self-perception	p=0.140 (3.9 vs. 3.9)	p=0.089 (3.9 vs. 3.7)	**p=0.002** (3.9 vs. 3.8)
Embarrassment	p=0.118 (4.0 vs. 4.0)	p=0.294 (4.0 vs. 4.0)	**p=0.015** (4.0 vs. 4.0)

Mann-Whitney U Test was used for all, **p≤0.05** (p values in bold type met statistical significance)
Median scores (in brackets) follow the p-value

Table 33 show the specific areas of the FIQL and PISQ-12 questionnaires, respectively, in which score were significantly worse for those having a subsequent CS.

Table 31: The effect of the mode of subsequent delivery on symptoms of PFD

	NVD-NVD vs. NVD-CS	OVD-NVD vs. OVD-CS	(NVD-NVD + OVD-NVD) vs. (NVD+CS + OVD-CS)
CCIS	p=0.309(5.5 vs. 6.5)	**p=0.010** (6.5 vs. 8.0)	**p=0.004** (5 vs. 7)
FIQLI	**p=0.036** (15.9 vs. 15.7)	**p=0.018** (15.7 vs. 15.1)	**p<0.001** (15.9 vs. 15.5)
ICIQ-SF	p=0.973 (4.0 vs. 3.0)	p=0.666 (3 vs. 3)	p=0.544 (4 vs. 3)
PISQ-12	**p=0.004** (38.5 vs. 34.5)	p=0.089 (34.5 vs. 35.5)	**p=0.001** (38 vs. 35)

Mann-Whitney U Test was used for all, **p≤0.05** (p values in bold type met statistical significance)
Median scores (in brackets) follow the p-value

Table 32: Assessment of QoL relating to faecal incontinence – Comparison of subsequent MoD

	NVD-NVD vs. NVD-CS	OVD-NVD vs. OVD-CS	(NVD-NVD + OVD-NVD) vs. (NVD+CS + OVD-CS)
FIQL	**p=0.036** (15.9 vs. 15.7)	**p=0.018** (15.7 vs. 15.1)	**p<0.001** (15.9 vs. 15.5)
Lifestyle	**p=0.023**(4.0 vs. 4.0)	p=0.133 (4.0 vs. 4.0)	**p<0.001** (4.0 vs. 4.0)
Coping/Behaviour	**p=0.037** (4.0 vs. 4.0)	**p=0.011** (4.0 vs. 3.7)	**p<0.001** (4.0 vs. 3.9)
Depression/Self-perception	p=0.140 (3.9 vs. 3.9)	p=0.089 (3.9 vs. 3.7)	**p=0.002** (3.9 vs. 3.8)
Embarrassment	p=0.118 (4.0 vs. 4.0)	p=0.294 (4.0 vs. 4.0)	**p=0.015** (4.0 vs. 4.0)

Mann-Whitney U Test was used for all, **p≤0.05** (p values in bold type met statistical significance)
Median scores (in brackets) follow the p-value

Table 33: Assessment of QoL relating to sexual health – Comparison of subsequent MoD

	NVD-NVD vs. NVD-CS	OVD-NVD vs. OVD-CS	(NVD-NVD + OVD-NVD) vs. (NVD+CS + OVD-CS)
PISQ-12	**p=0.004** (38.5 vs. 34.5)	p=0.089 (34.5 vs. 35.5)	**p=0.001** (38 vs. 35)
Behaviour	p=0.424 (11 vs. 10)	p=0.463 (11 vs. 10)	p=0.242 (11 vs. 10)
Physical	**p=0.003** (15 vs. 14)	p=0.782 (14 vs. 14)	**p=0.012** (15 vs. 13)
Partner	p=0.550 (14 vs. 13)	p=0.483 (14 vs. 13)	p=0.270 (14 vs. 14)

Mann-Whitney U Test was used for all, **p≤0.05** (p values in bold type met statistical significance)
Median scores (in brackets) follow the p-value

6.3.4 The personal impact of an OASI – free text comments

The final question of the questionnaire allowed the participants' free text to express any symptoms not already covered in the questionnaire and for them to make any further comments. The transcription of those that used this opportunity are in Appendix G.

On analysis of the transcripts it transpired that there were several recurrent themes, as well as areas in service provision and care received that, in the opinion of those sustaining OASI, were in need of improvement. These are listed below (Colour-coding correlates to the transcripts in Appendix G). Unsurprisingly, there was a correlation between questionnaire scores and the frequency in which participants provided comments; the worse the score, the more likely they were to use the opportunity to express themselves.

The recurrent themes are as follows:

- Psychological impact of sustaining an OASI
- Fear of subsequent delivery
- Isolation associated with no knowing others suffering with the same
- Isolation and taboo of speaking out due to embarrassment
- Seeing symptoms of PFD as the 'norm' or an expected outcome of childbirth

The areas for improvements in service provision are as follows:

- Better provision of accurate information regarding the long-term consequences, need for follow-up and subsequent deliveries to aid women in making informed choices
- Lack of continuity of care and collaborative thinking by medical professionals
- Training of medical-professionals regarding the long-term physical and psychological implications of the injury to aid more sympathetic and holistic consultations

6.4 Discussion

6.4.1 Main Findings

The aim of this research was to determine the effect sustaining an OASI has on symptoms of PFD and whether having a subsequent delivery, and the MoD of that subsequent delivery, influenced these symptoms. We found that those sustaining an OASI had significantly worse symptom questionnaire scores than the control population, especially if the delivery was operative. Having a subsequent delivery after an OASI did not result in a worsening of scores. Those subsequently delivering by a CS had worse questionnaire scores than those having a subsequent vaginal delivery.

6.4.2 Strengths and Limitations

This research has supported the findings of previous quantitative studies as well as provided evidence of the subjective personal effect that sustaining an OASI has on women. This data has shown the importance of giving women a voice to express the impact of sustaining an OASI to ensure that they a) do not need to suffer in silence (a common eventuality due to the societal taboo of talking about such symptoms) and b) access the holistic, patient-centred care needed to manage the ongoing physical and psychological impact of the condition. Furthermore, it highlighted the importance of charities such as MASIC (Mothers with Anal Sphincter Injuries in Childbirth)(238); focusing on supporting mothers, making the public aware and educating professionals, which aim to break the taboos and ensure that women receive the care they need.

There were unfortunately several limitations associated with the methodology and subsequent analysis of this study, which all bring into question the validity of the results.

Limitations associated with the Methodology

Postal questionnaires are notoriously bad for response rates.(237) Our study required the completion and return of two postal packs. It is therefore unsurprising that our response rates were so low (24.9%) and that 53 women (24.0%) who initially agreed to take part (by returning the first pack) did not complete their involvement (by returning the second pack). This would have been partly due to the inconvenience of a second postal pack but also due to the sensitive nature of the questions. Our first proposal, which was rejected by the ethics committee, was to invite potential participants by telephone as through this means there was a "potential for the topic of enquiry to be upsetting and cause distress". This was surprising considering that the pack comprised questionnaires routinely used in clinical practice and that research has shown women want to know more and are open to discussion concerning the effect of birth trauma.(135) Unfortunately, this

was more a reflection of the unfamiliarity of the review panel to the subject matter and its importance. Furthermore, we were not granted approval to send out reminders which, together with prohibition of telephone contact, further potentiated a poor response rate. Telephone contact would have reduced the cost and time implications to the researcher, as well as the inconvenience to the participants. Response rates have also been shown to be higher in studies recruiting via telephone.(239) Additionally, women would have been more willing to participate due to the relational/personal aspect of conversational rather than postal communications. In hindsight, it may have been even more fruitful to use internet-based questionnaires through an emailed link, considering a) the age of the participants and b) the convenience of this modality.

Recruitment may have been subject to bias as women would have been far more inclined to take part if they were symptomatic of their injury. Evidence of this is that the response rates in those on the worse end of the symptom score spectrum were far greater than those with the least symptoms (control 10.8%, OVD-CS 44.2%). Response rates also declined further the more time had elapsed since the delivery.

Unfortunately, in designing the study, there was a lack of awareness regarding alternative questionnaires that could have been more applicable to the OASI subject matter. The questionnaire selection was based on what was used in clinical practice at the host Trust. In hindsight, exploration into other possible questionnaires would have been beneficial. There also would have been value in including questions regarding pelvic organ prolapse, as the exclusion of this symptom of PFD was an oversight.

As previously discussed (section 1.3.6.6) a major limitation in cohort observational studies is that measures assessed are rarely in isolation from confounding factors. The best way to truly assess the impact of OASI and subsequent delivery modes on symptoms of PFD would be through an RCT. This would require the recruitment of asymptomatic women with normal anorectal physiology after an OASI and allocation of either a further VD or ElLSCS. There are however obvious ethical implications associated with this suggestion.

Limitations associated with the Analysis

The sample size calculation estimated that we would need a cohort size of 69 per group (those sustaining an OASI either with or without a subsequent delivery). We had initially only planned to carry out a combined analysis of all those having a single delivery (NVD + OVD) and all those with a subsequent delivery (NVD-NVD + OVD-NVD), but due to the known potentiating effect of OVD on both the risk of sustaining an OASI and also the resultant symptoms of PFD, we then performed additional analysis separating those delivering via OVD. Unfortunately, due to poor response rates, the desired sample size was not achieved.

Furthermore, due to small recruitment numbers of less common delivery outcomes, all those with two vaginal deliveries, but at least one an OVD, were grouped (OVD-NVD, OVD-OVD and NVD-OVD). Additionally, all categories of CS were combined to help boost the CS cohort, but based on the assumption that the CS under emergency circumstances were not due to reasons which would later affect symptoms of PFD.

There was vast variation in the time elapsing since the initial OASI (between one and twelve years), and an inability to adjust for time elapsing since the OASI and/or most recent delivery in the analysis. This meant that there was the potential for the bias of healing or changes in symptoms overtime, which could lead to a non-representative presentation of symptoms.

6.4.3 Interpretation

The effect of sustaining an OASI on symptoms of PFD

We found that those sustaining an OASI had significantly worse symptom questionnaire scores than the control population; even more so if the OASI was sustained at OVD. As no difference was seen when comparing the overall and individual questionnaire components of the OASI at NVD with OASI at OVD, and the combined NVD+OVD scores were significantly worse than the control cohort, this suggests that the resultant symptoms were due to the injury although potentiated by the MoD (OVD > NVD). The only measured difference in possible confounding variables, which made the OVD cohort at greater risk of long-term symptoms of PFD, was a prolonged 2nd stage of labour – a common indication for an OVD and known contributor to pudendal nerve damage (136-138). The results also are suggestive of OVD being a significant contributor to symptoms relating to all aspects of sexual health dysfunction. Overall, this reveals that is not just the OASI which potentiates the symptoms of PFD and the resultant effect of QoL, but more so the MoD during which the injury was sustained. Rather surprisingly, when reviewing the individual questionnaire components, sustaining an OASI was not associated with worse scores relating to faecal incontinence. Whether this is a true result, reflective of sufficient healing, or due to not having met the required sample size to show statistical difference would need to be determined.

The effect of subsequent delivery on symptoms of PFD

Our results suggest that having a subsequent delivery after an OASI, whether vaginally or by CS, does not result in a worsening of symptoms of PFD. This is in line with a meta-analysis of other studies and is suggestive of it being the initial injury which contributes most to the subsequent symptoms of PFD rather than having a subsequent delivery.(174, 224) Similarly, a recent retrospective cohort study which used a postal questionnaire (with telephone follow-up) to assess the PFD symptoms and QoL, did not observe any difference in symptomatology comparing those

with a subsequent VD after OASI with those who did not have a further delivery. They therefore advocated the relative safety of a subsequent VD. Although subject to similar limitations as our study of being low-powered and potential confusion bias with time since delivery, their results support our conclusion that the injury sustained at the initial delivery which is most important factor potentiating the symptoms of PFD.(239)

The effect of the mode of subsequent delivery on symptoms of PFD

To avoid potential aggravation of symptoms of PFD, some studies have concluded that an elective CS might be advisable and reported the relative safety of VD after an OASI.(240-242) Unexpectedly, we found those subsequently delivering by a CS had worse questionnaire scores than those having a subsequent vaginal delivery. We had expected to see better scores in the CS group due the the hypothesis that having a subsequent CS would protect against a deterioration in symptoms of PFD, but the converse was seen. The most reasonable explanation for this finding was that symptoms experienced were not secondary to the subsequent CS but related to the reason for the decision for that MoD, namely the persistent symptoms or alternated anorectal physiology secondary to the initial injury. The vast majority of the CS were elective.

Only a limited number of low-powered prospective studies that compare subsequent MoD are available in the literature. Our numbers were similarly low but also like other studies did not adjust for the CS indication and probable persistent symptoms of PFD.(243, Scheer, 2009 #65) It was possible to determine whether CS protects against progression in symptoms as we were unable to adjust for the potential bias of symptoms prior to the subsequent delivery.

Like our study, Jangö et al., used a postal questionnaire survey to compare symptoms in those who had a subsequent NVD with those who had a CS. Women with persistent symptoms prior to the second pregnancy were at an increased risk of long-term anal and faecal incontinence. They found both cohorts had a deterioration in symptoms, but after adjusting for influencing factors, having a subsequent CS did not significantly lower the risk of long-term AI (aOR 0.77, 95% CI 0.57-1.05, p=0.09) or faecal incontinence (aOR 1.04, 95% CI 0.76-1.43, p=0.79). They concluded that although a subsequent NVD is associated with higher risk of deterioration in symptoms, the most important predictors of long-term AI was the initial sphincter injury.(225) Although we were not able to analyse the true impact of the different modes of subsequent delivery, the above study's outcomes are in agreement with our conclusion above concerning the effect of a subsequent delivery (section 6.3.2).

Free text comments revealing the personal impact of sustaining an OASI

We saw the importance facilitating a platform through which participants could express their personal experiences. See Appendix G for the colour-coded transcript. All too often in the medical

profession, patients are defined by their condition or the resultant symptoms rather than by person affected by the condition, and there may be little consideration of the impact the condition may have on the patient's psychological and social wellbeing. In allowing participants the opportunity to express themselves, a whole new depth was given to the analysis; we put the people behind the numbers.

6.5 Conclusion

This research has shown that the most important indicator for long-term symptoms of PFD following an OASI, regardless of subsequent deliveries and the mode of the subsequent deliveries, is the initial OASI. The resultant symptoms and associated psychological trauma of the injury can have serious and lasting effect on QoL, affecting all aspects of life. This has therefore further highlighted the importance of focusing on interventional programmes, such as the OASI Care Bundle, to reduce the incidence, as well as on improvements in patient-centred, holistic care to ensure provision of accurate information and appropriate support to those affected.

Chapter 7 Concluding remarks and future focus

7.1 Research journey and hindrances encountered

I first came across the possibility of carrying out research surrounding the topic of OASIS whilst attempting to set up an unrelated research project (looking at the effectiveness of pelvic floor muscle training exercises in a condition called 'Overactive Bladder' (OAB)). I was invited to work alongside a clinical fellow on a small database project attempting to address the questions of how women subsequently deliver following an OASI, and what the risk of a recurrence was (Chapter 4). At that time, the clinical fellow had access to data regarding women who had sustained an OASI between 2004 and 2013. Data collection and subsequent analysis, although time-consuming, were thankfully quite straightforward and I went on to present the outcomes internationally (EUGA 2014 – 7th Leading Lights in Urogynaecology, European Urogynaecological Association, Athens). At that point it was decided that this could form the base upon which a thesis could eventually be build – a blessing as the OAB study had terminated prematurely due to difficulties in participant recruitment.

My initial literature review revealed several additional factors that made sustaining an OASI more likely, of interest; primiparity, operative vaginal delivery, first vaginal birth after a previous caesarean section, as well as a previous history of OASI. This led to a whole host of further questions that it was decided would be beneficial to explore. Thankfully, I was able use the initial dataset for the majority of the work by filtering out those that did not fit the inclusion criteria for the each of the research questions being addressed. However, when it came to the point of requiring further information to expand the study period, and also introduce a control comparison (Chapters 2 and 6), I came across opposition from the database custodians. Where the earlier data set had seemingly easily been released to my clinical colleague, it was now a very different situation for me, and a number of hurdles were placed. In addition to this being due to my research fellow, not clinical fellow, status, it was also speculated that this was secondary to animosity regarding the topic of the research as the resultant potentially controversial outcomes could lead to the need for change to clinical practice.

One such hurdle for further data to be released to me was that the custodians requested for formal ethical approval to be in place for each area I proposed to develop. Ethics approval was unequivocally required for the symptoms questionnaire study (Chapter 6) due to the direct patient contact and the sensitive nature of the questionnaire, however it should not have been required for the single-site maternity database research (Chapters 2, 3 and 4). I had an honorary contract, which should have been sufficient.

The additional data required from the database custodians was concerning those sustaining an OASI in the years 2014 and 2015, as well as a cohort of primiparous women without perineal injury for the entire study period (2004 – 2015). Unfortunately, even though I sought and gained ethical approval as requested the custodians only released control comparison data for 2014 and 2015. For this reason, frustratingly and at the possible determent of the studies, the control sample size did not match the number of OASI cases in the occasions where a control comparison was used.

Although there were a lot of hinderances and hurdles to overcome, with perseverance I am thankful to have achieved nine podium presentations, an international best paper prize, first authorship of three internationally recognised, peer-reviewed publications, and confidence in my own abilities which will serve me well for life.

See Figure 17: Thesis Timeline for the schematic detailing the thesis timeline.

Table 34: Record of achievements

	Primip NVD risk (Chapter 2)	**VBAC risk** (Chapter 3)	**rOASI risk** (Chapter 4)	**rOASI Multi-centre** (Chapter 5)	**Symptoms Qn** (Chapter 6)
	…Manual data collection…			Multi-site engagement	Entire set up
	…Statistical analysis…				
Presentations		IUGA ‘15 WSUGS ‘15 UKCS ‘18	EUGA ‘14 RSM ‘15 WSUGS ‘17	IUGA ‘18 SWOGS ‘18	SWOGS ‘19
Publications	IUJ	IUJ		IUJ	
Prizes				Best paper IUGA ‘18	

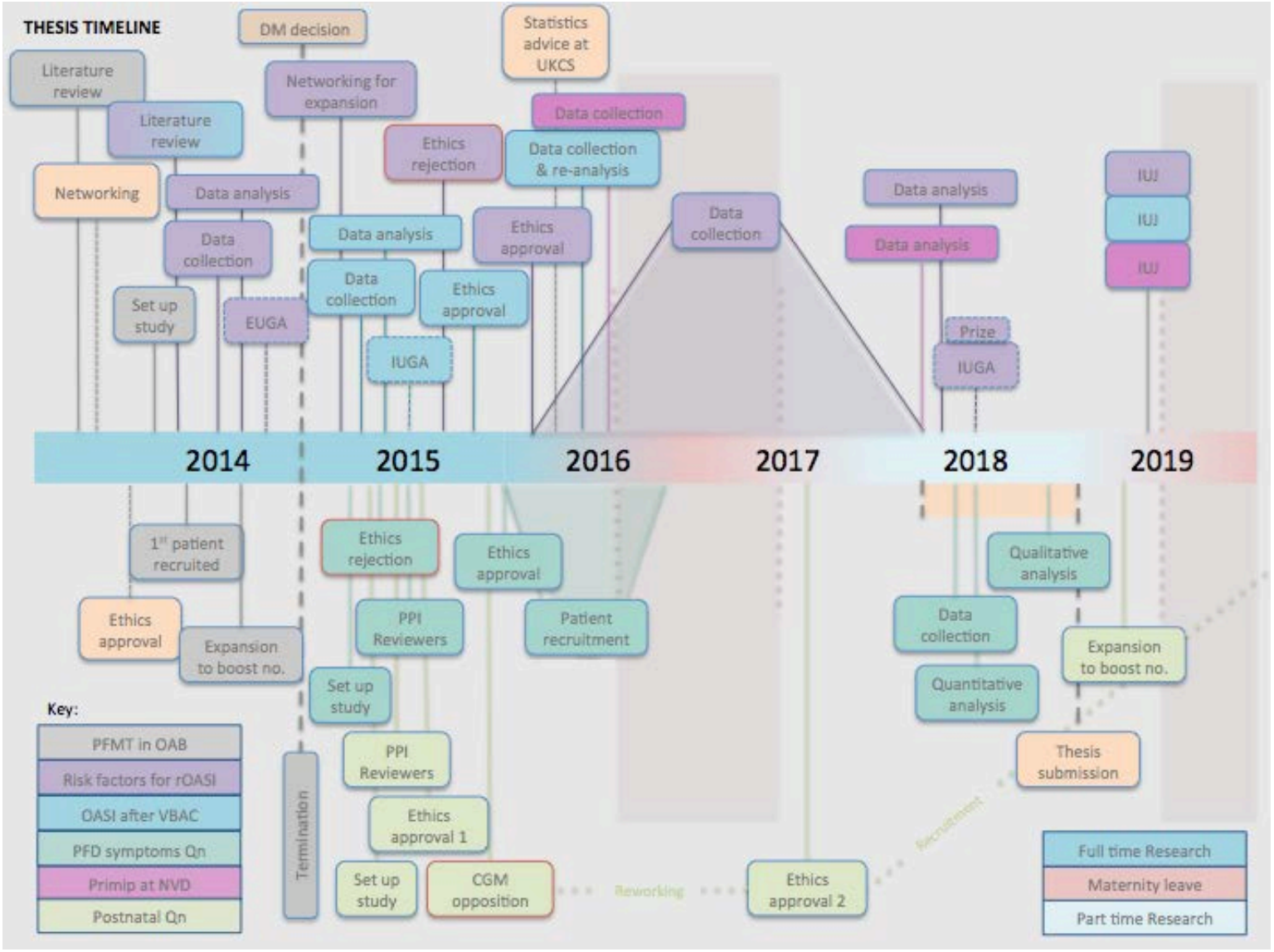

Figure 17: Thesis Timeline

7.2 New information this thesis has revealed

7.2.1 The risk of, and risk factors for, primiparous OASI at NVD

The risk factors for OASI which remain, after adjusting for OVD, in the primiparous population are:

- increased maternal age
- Asian ethnicity
- having a post-term delivery
- having a prolonged second stage
- having a higher birth weight

In contrast, when disassociated from OVD, regional anaesthesia was seen to be protective against sustaining an injury.

7.2.2 The risk of OASI at VBAC, and what baseline characteristics of the initial CS influence that risk

Women undergoing a VBAC delivery are at greater risk of sustaining an OASI than the background primiparous population. This risk is heightened with increasing maternal age and when the infant at the VBAC delivery is greater than four kilograms. The use of MLE is protective against sustaining an OASI at VBAC. The risk of an OASI at VBAC is doubled if the initial CS was an emergency (Category 1 or 2) possibly indicating suggestive of an obstructed labour or initial pelvic outlet problem and relative cephalopelvic disproportion, resulting in an increased risk of pressure on the perinea at subsequent vaginal birth.

7.2.3 Birthing outcomes, the risk of rOASI and the protective effect of MLE at subsequent delivery

Whilst the most common perineal outcome for a woman with a history of an OASI is a second-degree tear, her risk of a repeat sphincter injury is even greater than the risk she was exposed to at her first vaginal delivery. Factors in the increase of subsequent risk are increased maternal age, a birth weight at the subsequent delivery of greater than four kilograms and if a more severe degree of trauma was sustained at the initial delivery. MLE was protective against recurrent injury and a more liberal of this use could decrease the risk of recurrence by 80%. Women who had an elective CS after a previous OASI were more likely to be Caucasian, of increased age, to have had an OVD, a heavier baby at initial delivery and to have sustained a worse grade of sphincter injury.

7.2.4 The impact on symptoms of PFD of having a subsequent delivery after sustaining an OASI

When compared to a control population with intact perinea, those sustaining an OASI had significantly worse symptoms of PFD with a greater impact on QoL indicators. The effect was heightened when the delivery was operative. Surprisingly, having a subsequent vaginal delivery did not impact negatively on the questionnaire scores which, suggests that it is the initial injury which has the greatest impact on subsequent symptoms and QoL. The free text comments went someway in showing the psychological impact than an injury can have in causing isolation due to societal taboos and in provoking fear of subsequent deliveries. It also indicated a need for more thorough provision of accurate information regarding the long-term consequences of OASIs and the risk of repeat trauma at subsequent delivery, in order to enable health care providers to aid women in making informed choices.

7.3 As a result of this research we should…

The resounding and overriding conclusion the thesis is the need to focus on the prevention of primary OASI – not only in the primiparous population, but in those undergoing VBAC. This research has revealed that it is the initial injury, not potential subsequent births, that has the greatest impact on long-term symptoms and associated QoL indicators. Prevention of primary OASIS is not only important in the prevention of these potential long-term symptoms, but also in enabling the fortuitous sequela of a vastly reduced risk of OASI at any subsequent births.

In common with previous studies this thesis has also highlighted an ‘at risk’ population through the identification of certain risk factors which make sustaining an injury more likely. This also empathises the importance and need for further education of antenatal care providers, and patients alike, to ensure preventative measures are particularly established for these women i.e. - those who are primiparous, of advanced maternal age, of Asian ethnicity, carrying larger babies, who have had a previous urgent CS, and of course those with a history of an OASI. Discussions should be undertaken with these ‘at risk’ women to consider the impact that vaginal birth could have on their perinea, and more specifically their anal sphincters, in order to ensure that they are fully informed and engaged in decisions regarding the intrapartum care they receive. These discussions would include the use of preventative measures such as; MPP, warm perineal compress and low threshold for MLE, as well as a low threshold for LSCS in the event of prolonged second stage or when cephalopelvic disproportion is suspected. It obvious that the preventative measures (MPP, warm compresses and MLE) should be used universally and not just exclusively in those deemed high risk, as all women would benefit from such measures.

In addition to aiding prevention of primary injury, informed and factually accurate discussions with women regarding subsequent delivery mode after an OASI are also of utmost importance in supporting informed decision making. Although this thesis demonstrated that a further VD did not have a detrimental effect on symptoms of PFD and QoL, analysis of the effect of a repeat sphincter injury was beyond its scope. It would however be unsurprising for a cumulative effect on symptom progression to be demonstrated with a rOASI. Women need to be made aware that their risk of a recurrent injury is greater than the background primiparous risk; that this could exacerbate symptoms of PFD, and also that measures such as MLE could prevent a rOASI. This research has highlighted the need to update the RCOG-provided evidence currently used when counselling women regarding subsequent deliveries.

There is no doubt that projects like the 'OASI Care Bundle' will have significant impact in raising the profile of OASI prevention through education of the antenatal population and health care providers alike. This research has supported the need for such projects and the hope is that the proposed consequent work will also do so. The focus on prevention requires better knowledge, so that women are better prepared, leading to empowerment and reduced fear as well as better birthing outcomes, namely reduced perineal trauma and symptoms of pelvic floor dysfunction.

7.4 What we need…

Pregnancy is an ideal time for the provision of information, as women have frequent encounters with healthcare providers during the antenatal period, and are generally motivated to learn more by the pregnancy itself and for the good of their unborn child. Long before a woman becomes pregnant, her knowledge and expectation of topics surrounding pregnancy, childbirth and beyond are shaped by various sources of information, which convey a spectrum of realism and accuracy. However, research has revealed a relative lack of 'general childbirth knowledge' and the associated outcomes.(244, 245) Furthermore, the representation of childbirth in the media, the main source by which information is nowadays sought, is inherently negative. This predisposes women to develop ill-informed, biased conclusions.(246) In a qualitative study of college student's knowledge for childbirth, Dejoy et. al. found a deficit in knowledge manifested by an inaccurate perception of childbirth and which perpetuated a culture of fear. This is concerning as this cohort represents the next generation's perception of maternity care norms and social expectations.(245) Furthermore, and unsurprisingly, women who have a negative antenatal perception of childbirth have an increased likelihood of requiring medical interventions in childbirth.(244, 247) Therefore, the converse is also true; that provision of accurate information leads to better preparation and expectation, and a greater likelihood of an advantageous birthing outcomes. Antenatal classes at hospital maternity departments, and external organisations such as the National Childbirth Trust

(NCT), go some way in providing information regarding realistic expectations of childbirth and the available options; such as the location or environment of birth and the various forms of pain relief. However, a paucity of information regarding possible complications, such as instrumental delivery, emergency CS, perineal trauma and pelvic floor dysfunction can lead to inaccurate or unrealistic expectations and result in negative experiences with potentially long-lived effects.

There is a need for a public education focus on addressing knowledge gaps, discrepancies and inaccuracies, which serve only to perpetuate fear.(246) Discovering what is known or understood will enable the exposure of deficiencies in knowledge that can be addressed. Provision of information, especially regarding the physical effects of childbirth, will lead to a better and more realistic management of expectation. This will consequently result in a better ability to acknowledge, cope with and seek support where required, as well as an avoidance of women falling victim to societal taboos or becoming themselves perpetrators of the already negative portrayal of childbirth and beyond.

Over a decade ago, a United States based postpartum questionnaire study evaluating mothers' knowledge of childbirth associated pelvic floor changes, revealed that the provision of information relating to pelvic floor complications occurred significantly less frequently than for most general pregnancy topics (e.g. pre-term labour or pregnancy related weight gain). Nearly half of women surveyed received no information on PFMT (46.1% (CI 95%: 39.7-52.5%)) or UI (46.6% (CI 95%: 40.2-53.0%)). Even fewer women were aware of AI (80.6% (CI 95%: 75.5-85.7%)), neuropathy (84.9% (CI 95%: 80.3-89.5%)) or perineal stretching (72.8% (CI 95%: 67.1-78.5%) as complications of pregnancy and childbirth. The study also revealed that 53% were unaware that PFMT reduce the risk of UI and 58.6% didn't think that a caesarean section could prevent primary UI.(248) In addition to a relative unawareness of mothers regarding symptoms of PFD, a global survey of Obstetricians and Urogynaecologist revealed that, although the majority were aware of protective factors for PFD, many denied enquiring about symptoms in their consultations (only 33% antenatally, 25% postnatally) or counselling on prevention of postnatal PFD (39%).(249)

More recently Mumsnet, a UK based online community of shared knowledge, advice and support, carried out a survey of 1224 women who had experienced postnatal care between 2013 and 2016.(250) The survey revealed that 42% of women had ongoing continence or pelvic floor problems, and of those women 70% hadn't received or sought help focused on improving their symptoms. The article concluded by saying *"Despite being all too common…continence and pelvic floor problems following childbirth, remain taboo with many women suffering in silence and afraid to seek medical help…Helping women to share their experiences, and realise they are not alone, enables healthcare professionals to provide the best care to their patients."* This provided a platform to bring such issues into the public domain and gave women the permission to comfortably and

confidently speak up and seek advice. It also demonstrated that there is a need for such platforms to be provided, or even more importantly for discussions around these topics to become a normal part of antenatal information provision.

The MASIC (Mothers and Anal Sphincter Injuries in Childbirth) Foundation, is a charity which *"aims to reduce the incidence of birth injury as well as helping new mothers who may be suffering in silence from its symptoms which are too often hidden in society"*.(238) It is making great advances in coming into public awareness with a main focus on supporting mothers with, making the public aware of and educating professionals about OASIs and their impact. Their objectives not only incorporate education about injuries but also focuses on research in the prevention of OASIs.

Education efforts must address the knowledge discrepancies and potential inaccuracies, which may in turn result in fear. Firstly, however, we need to establish what is known or understood, in order to unearth deficiencies in knowledge so that they can be addressed. From a medical standpoint there is a wealth of knowledge concerning outcomes in pelvic floor dysfunction, perineal trauma and anal sphincter control following vaginal, instrumental or caesarean delivery. It is interesting to note that armed with such knowledge, the primary reasons given by Obstetricians for themselves or their partner to choose to deliver by CS, in the absence of any clinical indication, is the fear of perineal trauma and long-term sequelae of pelvic floor dysfunction. However, little is known about the general population's knowledge of such topics, and if armed with this information they would potentially come to similar conclusions. At the turn of this century, a survey of UK RCOG Obstetricians revealed that 64% would support a well-informed women's request for elective pre-labour CS for women with uncomplicated, singleton, cephalic pregnancy.(251) Whether or not well-informed patients should have a choice of the mode of delivery has been a topic of hot debate, raising the question of whether there is a role in modern obstetrics for elective CS for the prevention of pelvic floor disorders.(252) It is undeniable that some women would avoid serious damage to the pelvic floor if they delivered by a caesarean. It would be naïve however not to acknowledge the negative impact the resultant increased CS rate would have not only overall on an already economically stretched and time constrained NHS, but also in consequentially more complicated individual maternity journeys. It could be reasonable, however, to suggest that any potential economical insult could potentially be offset by a reduced need for future medical and/or surgical intervention for pelvic floor disorders.

Obviously there has to be a fine balance of information provision, in order to avoid increasing fear and anxiety of childbirth and leading to either disadvantageous birth experiences or an increase in the CS rate for maternal choice. Information provided needs to be both adequate and accurate in order to empower and equip women, with the aim of a greater likelihood of advantageous birthing

experiences through realistic expectation, the prevention of detrimental sequelae of childbirth and the breakdown of societal taboos which have left so many women feeling ostracised and isolated.

7.5 And now we should…

In order to ensure patient-centred care and the provision of information to aid women in informed decision making in the antenatal period, we need to establish what information is currently received and what women already know regarding perineal trauma and subsequent symptoms of PFD. Additionally, it would be useful to discover what they want to know regarding these topics, as well as what their perception the potential impact of a greater knowledgebase on their antenatal mental preparation e.g. whether this would be empowering or fear-inducing. This information would indicate gaps in knowledge and also ensure that relevant information was provided and lead to informed decision making, reduced associated fear and the break down societal taboos. See Figure 18: A model of how better knowledge leads to better outcomes below.

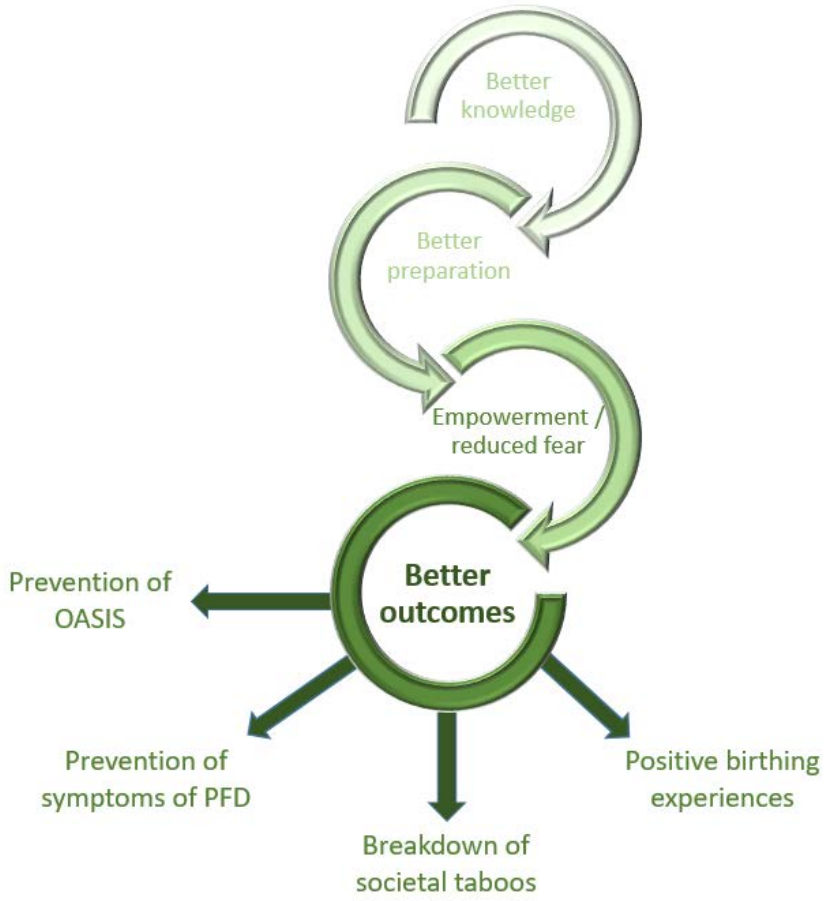

Figure 18: A model of how better knowledge leads to better outcomes

Gaining ethical approval for this research to take place was challenging due to its potential to induce fear, even though the overall aim of this research extension was to prevent fear and had best intentions of doing so. Gaining advice from the Board of Ethical Advisors and the local Governance Committee, the questionnaire went through multiple rounds of reviews, amendments and re-reviews of the questionnaire by impartial Patient and Public Involvement (PPI) reviewers to make it as clear, concise and 'patient-friendly' as possible. This resulted in a patient information sheet (PIS) and six question (with a total of 50 parts) self-administered online (via an emailed link) or paper questionnaire. Approval was given for this to be completed within the first 12 weeks postpartum, not antenatally, due to the concern of the Ethics Board that exploring these topics before delivery, but not providing any answers or support, could provoke fear. See Appendix A and Appendix H.

As a result, and as a direct follow-on from the research in thesis, a further research study has been set up to explore this with the following objectives:

- To understand women's current knowledge regarding Urogynaecological problems associated with childbirth, such as; pelvic floor dysfunction, perineal trauma and the associated risk factors
- To establish whether there is a need for providing further information and counselling to women during pregnancy on topics associated with pelvic floor problems and perineal trauma

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North West - Preston Research Ethics Committee
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29 September 2015

Mr Ash Monga
CONSULTANT UROGYNAECOLOGIST
University Hospital Southampton NHS Foundation Trust
PRINCESS ANNE HOSPITAL
COXFORD ROAD
SOUTHAMPTON
SO16 5YA

Dear Mr Monga

Study title:	**Are women having vaginal birth after Caesarean (VBAC) predisposed to sustaining obstetric anal sphincter injuries (OASIS)?**
REC reference:	**15/NW/0782**
IRAS project ID:	**186140**

The Proportionate Review Sub-committee of the North West - Preston Research Ethics Committee reviewed the above application on 25 September 2015.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mrs Carol Ebenezer, nrescommittee.northwest-preston@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

The members had no ethical issues with this application.

Approved documents

The documents reviewed and approved were:

Document	Version	Date
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsorship letter - VBAC Study, 07.08.2015]	1.0	07 August 2015
Other [VBAC Study Peer Review pg2 29.07.15]	1	29 July 2015
Other [15.NW.0709 (PR) Invalid application. 28.08.15]	1	28 August 2015
Other [clarification of access to data]		21 September 2015
REC Application Form [REC_Form_18092015]		18 September 2015
Referee's report or other scientific critique report [VBAC Study Peer Review pg1 29.07.15]	1	29 July 2015
Research protocol or project proposal [Protocol - Are women having VBAC predisposed to sustaining OASIS_ Version 1.0 24.06.15]	1.0	24 June 2015
Summary CV for Chief Investigator (CI) [CV- Ash Monga (CI), v1.0, 20.08.15]	1.0	20 August 2015
Summary CV for student [CV- Joanna D'Souza (Student), v1.0, 20.08.15]	1.0	20 August 2015

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

15/NW/0782 **Please quote this number on all correspondence**

Yours sincerely

Dr Patricia Wilkinson
Chair

Email: nrescommittee.northwest-preston@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers"

Copy to: *Mrs Sharon Davies-Dear, University Hospital Southampton NHS Foundation Trust*

University Hospital Southampton NHS Foundation Trust

Please reply to: Research and Development
SGH - Level E, Laboratory & Pathology Block, SCBR - MP 136
Southampton University Hospitals NHS

Telephone: 023 8120 5078
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Dr Joanna D'Souza
University Hospital Southampton NHS Foundation Trust
Princess Anne Hospital
Coxford Road
Southampotn
Hampshire
SO16 5YA

06 October 2015

Dear Dr D'Souza

ID: RHM O&G0234 Are women having vaginal birth after Caesarean (VBAC) predisposed to sustaining obstetric anal sphincter injuries (OASIS)?

EudraCT:

Thank you for submitting all the required documentation for Trust R&D approval. I write to inform you that your study has full UHS R&D approval. Please find attached the Conditions of Trust R&D approval which you are obliged to adhere to.
You are required to keep copies of all your essential documents relating to this study. Please download a copy of the relevant Investigator Site File template from the R&D website:
http://www.uhs.nhs.uk/Research/For-investigators/Sitefile.aspx.

Your project is subject to R&D monitoring and you will be contacted by our office to arrange this.

Please note: A condition of approval is that any changes need to be timeously notified to the R&D office. This includes providing copies of:
. All NRES substantial amendments and favourable opinions;
. All Serious Adverse Events (SAEs);
. NRES Annual Progress Reports;
. Annual MHRA Safety Reports;
. NRES End of Study Declaration;
. Notifications of significant breaches of GCP or protocol

Please quote the above RHM No. On any correspondence with our office.

Should you, or any of your team, require training in any of the policies and procedures required to ensure compliance with the conditions of approval, please refer to the R&D Training website http://www.uhs.nhs.uk/Research/For-investigators/Mandatory-training-governance-and-safety-management/Mandatory-training-governance-and-safety-management.aspx for an up-to-date calendar of training events.

Yours sincerely

Sharon Davies-Dear
Research Governance Officer

Appendix for R&D approval letter dated: 06 October 2015

RHM O&G0234
Study Title: Are women having vaginal birth after Caesarean (VBAC) predisposed to sustaining obstetric and sphincter injuries (OASIS)?

The following documents have been reviewed as part of the R&D approval.

Document	Version	Date
Protocol	1	24 June 2015
IRAS Form – SSI Form	n.a.	01 October 2015
Sponsor letter	n.a.	07 August 2015
CV – Mr A Monga	n.a.	20 August 2015
CV – Dr J D'Souza	n.a.	20 August 2015
REC approval letter	n.a.	29 September 2015

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05 January 2016

Mr Ash Monga
Consultant Urogynaecologist
UHS NHS FT
J 19 'J level', Princess Anne Hospital
Coxford Road
Southampton
SO16 5YA

Dear Mr Monga

Study title:	**A retrospective study with up to date follow up of women who sustained obstetric anal sphincter injuries (OASIS) and their pelvic floor outcomes.**
REC reference:	**15/NW/0867**
Protocol number:	**RHM O&G0230**
Amendment number:	**1**
Amendment date:	**01 January 2016**
IRAS project ID:	**193547**

Inclusion of a control group.

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The members had no ethical issues with this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Non-validated questionnaire	1.2	10 December 2015
Notice of Substantial Amendment (non-CTIMP)	1	01 January 2016
Other [follow up letter]	1	10 December 2015
Other [welcome letter]	1.1	10 December 2015
Participant information sheet (PIS)	1.3	10 December 2015
Participant information sheet (PIS) [controls]	1	10 December 2015
Research protocol or project proposal	1.3	10 December 2015

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

15/NW/0867:	**Please quote this number on all correspondence**

Yours sincerely

Mrs Julie Brake
Chair

E-mail: nrescommittee.northwest-liverpoolcentral@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Mrs Sharon Davies-Dear, University Hospitals Southampton NHS Foundation Trust*

North West - Liverpool Central Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 05 January 2016

Committee Members:

Name	Profession	Present	Notes
Mrs Julie Brake	Specialist Diabetes Nurse / Chair	Yes	
Mr Derek Hollingsbee	Pharmacist	Yes	

Also in attendance:

Name	Position (or reason for attending)
Mrs Carol Ebenezer	REC Manager

Appendix for R&D approval letter dated: 07 January 2016

RHM O&G0230
Study Title: A retrospective study with up to date follow up of women with sustained obstetric anal sphincter injuries (OASIS) and their pelvic floor outcomes

The following documents have been reviewed as part of the amendment number 1 dated 01 January 2016.

Document	Version	Date
REC amendment approval letter	n.a.	05 January 2016
Notice of substantial amendment	1	01 January 2016
Participant Information Sheet	1.3	10 December 2015
Participant Information Sheet – Control	1	10 December 2015
Questionnaire	1.2	10 December 2015
Follow up letter	1	10 December 2015
Welcome up letter	1.1	10 December 2015
Protocol	1.3	10 December 2015

University Hospital Southampton NHS Foundation Trust NHS

Please reply to: Research and Development
SDH - Level E, Laboratory & Pathology Block, SCBR - MP 136
Southampton University Hospitals NHS

Telephone: 023 8120 5078
Fax: 023 8120 8578
E-mail: sharon.davies-dear@uhs.nhs.uk

Dr Joanna D'Souza
University Hospital Southampton NHS Foundation Trust
Princess Anne Hospital
Coxford Road
Southampotn
Hampshire
SO16 5YA

07 January 2016

Dear Dr D'Souza

ID: RHM O&G0230 **A retrospective study with up to date follow up of women with sustained obstetric anal sphincter injuries (OASIS) and their pelvic floor outcomes**

Thank you for sending us a copy of amendment 1 dated 01 January 2016, which has been assessed by R&D. We are pleased to inform you that this amendment does not affect local management approval of your research. We have therefore updated our database and your project file.

Please forward all future amendment applications and approvals to us.

Yours sincerely

Sharon Davies-Dear

Research Governance Officer

NHS
Health Research Authority

South Central - Hampshire B Research Ethics Committee
Level 3 Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1384

25 February 2016

Mr Ash Monga
CONSULTANT UROGYNAECOLOGIST
University Hospital Southampton NHS Foundation Trust
PRINCESS ANNE HOSPITAL
COXFORD ROAD
SOUTHAMPTON
SO16 5YA

Dear Mr Monga

Study title:	**Perineal trauma in women having vaginal delivery after previous obstetric anal sphincter injury**
REC reference:	**16/SC/0126**
IRAS project ID:	**185979**

The Proportionate Review Sub-committee of the South Central - Hampshire B Research Ethics Committee reviewed the above application on 24 February 2016.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mrs Siobhan Bawn, nrescommittee.southcentral-hampshireb@nhs.net . Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Recommendation

The Proportionate Review Sub-Committee recommended the applicants consider including information in A6-1 indicating what data is being examined, along with the key outcome measure and any hypotheses that are being tested. If the applicants choose to amend the content of A6-1, the new wording should be sent to the REC via email and the database will be amended manually, rather than requiring a re-write of the IRAS form.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Approved documents

The documents reviewed and approved were:

Document	Version	Date
Covering letter on headed paper [Cover letter – OASIS Study (Perineal trauma after previous OASIS). v1.1 15.02.16]	1.1	15 February 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsorship letter - OASIS Study, 07-08-2015]	1.0	07 August 2015
IRAS Checklist XML [Checklist_17022016]		17 February 2016
Other [2015.08.21 15-0318 Application invalid-2]	1	21 August 2015
Other [2015.09.18 15WM0351 PR unfavourable opinion]		18 September 2015
Other [Clarification re: Access to data]		18 February 2016
Other [Confirmation of request for exceptional review]		18 February 2016
REC Application Form [REC_Form_17022016]		17 February 2016
Research protocol or project proposal	1.2	18 February 2016
Summary CV for Chief Investigator (CI) [CV- Ash Monga (CI), v1.0, 20.08.15]	1.0	20 August 2015
Summary CV for student [CV- Joanna D'Souza (Student), v1.0, 20.08.15]	1.0	20 August 2015

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

16/SC/0126 **Please quote this number on all correspondence**

Yours sincerely

Mr Brian Birch
Vice Chair

Email: nrescommittee.southcentral-hampshireb@nhs.net

Enclosures: List of names and professions of members who took part in the review

"After ethical review – guidance for researchers"

Copy to: Mrs Sharon Davies-Dear

University Hospital Southampton NHS Foundation Trust NHS

Please reply to: Research and Development
SGH - Level E, Laboratory & Pathology
Block, SCBR - MP 136
Southampton University Hospitals NHS

Telephone: 023 8120 5078
Fax: 023 8120 8678
E-mail: sharon.davies-dear@uhs.nhs.uk

Dr Joanna D'Souza
University Hospital Southampton NHS Foundation Trust
Princess Anne Hospital
Coxford Road
Southampotn
Hampshire
SO16 5YA

04 March 2016

Dear Dr D'Souza

ID: RHM O&G0235 Perineal trauma in women having vaginal delivery after previous OASIS

EudraCT:

Thank you for submitting all the required documentation for Trust R&D approval. I write to inform you that your study has full UHS R&D approval. Please find attached the Conditions of Trust R&D approval which you are obliged to adhere to.
You are required to keep copies of all your essential documents relating to this study. Please download a copy of the relevant Investigator Site File template from the R&D website:
http://www.uhs.nhs.uk/Research/For-investigators/Sitefile.aspx.
Your project is subject to R&D monitoring and you will be contacted by our office to arrange this.
Please note: A condition of approval is that any changes need to be timeously notified to the R&D office. This includes providing copies of:
. All NRES substantial amendments and favourable opinions;
. All Serious Adverse Events (SAEs);
. NRES Annual Progress Reports;
. Annual MHRA Safety Reports;
. NRES End of Study Declaration;
. Notifications of significant breaches of GCP or protocol

Please quote the above RHM No. On any correspondence with our office.

Should you, or any of your team, require training in any of the policies and procedures required to ensure compliance with the conditions of approval, please refer to the R&D Training website http://www.uhs.nhs.uk/Research/For-investigators/Mandatory-training-governance-and-safety-management/Mandatory-training-governance-and-safety-management.aspx for an up-to-date calendar of training events.

Yours sincerely

Sharon Davies-Dear
Research Governance Officer

Appendix for R&D approval letter dated: 04 March 2016

RHM O&G0235
Study Title: Perineal trauma in women having vaginal delivery after previous OASIS

The following documents have been reviewed as part of the R&D approval.

Document	Version	Date
Protocol	1.2	18 February 2016
IRAS Form – SSI Form	n.a.	26 February 2016
Sponsor letter	n.a.	07 August 2015
CV – Dr J D'Souza	n.a.	20 August 2015
CV – Mr A Monga	n.a.	20 August 2015
REC approval letter	n.a.	25 February 2016

Appendix B Raw Data – Perineal trauma in subsequent delivery after previous OASI: A Multi-Centre Study

	UHS	Croydon	Poole	Leicester	Total
Total Delivery	68606	48492	47202	113739	278039
Vaginal (Singleton)	52412	34143	36161	86868	209584
Singleton, term, cephalic OASIs	1862	1383	1220	1953	6418
Primiparous (Singleton, term, cephalic) births	21605	12570	15709	35806	85690
Primiparous (Singleton, term, cephalic) OASIs	1269	847	915	1928	4959
Total P2 Vaginal births (previous OASI)	495	211	288	775	1769
Total P2 repeat OASI	43	18	31	88	180

	UHS	Croydon	Poole	Leicester	Average
Overall OASI rate	3.6%	4.1%	3.4%	2.2%	3.3%
Primiparous OASI rate	5.9%	6.7%	5.8%	5.4%	6.0%
OASI recurrence rate	8.7%	8.5%	10.8%	11.4%	9.8%

P2 Mode of Delivery

	UHS	Croydon	Poole	Leicester	Total
Normal VD	471	195	277	743	1686
Vacuum Extraction	9	13	3	20	45
Forceps	15	3	8	12	38
Total VD	**495**	**211**	**288**	**775**	**1769**
Elective LSCS	106	31	132	149	418
Emergency LSCS	24	11	17	33	85
Total all births	625	253	437	957	**2272**

P2 Perineal condition

	UHS	Croydon	Poole	Leicester	Total	Percentage
Intact	109	41	60	144	354	20.0%
1st	47	12	18	108	185	10.5%
2nd	296	140	179	435	1050	59.4%
3rd	41	18	31	82	172	9.7%
4th	2	0	0	6	8	0.5%
Episiotomy	68	49	33	126	276	15.6%

P2 = Second delivery

Appendix C A Brief Survey of Obstetricians Regarding rOASI

This is the paper form format of the questionnaire circulated to clinicians. In the interest of time and efficiency, a link to an online version was circulated via email.

University Hospital Southampton NHS
NHS Foundation Trust

Childbirth following previous OASI – A survey of clinicians

The purpose of this short survey is to establish what influences clinicians' decision making regarding mode of delivery after previous obstetric anal sphincter injury (OASI). The results will be entirely confidential and used in a University thesis.

Your participation is greatly appreciated.

Participant info:

- Specialty
- (Sub-specialism)...
- Grade

1. The RCOG GTG 29 on 'Management of Third- and Fourth-Degree Perineal Tears' states, "If facilities are available and resources allow, follow-up of women with OASIS should be in a dedicated perineal clinic with access to endoanal ultrasonography [EAUS] and anal manometry [AM] as this can aid decision making regarding future delivery."

Regarding physiological testing (EAUS and AM) in patients who have sustained an OASI, which is the most relevant to your practice:

[ ] I am not aware of these tests being available at my Trust
[ ] If asymptomatic I do not refer patients for testing
[ ] I refer only those who have sustained a 4th-degree tear
[ ] I refer only those with a 3c (complete internal anal sphincter tear) or 4th-degree tear
[ ] I refer only those with a 3b (partial internal sphincter tear) or worse (3c, 4th)
[ ] I refer all who have sustained an OASI regardless of grade of tear

2. **When counseling patients with a history of OASI in an antenatal setting, what information do you provide regarding subsequent delivery?**
Free text

3. **Regarding mode of delivery following previous OASI**

Mark an 'x' to indicate the level of agreement (where 100% = completely agree)

My decision to recommend a subsequent elective LSCS following previous OASI is influenced by...	
Results of EAUS	0 .....100%
Results of AM	0 .....100%
My knowledge of risk factors for recurrent OASI	0 .....100%
Patient choice in the absence of symptoms	0 .....100%
Patient ethnicity	0 .....100%
I think all women who have sustained a previous OASI should have an elective LSCS	
	0 .....100%

4. **The risk of a recurrent OASI is:**

[ ] The same as multipara having had a previous vaginal delivery but without a history of OASI
[ ] Worse than the multipara risk of sustaining an OASI but not as bad as than the primpara risk
[ ] The same as the primipara risk of sustaining an OASI
[ ] Worse that the prmipara risk of sustaining an OASI

5. **The approximate rate of a recurrent/repeat OASI is ...**

---

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 % of those having a subsequent vaginal delivery with a history of previous OASI

6. **What factors affect the risk of sustaining a recurrent/repeat OASI?**

(Please tick one box per row)

	More likely	No effect	Less likely
Having the initial delivery at a young age			
Having an operative vaginal at the initial delivery			
Having a more significant degree of OASI at initial injury			
Having a short time interval between births			
Having the subsequent delivery at an older age			
Having a subsequent baby weighing more than 4kg (8lb 13oz)			
Being of Asian ethnicity			
Having a mediolateral episiotomy during a subsequent operative (forceps or ventouse) vaginal delivery			
Having a mediolateral episiotomy during a subsequent normal vaginal delivery			

7. **The risk of worsening symptoms of anal incontinence following a subsequent vaginal delivery after previously sustaining an OASI is...**

---

0 5 10 15 20 25 30 35 % experience worsening of symptoms

8. **How are those sustaining a repeat OASI followed up with regards to assessment of anal incontinence?**
Free text

Appendix D Raw Data – A Brief Survey of Obstetricians

What influences the decision-making?

Clinician No.	EAUS result	AM result	Own knowledge	Patient choice	Patient Ethnicity
1	10	0	8	9	3
2	10	9	8	9	5
3	10	10	10	10	5
4	-	-	-	-	-
5	10	10	9	9	0
6	8	0	6	10	0
7	10	8	7	3	3
8	8	8	8	6	6
Median	**10**	**8**	**8**	**9**	**3**

Key:
0 = no influence
10 = high influence

The risk of rOASI and AI

Clinician No.	Risk of rOASI	% of rOASI	Risk of AI with rOASI (%)
1	= primip	5	5
2	> primip	7	20
3	= primip	6	17
4	> multip	6	50
5	> primip	10	17
6	> primip	5	5
7	= primip	7	17.5
8	> primip	6	20
Median		**6%**	**17.5%** (range 5-50)

Factors that influence the risk of a rOASI

Clinician No.	worse degree initial OASI	older age	>4Kg	Asian	MLE OVD	MLE NVD
1	n	n	m	n	m	n
2	m	m	m	m	l	l
3	m	n	m	m	n	n
4	m	n	m	m	l	l
5	m	n	m	m	n	n
6	n	n	m	n	n	n
7	m	m	m	m	l	l
8	m	m	m	m	l	n
Actual	**m**	**m**	**m**	**m**	**l**	**l**
% of actual	**75%**	**37.5%**	**100%**	**75%**	**50%**	**37.5%**

Key:
l = less likely
m = more likely
n = no difference

Appendix E Participant Paperwork – Symptoms Questionnaire

University Hospital Southampton NHS
NHS Foundation Trust

Division C Care Group - Women's Health
Gynaecology
J Level, Mailpoint 105
Princess Anne Hospital
Coxford Road
Southampton
SO16 5YA

Dear

RE: Symptom Questionnaire Study - Outcomes after OASIS

Main title: ***A retrospective study with up to date follow up of women who sustained obstetric anal sphincter injuries (OASIS) and their pelvic floor outcomes***

At Princess Anne Hospital we are carrying out a research project which we would really appreciate your help with.

The research is a postal questionnaire-based study asking women who have a natural (vaginal) birth about symptoms they may later experience. We will be comparing the answers of women who did not have a tear during childbirth with those that did have a tear. We will also be identifying whether the type of childbirth (vaginal or C-section), at the birth of their second child, makes a difference to symptoms experienced later on in women who had a tear at the birth of their first child.
You are being invited to be a part of this research because you fit the criteria, which makes you eligible to be a part of this study.

If you decide to take part, all that we require of you is that you complete a 10-15 minute questionnaire and post it back to us in the prepaid envelope. If after reading the enclosed Patient Information Sheet you would like to take part, please fill out the slip below and post it to back us. We will then send the questionnaire to you.
In order to get the most out of this research, we would really appreciate you doing this as soon as possible. We would encourage you to contact either of us if you have any questions in the meantime. Our contact details are below.

By asking several hundred women to complete this questionnaire, our hope is that the information gained will educate not only our hospital but also other maternity healthcare providers in the UK. The study will also allow us to inform patients of the symptoms they may experience as a result of their childbirth experience. The results of the research we hope will enable us to guide doctors in recommending the most appropriate type of delivery following a tear.

Yours sincerely

Mr. Ash Monga
Chief Investigator
Consultant in Urogynaecology
Direct tel: +44(0)2381208504

Dr. Joanna D'Souza
Principle Investigator
Research Fellow in Urogynaecology
email: joanna.d'souza@uhs.nhs.uk

I have read the information sheet and I am happy to take part in this research ☐
I give you permission to send me a questionnaire to complete. ☐

Signed: Name:

Dated:

University Hospital Southampton NHS
NHS Foundation Trust

Participant Information Sheet

Symptom Questionnaire Study - Outcomes after OASIS

Main title: *A retrospective study with up to date follow up of women who sustained obstetric anal sphincter injuries (OASIS) and their pelvic floor outcomes*

Name of Lead Researcher:	Dr. J D'Souza, Urogynaecology Research Fellow.
Location of Research:	Urogynaecology Dept. Princess Anne Hospital, Southampton SO16 5YA

Introduction:

You are being invited to take part in a research project. This sheet will tell you about the research and why we are doing it. If you would like more information or further explanation, then please contact us - my contact details are at the end of this information sheet.

What is the purpose of this study?

The pelvic floor is a group of muscles that make a sling around the organs in the pelvis including the vagina and uterus (womb), the rectum (back passage) and bladder.
Around 85% of women have some level of tearing during vaginal childbirth. Some women have a tear that extends to the anal sphincter (the muscles of the back passage) and sometimes into the back passage. Women who have had these tears are at greater risk of pelvic floor problems. Problems with the pelvic floor can cause urinary incontinence (leaking urine), faecal incontinence (leaking poo) and sexual dysfunction. Due to embarrassment many women avoid seeking advice. This means that there are many women suffering who are not known about.
Some women who have tears in their first birth go on to have an elective caesarean section at their second delivery, others will have vaginal deliveries and some will have emergency caesarean sections.
Firstly, the purpose of this questionnaire is to compare the symptoms of two groups of women who have each had one vaginal birth – a group of women who did not sustain a tear with a group of women who did. We will then be able to find out what effect having a tear has on pelvic floor symptoms. Secondly, we will compare the symptoms of those that had a tear with a similar group of women who went on to have a second child (either vaginal or C-section). We can then find out if having another birth, and the type of birth at the second delivery, has an effect on the long-term symptoms.
We will also look at whether women had endoanal ultrasounds (scans of the back passage) after they had the tear, and if they did, what was understood from this procedure and any advice given.

Why have you been invited?

You have been invited to take part in this research because you fulfil the following criteria:

- You are a female of at least 18 years of age
- You have had a previous third or fourth degree tear (a significant tear at the birth of your baby)
- You have either had:
  - no further deliveries
  - a further delivery either by normal vaginal delivery or Caesarean section

If any of the above do not apply to you, please do let the researcher know, as your participation in this trial may not be appropriate.

University Hospital Southampton NHS
NHS Foundation Trust

Participant Information Sheet

Symptom Questionnaire Study - Outcomes after OASIS

Main title: *A retrospective study with up to date follow up of women who sustained obstetric anal sphincter injuries (OASIS) and their pelvic floor outcomes*

Name of Lead Researcher:	Dr. J D'Souza, Urogynaecology Research Fellow.
Location of Research:	Urogynaecology Dept. Princess Anne Hospital, Southampton SO16 5YA

Introduction:

You are being invited to take part in a research project. This sheet will tell you about the research and why we are doing it. If you would like more information or further explanation, then please contact us - my contact details are at the end of this information sheet.

What is the purpose of this study?

The pelvic floor is a group of muscles that make a sling around the organs in the pelvis including the vagina and uterus (womb), the rectum (back passage) and bladder.
Around 85% of women have some level of tearing during vaginal childbirth. Some women have a tear that extends to the anal sphincter (the muscles of the back passage) and sometimes into the back passage. Women who have had these tears are at greater risk of pelvic floor problems. Problems with the pelvic floor can cause urinary incontinence (leaking urine), faecal incontinence (leaking poo) and sexual dysfunction. Due to embarrassment many women avoid seeking advice. This means that there are many women suffering who are not known about.
Some women who have tears in their first birth go on to have an elective caesarean section at their second delivery, others will have vaginal deliveries and some will have emergency caesarean sections.
Firstly, the purpose of this questionnaire is to compare the symptoms of two groups of women who have each had one vaginal birth – a group of women who did not sustain a tear with a group of women who did. We will then be able to find out what effect having a tear has on pelvic floor symptoms. Secondly, we will compare the symptoms of those that had a tear with a similar group of women who went on to have a second child (either vaginal or C-section). We can then find out if having another birth, and the type of birth at the second delivery, has an effect on the long-term symptoms.

Why have you been invited?

You have been invited to take part in this research because you fulfil the following criteria:

- You are a female of at least 18 years of age
- You have had a baby naturally (by vaginal delivery) and you did not sustain any tears.
- You have not had any more babies

If any of the above do not apply to you, please do let the researcher know, as your participation in this trial may not be appropriate.

If you are happy to take part you will be part of the 'control group' to help us determine whether women that don't have a tear at delivery also suffer for pelvic floor symptoms.

Do I have to take part?

It is up to you to decide whether or not you wish to take part. If you decide to take part, you will be asked to sign a consent form. Even after you decide to take part, you are still free to withdraw from the study at any time and without giving a reason. Declining the invitation to take part or withdrawing at a later stage will not affect the standard of care that you receive.

What will happen to me if I take part?

If you take part in the trial you will need to fill out a consent form and a simple questionnaire on any symptoms you may have had of pelvic floor dysfunction. These include questions about your bladder, bowel and sexual function. We think the consent form and the questions will take about 15 minutes to complete. We would also access your maternity medical records to ensure you meet the inclusion criteria. No other area of your medical records would be accessed and only the direct research team, listed at the end of this information sheet, would have access to these records for the period of this research only.

What are the possible disadvantages and risks of taking part?

If you decide to take part in the trial you will be required to commit to filling out a questionnaire. There are no health or safety risks associated with taking part in this trial. This trial does not involve the use of drugs, devices or anything that could potentially adversely affect your health or well-being. The questionnaire asks about personal and sometimes embarrassing symptoms of bladder, bowel and sexual function. The chief investigator, Ash Monga (his contact details are below), runs a special clinic for women who have these types of symptoms. He will be able to provide support with any issues that may arise. Alternatively, you may wish to speak to your own GP- we can contact them on your behalf should you wish us to do so

What are the possible benefits of taking part?

You will not receive any direct benefits from taking part but your involvement in the study has the potential to help improve our management of future deliveries in women who have had previous significant tears not only in our hospital but also other maternity healthcare providers in the UK. The study will also allow us to inform patients of the symptoms they may experience as a result of their childbirth experience. As a result of the research we hope to be able to guide doctors in recommending the most appropriate type of delivery following a tear.

What will happen to the results of the research?

Only the researcher and medical personnel involved in your treatment will have access to any results of the research. These results will be kept for up to one year to ensure enough time for the analysis of the data produced. We hope that by publishing the results from this research, we will have further information regarding the affects of different modes of delivery after sustaining a tear. This will help guide health care professionals when recommending what type of birth to have and what likely outcomes in terms of pelvic floor symptoms there may be from it.
Once we have established the results of the study we will write to you to let you know what we found out.
Any results from this research will remain anonymous. The study is being carried out as part of an educational qualification for Dr. D'Souza (DM thesis at the University of Southampton).

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Will my participation in the study be kept confidential?

Yes. Any information we gain about you will be anonymised and only identifiable by a code allocated to your questionnaire- a 'participant's code'. Only members of the research team will have access to the information linking that code back to you.

Where can I find out more about research in general?

INVOLVE is a national advisory group, funded by the National Institute for Health Research (NIHR). Its role is to support and promote active public involvement in NHS, public health and social care research. http://www.invo.org.uk/ or Wessex House, Upper Market Street, Eastleigh, Hampshire, SO50 9FD, Telephone: 02380 651088 Email admin@invo.org.uk

What if something goes wrong?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Please raise your concerns in the first instance with the chief investigator, Mr Ash Monga. If you wish to make a more formal complaint, please contact the hospital's Patient Support Services. All contact details are at the end of this information sheet.

Which insurance provisions are in place?

In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the Sponsor, Southampton University Hospitals NHS Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanism will still be available to you.
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by North West - Liverpool Central Research Ethics Committee.

Research team contact details:

Principle Investigator
Dr. Joanna D'Souza
Research Fellow in Urogynaecology
Direct tel: +44(0)7759369113
email: joanna.d'souza@uhs.nhs.uk

Chief Investigator
Mr. Ash Monga
Consultant in Urogynaecology
Direct tel: +44(0)2381208504

Contacts for further information:

If you would like to speak to someone independent about taking part in the study you can contact the Patient Support services:

Patient Support Services, C Level Centre Block, Mailpoint 81,
Southampton General Hospital, Tremona Road,
Southampton, SO16 6YD

Email: PatientSupportServices@uhs.nhs.uk
Tel: 023 8120 6325

9 am to 4.30 pm Monday to Friday
(There is an out of hours answerphone).

Thank you for taking the time to read this information sheet.

Please let us know whether or not you would like to take part by completing the slip on the covering letter and send it back to us. Thank you.

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NHS Foundation Trust

Division C Care Group - Women's Health
Gynaecology
J Level, Mailpoint 105
Princess Anne Hospital
Coxford Road
Southampton
SO16 5YA

Dear

RE: Symptom Questionnaire Study - Outcomes after OASIS

Main title: ***A retrospective study with up to date follow up of women who sustained obstetric anal sphincter injuries (OASIS) and their pelvic floor outcomes***

I hope this finds you well.

Many thanks for sending the slip back to me expressing your interest in participating in this research looking at pelvic floor symptoms following childbirth. This is a unique piece of research, which has never been carried out in the UK before now and we believe it will be a very worthwhile study.

We hope to use the results of this study to guide doctors, not only our hospital but also other maternity healthcare providers in the UK, in recommending the most appropriate type of delivery following a tear. This research will also allow us to inform patients of the symptoms they may experience as a result of their childbirth experience.

Please find enclosed another Participant Information Sheet (the same as the last one you received), two Consent Forms, the Questionnaire and a prepaid envelope.
We would recommend you re-read the Participant Information Sheet to refamilarise yourself with the study. If you are still happy to take part, please sign both Consent Forms; keep one for yourself and send the other back to me with your completed Questionnaire in the prepaid envelope.
If you are no longer happy to take part, I'd really appreciate you using the prepaid envelope to send a note with your name on it to let me know. I will then remove your details from the participant list.

In order to get the most out of this research, I would really appreciate you doing this as soon as possible. I would encourage you to contact me if you have any questions in the meantime. My contact details are below.

Many thanks again- I look forward to hearing from you soon.

Kind regards,

Dr. Joanna D'Souza
Principle Investigator
Research Fellow in Urogynaecology
email: joanna.d'souza@uhs.nhs.uk
tel: 07759369113

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Consent Form

Title of study:	**Symptom Questionnaire Study – Outcomes after OASIS** A retrospective study with up to date follow up of women who sustained obstetric anal sphincter injuries and their pelvic floor outcomes.
Name of Principal Investigator:	Dr J D'Souza
Centre/Site number:	Princess Anne Hospital, Southampton
Study number:	O&G 0230
REC approval number:	15/NW/0867

Thank you for reading the information about our research project.
If you would like to take part, please read and sign this form.

PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1. I have read the information sheet dated 10.12.2015 for the above study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I agree to fill out questionnaires as part of the research in this study and I understand how and when to complete the questionnaires. I understand that doing these assessments for this research is voluntary and that I am free to withdraw my approval for use of the data collected at any time. ☐
4. I understand that relevant sections of my medical notes, and data collected during the study, may be looked at by individuals from regulatory authorities, from the University of Southampton or from Southampton University Hospitals NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
5. I understand that I will not benefit financially if this research leads to the development of a new treatment or test. ☐
6. I know how to contact the research team if I need to. ☐
7. I agree to participate in this study ☐

Participant:	**Date**	**Signature**
Researcher taking consent:	**Date**	**Signature**

Contact details:

Mr. Ash Monga
Chief Investigator
Consultant in Urogynaecology
Direct tel: +44(0)2381208504

Dr. Joanna D'Souza
Principle Investigator
Research Fellow in Urogynaecology
email: joanna.d'souza@uhs.nhs.uk

Participant's code:.....

University Hospital Southampton NHS
NHS Foundation Trust

Participant Questionnaire

Symptom Questionnaire Study - Outcomes after OASIS

Main title: *A retrospective study with up to date follow up of women who sustained obstetric anal sphincter injuries (OASIS) and their pelvic floor outcomes*

As a result of injuries that occur at childbirth, women can suffer from symptoms of pelvic floor dysfunction, such as incontinence of urine, stool or flatus (leakage of wee, poo or wind), prolapse (bulging of pelvic organs into the vagina) or sexual dysfunction. These can have a damaging impact on the physical, social and psychological wellbeing of an individual.

Firstly, the purpose of this questionnaire is to compare the symptoms of two groups of women who have each had one vaginal birth – a group of women who did not sustain a tear with a group of women who did. We will then be able to find out what effect having a tear has on pelvic floor symptoms. Secondly, we will compare the symptoms of those that had a tear with a similar group of women who went on to have a second child (either vaginal or C-section). We can then find out if having another birth, and the type of birth at the second delivery, has an effect on the long-term symptoms.

We would be grateful if you could please answer every question. Due to the nature of the subject matter, some of the questions are personal but all of them have been created with a view to helping prevent women in the future from suffering from these symptoms by improving our management of future deliveries. Please be reassured that the results will remain strictly confidential.

1. Your background information

Please fill in some basic information about yourself. This will be used to check you are still suitable for the study.

a) Age: what is your age?

18-24 years old [ ]
25-29 years old [ ]
30-34 years old [ ]
35-39 years old [ ]
40+ years old [ ]
Prefer not to say [ ]

b) Are you currently pregnant?: Yes [ ] No [ ]

c) Do you have any medical problems?

Yes [ ] No [ ] I do not wish to say [ ]

If 'yes' please tell us what medical problems you have:

d) Have you had any treatment for any previous problems with your pelvic floor?

Yes [ ] No [ ] I do not wish to say [ ]

If 'yes' please tell us about the treatment you have had:

2. The birth of your child(ren)

a) Please fill in the dates of birth of your child(ren), how old you were at that delivery and if the delivery was a normal vaginal delivery, instrumental (forceps or Ventouse) or an elective or emergency C-section.

Child 1: -- /-- /---- Your age: ..... Delivery: .....

Child 2: -- /-- /---- Your age: ..... Delivery: .....

Child 3: -- /-- /---- Your age: ..... Delivery: .....

Child 4: -- /-- /---- Your age: ..... Delivery: .....

b) Did you receive any hospital follow-up after your first delivery?

Yes [ ] No [ ] (→ Go to the next page) I do not wish to say [ ]

c) If 'Yes' to part b), did they perform a scan of the muscles of your back passage?

Yes [ ] No [ ] (→ Go to the next page) I do not wish to say [ ]

d) If 'Yes' to part c), can you recall what the outcome of the scan was and any advice you were given about future pregnancies/ deliveries?

Participant's code:.....

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3. Symptoms you might be experiencing

CCIS (Cleveland Clinic Incontinence Score)

Many people leak stool (poo) some of the time. We are trying to find out how many people leak, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the **PAST FOUR WEEKS.**

Q1: Please **circle one box** in each row to indicate on average how often you experience the following:

	Never	Rarely Less than once a month	Sometimes Less than once a week	Usually Less than once a day	Always Everyday
a. Solid stool (poo) leakage	1	2	3	4	5
b. Liquid stool (poo) leakage	1	2	3	4	5
c. Gas leakage	1	2	3	4	5
d. Pad use (for stool/ poo)	1	2	3	4	5
e. Lifestyle restriction	1	2	3	4	5

FIQLI (Fecal Incontinence Quality of Life Instrument)

Q2: In general, would you say your health is:

Excellent	Very Good	Good	Fair	Poor
1	2	3	4	5

Q3: For each of the items, please indicate how much of the time the issue is a concern for you **due to accidental bowel leakage** (leakage of wind/poo)

	Most of the time	Some of the time	A little of the time	None of the time
a. I am afraid to go out	1	2	3	4
b. I avoid visiting friends	1	2	3	4
c. I avoid staying overnight away from home	1	2	3	4
d. It is difficult for me to get out and do things like going to a movie or shopping trips	1	2	3	4
e. I cut down how much I eat before I go out	1	2	3	4
f. Whenever I am away from home, I try to stay near a toilet as much a possible	1	2	3	4
g. It is important to plan my schedule (daily activities) around my bowel (toileting to pass poo) pattern	1	2	3	4
h. I avoid travelling	1	2	3	4
i. I worry about not being able to get to a toilet in time	1	2	3	4
j. I feel I have no control over my bowels (when I poo)	1	2	3	4
k. I can't hold my bowel movement long enough to get to the toilet	1	2	3	4
l. I leak stool (poo) without even knowing it	1	2	3	4
m. I try to prevent accidents by staying very near a toilet	1	2	3	4

Participant's code:.....

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Q4:	**Due to accidental bowel leakage,** indicate the extent to which you AGREE or DISAGREE with each of the following items.				
		Strongly Agree	**Somewhat Agree**	**Somewhat Disagree**	**Strongly Disagree**
	a. I feel ashamed	1	2	3	4
	b. I can not do many of the things I want to do	1	2	3	4
	c. I worry about bowel accidents	1	2	3	4
	d. I feel depressed	1	2	3	4
	e. I worry about others smelling stool/poo on me	1	2	3	4
	f. I feel like I am not a healthy person	1	2	3	4
	g. I enjoy life less	1	2	3	4
	h. I have sex less often than I would like to	1	2	3	4
	i. I feel different from other people	1	2	3	4
	j. The possibility of bowel accidents is always on my mind	1	2	3	4
	k. I am afraid to have sex	1	2	3	4
	l. I avoid travelling by plane or train	1	2	3	4
	m. I avoid going out to eat	1	2	3	4
	n. Whenever I go someplace new, I specifically locate where the toilets are	1	2	3	4

Q5:	During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?					
	Extremely So- to the point that I have just about given up	**Very Much So**	**Quite a bit**	**Some-** Enough to bother me	**A Little Bit**	**Not At All**
	1	2	3	4	5	6

ICIQ-UI **(International Consultant on Incontinence Modular Questionnaire – Urinary Incontinence)**

Many people leak urine some of the time. We are trying to find out how many people leak urine (wee), and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the **PAST FOUR WEEKS**.

Q6:	How often do you leak urine (wee):					
	Never	**About once a week or less often**	**Two or three times a week**	**About once a day**	**Several times a day**	**All of the time**
	0	1	2	3	4	5

Q7:	How much urine (wee) do you think you usually leak (whether you wear protection/ a pad or not)?			
	None	**A small amount**	**A moderate amount**	**A large amount**
	0	2	4	6

Q8: Overall, how much does leaking urine (wee) **interfere** with your everyday life?
Please **circle** the number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

Not at all A great deal

Participant's code:.....

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Q9:	When does urine (wee) leak? (Please **tick all that apply** to you)	
	Never- urine (wee) does not leak	
	Leaks before you can get to the toilet	
	Leaks when you cough or sneeze	
	Leaks when you are asleep	
	Leaks when you a physically active/exercising	
	Leaks when you have finished going to the toilet and are dressed	
	Leaks for no obvious reason	
	Leaks all of the time	

PISQ-12 (Pelvic Organ Prolapse/ Urinary Incontinence Sexual Function Questionnaire)

Following are a list of questions about you and your partner's sex life. Your confidential answers will be used only to help doctors understand what is important to patients about their sex life.

Q10: Are you currently sexually active?

No ☐ → Go to **Q11** Yes ☐ → Go to **Q13 to the end.**

For those who <u>are NOT</u> sexually active only

Q11:	The following are a list of reasons why you might **not** be **sexually active**, for each one please indicate how strongly you AGREE or DISAGREE with it as a reason that you are not sexually active.				
		Strongly Agree	**Somewhat Agree**	**Somewhat Disagree**	**Strongly Disagree**
	a. No partner	1	2	3	4
	b. No interest	1	2	3	4
	c. Due to urinary (wee) leakage	1	2	3	4
	d. Due to faecal (poo) leakage	1	2	3	4
	e. Because of my other health problems	1	2	3	4
	f. Because of pain	1	2	3	4

Q12: How much does the **fear** of leaking urine and/or stool cause you to **avoid or restrict** your sexual activity?

1 ☐ Not at all 2 ☐ A little 3 ☐ Some 4 ☐ A lot

(Please now turn to Q26 on the final page)

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For those who are sexually active

Please **circle** the number that best answers the questions for you.						
		Always	**Usually**	**Sometimes**	**Rarely**	**Never**
Q13.	How frequently do you feel sexual desire? This feeling may include wanting to have sex, planning to have sex, feeling frustrated due to lack of sex.	0	1	2	3	4
Q14.	Do you climax (have an orgasm) when having sexual intercourse with your partner?	0	1	2	3	4
Q15.	Do you feel excited (turned on) when having sexual intercourse with your partner?	0	1	2	3	4
Q16.	How satisfied are you with the variety of sexual activity in your current sex life?	0	1	2	3	4

Please **circle** the number that best answers the questions for you.						
		Never	**Rarely**	**Sometimes**	**Usually**	**Always**
Q17.	Are you incontinence of urine (leak wee) with sexual activity?	0	1	2	3	4
Q18.	Does fear of incontinence (either of stool/poo or urine/wee) restrict your sexual activity?	0	1	2	3	4
Q19.	Do you avoid sexual intercourse because of bulging in the vagina (either the bladder, rectum or vagina falling out)?	0	1	2	3	4
Q20.	When you have sex with your partner, do you have negative emotional reactions such as fear, disgust, shame or guilt?	0	1	2	3	4
Q21.	Does your partner have problems with erections that affects your sexual activity?	0	1	2	3	4
Q22.	Does your partner have problems with premature ejaculation that affects your sexual activity?	0	1	2	3	4
Q23.	Do you feel pain during sexual intercourse?	0	1	2	3	4
Q24.	If you do experience pain, where is the pain? Please state:					

Please **circle** the number that best answers the questions for you.						
		Much less intense	**Less intense**	**Same intensity**	**More intense**	**Much more intense**
Q25.	Compared to orgasms you have had in the past, how intense are the orgasms you have had since the delivery of your child? (If you have more than one child, please compare now with before the birth of your youngest child.)	0	1	2	3	4

Participant's code:.....

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Q26

a) Are there any symptoms that this questionnaire has not covered that you have been experiencing?

b) Do you have any further comments?

Many thanks for taking the time to complete this questionnaire.

We really appreciate your participation in this research.

If completion of this questionnaire has highlighted any concerns or problems you might be dealing with, please do not suffer in silence! Do express these to your GP so that they can refer you to a hospital team that might be able to help you.
Alternatively, for more information, please contact:

- Mr Ash Monga (Consultant specialising in pelvic floor problems) on 023 8120 8504

or

- Dr. Joanna D'Souza (Urogynaecology Research Fellow) on 07759369113 or joanna.d'souza@uhs.nhs.uk

Appendix F Raw Data – Symptoms Questionnaire Results

Group	
C	Control (intact perineum)
NVD	Normal VD (NVD), OASI sustained, no further delivery
OVD	Operative VD (OVD), OASI sustained, no further delivery
NVD - NVD	Subsequent NVD after previous NVD, no OASI recurrent
NVD - CS	Subsequent Caesarean Section (CS) after previous NVD with OASI sustained
OVD - NVD *	Subsequent NVD after previous OVD, no OASI recurrent
OVD - CS	Subsequent Caesarean Section (CS) after previous OVD with OASI sustained

*OVD-NVD includes all deliveries where at least one of them was an OVD e.g. OVD-OVD, NVD-OVD

Control	CCIS total	Av Lifestyle	Av Coping	Av Depression	Av Embarrassment	FIQL Total	ICIQ total	Behavioural	Physical	Partner	PISQ-12 total
C5	5.0	4.0	4.0	3.9	4.0	15.9	7.0	13.0	15.0	15.0	43.0
C12	6.0	4.0	4.0	3.8	4.0	15.8	3.0				
C24	5.0	4.0	4.0	3.9	4.0	15.9	5.0	14.0	15.0	14.0	43.0
C30	5.0	4.0	3.9	3.9	4.0	15.8	6.0	15.0	15.0	14.0	44.0
C35	5.0	4.0	4.0	4.0	4.0	16.0	0.0	14.0	16.0	14.0	44.0
C39	5.0	4.0	4.0	3.8	4.0	15.8	3.0	16.0	13.0	15.0	44.0
C50	5.0	4.0	4.0	4.0	4.0	16.0	0.0	11.0	15.0	14.0	40.0
C75	7.0	4.0	4.0	4.0	3.3	15.3	0.0	11.0	15.0	14.0	40.0
C92	6.0	4.0	4.0	3.8	4.0	15.8	0.0	9.0	16.0	13.0	38.0
C95	5.0	4.0	4.0	3.9	4.0	15.9	0.0	7.0	14.0	15.0	36.0
C112	8.0	4.0	3.9	3.8	4.0	15.7	4.0	12.0	15.0	9.0	36.0
C120	7.0	4.0	4.0		4.0		0.0	9.0	15.0	14.0	38.0
C121	5.0	4.0	4.0	3.8	4.0	15.8	0.0	13.0	16.0	14.0	43.0
C122	5.0	4.0	4.0	3.9	4.0	15.9	0.0				
C123	12.0	4.0	3.2	3.9	3.7	14.8	5.0	9.0	12.0	15.0	36.0
C126	6.0	4.0	4.0	3.9	4.0	15.9	0.0	14.0	16.0	14.0	44.0
C162	6.0	4.0	4.0	3.9	4.0	15.9	4.0	12.0	16.0	14.0	42.0
C164	5.0	4.0	3.9	4.0	4.0	15.9	3.0	6.0	16.0	14.0	36.0
Average	**6.0**	**4.0**	**3.9**	**3.9**	**3.9**	**15.8**	**2.2**	**11.6**	**15.0**	**13.9**	**40.4**
Median	**5.0**	**4.0**	**4.0**	**3.9**	**4.0**	**15.9**	**1.5**	**12.0**	**15.0**	**14.0**	**41.0**

NVD	CCIS total	Av Lifestyle	Av Coping	Av Depression	Av Embarrassment	FIQL Total	ICIQ total	Behavioural	Physical	Partner	PISQ-12 total
N12	5.0	4.0	3.1	3.6	4.0	14.7	6.0	7.0	10.0	13.0	30.0
N32	7.0	4.0	4.0	3.8	4.0	15.8	9.0				
N39	9.0	4.0	4.0	3.8	4.0	15.8	0.0				
N42	9.0	4.0	4.0	3.8	4.0	15.8	5.0	8.0	13.0	13.0	34.0
N46	9.0	4.0	4.0	3.9	4.0	15.9	0.0	13.0	14.0	14.0	41.0
N47		3.7	3.1	3.7	4.0	14.6	4.0	4.0	14.0	12.0	30.0
N61	6.0	3.6	3.2	2.6	2.0	11.4	0.0	12.0	13.0	11.0	36.0
N65	9.0	4.0	4.0	3.9	4.0	15.9	6.0	11.0	14.0	14.0	39.0
N67	9.0	4.0	4.0	4.0	4.0	16.0	0.0	8.0	16.0	14.0	38.0
N72		3.7	3.4	3.3	4.0	14.5	0.0	7.0	15.0	14.0	36.0
N76	8.0	4.0	4.0	3.9	4.0	15.9	4.0	8.0	13.0	14.0	35.0
N77	9.0	4.0	4.0	3.8	4.0	15.8	0.0				
N100	9.0	4.0	4.0	3.7	4.0	15.7	4.0	15.0	13.0	16.0	44.0
N102	9.0	3.6	3.4	3.6	3.3	13.9	6.0	7.0	12.0	12.0	31.0
N107	9.0	4.0	4.0	3.9	4.0	15.9	4.0	7.0	16.0	13.0	36.0
N109	9.0	4.0	4.0	3.9	4.0	15.9	5.0	10.0	15.0	14.0	39.0
N117	9.0	4.0	4.0	3.9	4.0	15.9	0.0				
N123	9.0	4.0	4.0	3.9	4.0	15.9	8.0	12.0	12.0	12.0	36.0
N130	9.0	4.0	4.0	3.9	4.0	15.9	4.0	14.0	15.0	15.0	44.0
N139	9.0	4.0	4.0	4.0	4.0	16.0	0.0	13.0	16.0	15.0	44.0
N144	7.0	4.0	3.7	3.9	3.3	14.9	12.0	3.0	16.0	12.0	31.0
N149	9.0	4.0	4.0	4.0	4.0	16.0	0.0	13.0	16.0	14.0	43.0
N150	7.0	4.0	3.9	3.9	4.0	15.8	4.0	9.0	14.0	8.0	31.0
N156	6.0	3.4	2.8	3.2	2.7	12.1	9.0	11.0	12.0	14.0	37.0
N159	9.0	4.0	4.0	3.7	4.0	15.7	0.0	13.0	16.0	14.0	43.0
Average	**8.3**	**3.9**	**3.8**	**3.7**	**3.8**	**15.3**	**3.6**	**9.8**	**14.0**	**13.2**	**37.0**
Median	**9.0**	**4.0**	**4.0**	**3.9**	**4.0**	**15.8**	**4.0**	**10.0**	**14.0**	**14.0**	**36.0**

Appendix F

OVD	CCIS total	Av Lifestyle	Av Coping	Av Depression	Av Embarrassment	FIQL Total	ICIQ total	Behavioural	Physical	Partner	PISQ-12 total
I1	6.0	4.0	4.0		4.0		12.0	11.0	14.0	12.0	35.0
I19	10.0	1.6	2.3		3.3		8.0	8.0	10.0	12.0	28.0
I21	6.0	4.0	4.0	3.9	4.0	15.9	0.0	13.0	13.0	13.0	37.0
I22	7.0	4.0	3.4	3.5	4.0	14.9	4.0				
I23	9.0	4.0	4.0	3.9	3.3	15.2	3.0	13.0	16.0	14.0	41.0
I31	5.0	4.0	4.0	4.0	4.0	16.0	0.0	13.0	14.0	14.0	39.0
I38	15.0	2.0	2.1	2.5	2.7	9.3	0.0	10.0	12.0	7.0	29.0
I43	8.0	4.0	4.0	4.0	4.0	16.0	0.0	14.0	16.0	14.0	44.0
I48	9.0	3.8	2.8	2.8	2.3	11.7	0.0	8.0	11.0	10.0	29.0
I49			3.6	3.5	4.0		8.0	8.0	14.0	9.0	31.0
I52	18.0	4.0	3.7	3.2	3.7	14.5	5.0	9.0	10.0	9.0	28.0
I69	10.0	3.7	2.9	2.2	2.3	11.2	0.0	4.0	14.0	9.0	27.0
I75	7.0	4.0	4.0	3.9	4.0	15.9	0.0	7.0	14.0	12.0	33.0
I81	5.0	4.0	4.0	3.9	4.0	15.9	4.0	9.0	15.0	13.0	37.0
I86	10.0	4.0	4.0	4.0	3.7	15.7	4.0	11.0	15.0	14.0	40.0
I88	7.0	4.0	4.0	3.7	4.0	15.7	6.0	7.0	15.0	13.0	35.0
I92	9.0	3.9	3.7	3.9	3.0	14.5	0.0	4.0	12.0	10.0	26.0
I95	5.0	4.0	4.0	3.6	4.0	15.6	3.0	12.0	16.0	14.0	42.0
I96	6.0	4.0	4.0	4.0	4.0	16.0	3.0	15.0	16.0	16.0	47.0
I101	6.0	4.0	4.0	3.7	4.0	15.7	6.0	7.0	12.0	10.0	29.0
I105	6.0	4.0	3.9	3.7	4.0	15.6	3.0	6.0	14.0	13.0	33.0
I106	5.0	4.0	4.0	3.9	4.0	15.9	0.0	6.0	12.0	12.0	30.0
I108	8.0	3.9	3.8	3.8	4.0	15.4	4.0	9.0	15.0	13.0	37.0
I110	5.0	4.0	4.0	4.0	4.0	16.0	4.0	8.0	14.0	11.0	33.0
I112	5.0	4.0	4.0	3.9	4.0	15.9	5.0	10.0	15.0	14.0	39.0
I115	5.0	4.0	4.0	4.0	4.0	16.0	0.0	7.0	16.0	12.0	35.0
I121	9.0	4.0	3.8	3.9	3.7	15.3	7.0	10.0	15.0	14.0	39.0
I128	8.0	4.0	3.0	3.5	4.0	14.5	3.0				
I132	5.0	4.0	4.0	3.8	4.0	15.8	0.0	7.0	16.0	14.0	37.0
I136	5.0	4.0	4.0	4.0	4.0	16.0	4.0	9.0	13.0	13.0	35.0
I138	6.0	3.7	3.8	3.3	3.7	14.5	4.0	12.0	14.0	11.0	37.0
I140	7.0	4.0	3.7	3.8	4.0	15.5	4.0	9.0	15.0	14.0	38.0
Average	**7.5**	**3.8**	**3.7**	**3.7**	**3.7**	**15.0**	**3.3**	**9.2**	**13.9**	**12.2**	**35.0**
Median	**7.0**	**4.0**	**4.0**	**3.8**	**4.0**	**15.7**	**3.5**	**9.0**	**14.0**	**13.0**	**35.0**

NVD - NVD	CCIS total	Av Lifestyle	Av Coping	Av Depression	Av Embarrassment	FIQL Total	ICIQ total	Behavioural	Physical	Partner	PISQ-12 total
NN1	9.0	4.0	4.0	4.0	4.0	16.0	4.0	12.0	16.0	15.0	43.0
NN3	5.0	4.0	4.0	4.0	4.0	16.0	0.0				
NN6	7.0	4.0	4.0	3.5	3.3	14.8	4.0	10.0	12.0	12.0	34.0
NN7	6.0	4.0	4.0	3.9	4.0	15.9	4.0	4.0	10.0	10.0	24.0
NN8	5.0	4.0	4.0	3.9	4.0	15.9	0.0				
NN9	5.0	4.0	4.0	3.7	4.0	15.7	7.0				
NN11	5.0	4.0	4.0	3.8	4.0	15.8	0.0	10.0	15.0	12.0	37.0
NN12	5.0	4.0	4.0	3.9	4.0	15.9	6.0	12.0	14.0	13.0	39.0
NN18	5.0	4.0	4.0	3.9	4.0	15.9	7.0	11.0	15.0	11.0	37.0
NN22	5.0	4.0	4.0	4.0	4.0	16.0	0.0	8.0	14.0	12.0	34.0
NN25	9.0	4.0	4.0	3.9	4.0	15.9	6.0	6.0	15.0	13.0	34.0
NN26	5.0	4.0	4.0	4.0	4.0	16.0	0.0	15.0	11.0	15.0	41.0
NN28	5.0	4.0	4.0	3.9	4.0	15.9	14.0				
NN31	6.0	4.0	4.0	3.9	4.0	15.9	13.0				
NN33	6.0	4.0	4.0	3.9	4.0	15.9	0.0	13.0	15.0	14.0	42.0
NN34	5.0	4.0	4.0	3.9	4.0	15.9	4.0	7.0	16.0	14.0	37.0
NN35	7.0	4.0	4.0	3.9	4.0	15.9	6.0	9.0	11.0	10.0	30.0
NN36	7.0	4.0	4.0	4.0	4.0	16.0	14.0	11.0	16.0	9.0	36.0
NN39	5.0	4.0	4.0	3.9	4.0	15.9	5.0	11.0	11.0	12.0	34.0
NN47	8.0	4.0	3.8	4.0	4.0	15.8	0.0	10.0	16.0	13.0	39.0
NN50	5.0	3.9	4.0	4.0	4.0	15.9	4.0	14.0	15.0	14.0	43.0
NN53	6.0	4.0	4.0	3.9	4.0	15.9	0.0	12.0	14.0	14.0	40.0
NN59	5.0	4.0	4.0	4.0	4.0	16.0	0.0	13.0	16.0	14.0	43.0
NN62	20.0	4.0	3.6	3.5	3.0	14.0	15.0	8.0	15.0	14.0	37.0
NN64	6.0	4.0	4.0	3.9	4.0	15.9	3.0	10.0	16.0	14.0	40.0
NN66	8.0	4.0	4.0	3.9	4.0	15.9	4.0	9.0	14.0	14.0	37.0
NN69	5.0	4.0	4.0	3.9	4.0	15.9	0.0	3.0	16.0	14.0	33.0
NN73	6.0	4.0	4.0	4.0	4.0	16.0	3.0	13.0	16.0	13.0	42.0
NN74	5.0	4.0	3.9	3.9	4.0	15.8	5.0	13.0	14.0	14.0	41.0
NN78	5.0	4.0	4.0	4.0	4.0	16.0	0.0	13.0	16.0	14.0	43.0
NN83	7.0	4.0	4.0	3.9	3.7	15.6	4.0	14.0	16.0	14.0	44.0
NN88	5.0	4.0	4.0	3.9	4.0	15.9	4.0	9.0	15.0	14.0	38.0
NN98	6.0	4.0	4.0	3.7	4.0	15.7	0.0	12.0	16.0	14.0	42.0
NN106	8.0	4.0	4.0	3.9	4.0	15.9	0.0	8.0	14.0	13.0	35.0
NN109	5.0	4.0	4.0	3.8	4.0	15.8	7.0	11.0	13.0	14.0	38.0
NN113	5.0	4.0	4.0	4.0	4.0	16.0	0.0	13.0	16.0	15.0	44.0
NN118	8.0	4.0	3.9	3.9	3.7	15.4	3.0	11.0	15.0	15.0	41.0
NN122	11.0	4.0	4.0	3.9	4.0	15.9	3.0	9.0	15.0	13.0	37.0
NN123	5.0	4.0	4.0	3.9	4.0	15.9	3.0	15.0	16.0	15.0	46.0
NN131	9.0	4.0	3.3	3.5	3.3	14.2	5.0	10.0	12.0	10.0	32.0
NN132	5.0	4.0	4.0	3.7	4.0	15.7	4.0	13.0	15.0	14.0	42.0
NN133	8.0	4.0	3.9	3.1	2.7	13.6	12.0	6.0	15.0	13.0	34.0
NN141	9.0	3.3	3.1	2.9	3.3	12.6	14.0				
NN143	5.0	4.0	4.0	3.9	4.0	15.9	0.0	14.0	16.0	15.0	45.0
NN151	5.0	4.0	4.0	4.0	4.0	16.0	0.0	14.0	16.0	14.0	44.0
NN156	6.0	4.0	4.0	3.9	4.0	15.9	9.0	7.0	15.0	15.0	37.0
NN160	9.0	2.6	2.7	2.1	2.3	9.7	8.0	8.0	9.0	8.0	25.0
NN166	5.0	4.0	4.0	3.9	4.0	15.9	15.0	11.0	14.0	14.0	39.0
Average	**6.5**	**4.0**	**3.9**	**3.8**	**3.9**	**15.5**	**4.6**	**10.5**	**14.5**	**13.2**	**38.2**
Median	**5.5**	**4.0**	**4.0**	**3.9**	**4.0**	**15.9**	**4.0**	**11.0**	**15.0**	**14.0**	**38.5**

OVD - NVD	CCIS total	Av Lifestyle	Av Coping	Av Depression	Av Embarrassment	FIQL Total	ICIQ total	Behavioural	Physical	Partner	PISQ-12 total
NI2	7.0	4.0	4.0	4.0	4.0	16.0	0.0	13.0	16.0	13.0	42.0
IN13	5.0	4.0	4.0	3.3	3.7	15.0	3.0	9.0	13.0	11.0	33.0
IN15	5.0	4.0	4.0	4.0	4.0	16.0	6.0	10.0	14.0	12.0	36.0
IN23	5.0	4.0	4.0	4.0	4.0	16.0	0.0	9.0	14.0	15.0	38.0
IN25	5.0	4.0	4.0	4.0	4.0	16.0	6.0	13.0	14.0	15.0	42.0
IN26	5.0	4.0	4.0	4.0	4.0	16.0	3.0	12.0	16.0	13.0	41.0
IN30	5.0	4.0	4.0	3.9	4.0	15.9	0.0	15.0	16.0	14.0	45.0
IN35		1.2	1.4	2.3	1.7	6.6	15.0	8.0	10.0	13.0	31.0
IN48	5.0	4.0	4.0		4.0		0.0	11.0	15.0	14.0	40.0
IN53	7.0	4.0	4.0	4.0	4.0	16.0	4.0	10.0	15.0	14.0	39.0
IN64	8.0	4.0	4.0	3.9	4.0	15.9	5.0	11.0	14.0	15.0	40.0
IN71	5.0	4.0	4.0	4.0	4.0	16.0	7.0	15.0	15.0	14.0	44.0
IN72	5.0	4.0	4.0	3.7	4.0	15.7	7.0				
IN73	7.0	4.0	4.0	3.7	4.0	15.7	0.0	8.0	14.0	14.0	36.0
IN77	5.0	4.0	4.0	3.9	4.0	15.9	0.0	12.0	14.0	15.0	38.0
IN80	8.0	4.0	3.6	3.5	3.0	14.0	3.0	4.0	11.0	10.0	24.0
IN81	11.0	3.7	3.6	3.7	2.7	13.7	3.0	11.0	15.0	12.0	37.0
I7	7.0	4.0	3.8	3.6	4.0	15.4	8.0	9.0	11.0	12.0	30.0
Average	**6.2**	**3.8**	**3.8**	**3.7**	**3.7**	**15.0**	**3.9**	**10.6**	**13.9**	**13.3**	**37.4**
Median	**5.0**	**4.0**	**4.0**	**3.9**	**4.0**	**15.9**	**3.0**	**11.0**	**14.0**	**14.0**	**38.0**

NVD - CS	CCIS total	Av Lifestyle	Av Coping	Av Depression	Av Embarrassment	FIQL Total	ICIQ total	Behavioural	Physical	Partner	PISQ-12 total
NC7	7.0	4.0	4.0	3.9	4.0	15.9	3.0	9.0	14.0	14.0	35.0
NC14	12.0	3.5	2.3	3.0	3.0	11.8	0.0	4.0	12.0	12.0	27.0
NC16	5.0	4.0	4.0	4.0	4.0	16.0	3.0	9.0	14.0	13.0	34.0
NC18	5.0	4.0	4.0	3.9	4.0	15.9	8.0	11.0	14.0	15.0	37.0
NC19	11.0	3.8	3.8	3.7	3.3	14.7	5.0	13.0	13.0	13.0	37.0
NC24	5.0	4.0	4.0	3.8	4.0	15.8	3.0	3.0	14.0	14.0	29.0
NC28	5.0	4.0	4.0	3.9	4.0	15.9	0.0	13.0	14.0	13.0	39.0
NC29	5.0	3.1	2.2	1.9	2.7	9.9	0.0	7.0	9.0	13.0	27.0
NC31	6.0	4.0	3.9	3.6	4.0	15.5	6.0	8.0	14.0	13.0	33.0
NC33	8.0	4.0	4.0	3.9	4.0	15.9	10.0	12.0	8.0	13.0	32.0
NC37	8.0	3.7	3.9	4.0	4.0	15.6	2.0	8.0	13.0	14.0	33.0
NC41	8.0	4.0	3.7	3.5	3.7	14.8	8.0	12.0	11.0	12.0	35.0
NC42	7.0	4.0	4.0	3.9	3.0	14.9	9.0	11.0	16.0	12.0	36.0
NC47	6.0	4.0	4.0	3.9	4.0	15.9	2.0	16.0	14.0	16.0	42.0
Average	**7.0**	**3.9**	**3.7**	**3.6**	**3.7**	**14.9**	**4.2**	**9.7**	**12.9**	**13.4**	**34.0**
Median	**6.5**	**4.0**	**4.0**	**3.9**	**4.0**	**15.7**	**3.0**	**10.0**	**14.0**	**13.0**	**34.5**

OVD - CS	CCIS total	Av Lifestyle	Av Coping	Av Depression	Av Embarrassment	FIQL Total	ICIQ total	Behavioural	Physical	Partner	PISQ-12 total
IC1	8.0	3.9	3.7	3.9	3.3	14.8	3.0	7.0	14.0	13.0	32.0
IC6	5.0	4.0	4.0	3.9	4.0	15.9	0.0	10.0	16.0	14.0	38.0
IC10	11.0	3.9	3.2	3.5	3.3	13.9	3.0	10.0	14.0	13.0	35.0
IC11	8.0	4.0	3.9	3.9	4.0	15.8	1.0	12.0	13.0	13.0	37.0
IC15	8.0	4.0	4.0	3.7	4.0	15.7	4.0				
IC16	7.0	4.0	3.2	3.9	4.0	15.1	2.0	10.0	14.0	14.0	36.0
IC20	8.0	4.0	3.7	3.9	4.0	15.5	3.0	11.0	14.0	14.0	37.0
IC21	17.0	3.6	2.4	2.4	2.0	10.4	5.0	10.0	11.0	12.0	31.0
IC24	5.0	4.0	3.0	3.1	3.3	13.4	3.0	12.0	11.0	8.0	31.0
IC27	15.0	3.2	1.8	2.6	2.7	10.3	3.0	7.0	12.0	12.0	29.0
IC30	5.0	3.8	3.8	3.7	4.0	15.3	3.0	8.0	14.0	13.0	34.0
IC31	15.0	3.9	2.2	2.1	2.0	10.2	0.0	7.0	11.0	12.0	27.0
IC34	10.0	3.8	3.4	3.7	2.7	13.7	3.0	7.0	15.0	14.0	34.0
IC39	6.0	4.0	4.0	3.8	4.0	15.8	7.0	14.0	16.0	14.0	42.0
IC40	5.0	4.0	4.0	3.8	4.0	15.8	3.0	13.0	16.0	15.0	41.0
IC41	6.0	4.0	4.0	3.9	4.0	15.9	4.0				
IC42	7.0	4.0	4.0	4.0	4.0	16.0	4.0	11.0	16.0	13.0	39.0
IC46	7.0	3.7	2.9	3.5	2.7	12.7	0.0	13.0	13.0	12.0	37.0
IC49	16.0	3.9	2.7	3.6	3.7	13.8	9.0				
IC50	9.0	4.0	3.4	3.6	4.0	15.0	0.0	5.0	13.0	14.0	30.0
IC52	7.0	4.0	4.0	3.9	4.0	15.9	4.0	11.0	16.0	13.0	39.0
Average	**8.8**	**3.9**	**3.4**	**3.5**	**3.5**	**14.3**	**3.0**	**9.9**	**13.8**	**12.9**	**34.9**
Median	**8.0**	**4.0**	**3.7**	**3.7**	**4.0**	**15.1**	**3.0**	**10.0**	**14.0**	**13.0**	**35.5**

	CCIS total	Av Lifestyle	Av Coping	Av Depression	Av Embarrassment	FIQL Total	ICIQ total	Behavioural	Physical	Partner	PISQ-12 total
NVD+OVD	8.0	4.0	4.0	3.9	4.0	15.8	4.0	9.0	14.0	13.0	36.0
NVD-NVD + OVD-NVD	5.0	4.0	4.0	3.9	4.0	15.9	4.0	11.0	15.0	14.0	38.0
NVD-CS + OVD+CS	7.0	4.0	3.9	3.8	4.0	15.5	3.0	10.0	14.0	13.0	35.0

Appendix G Free Text Comments – Symptoms Questionnaire Study

Colour Key:

Recurrent themes:

- Psychological impact of sustaining an OASI
- Fear of subsequent delivery
- Isolation associated with no knowing others suffering with the same
- Isolation and taboo of speaking out due to embarrassment
- Seeing symptoms of PFD as the 'norm' or an expected outcome of childbirth

Areas in need of improvement:

- Better provision of accurate information regarding the long-term consequences, need for follow-up and subsequent deliveries to aid women in making informed choices
- Lack of continuity of care and collaborative thinking by medical professionals
- Training of medical professionals regarding the long-term physical and psychological implications of the injury to aid more sympathetic and holistic consultations

NVD

"I feel lucky that I have recovered really well and only have minor residual symptoms and whilst not expecting another child yet would ideally like to try for another vaginal delivery. Knowing what the best decision to make is difficult as I wouldn't want to exacerbate the problem and whilst I appreciate the opportunity to have a say in the method of delivery myself, I do find it also increases my anxiety… I am reluctant and anxious to rush to become pregnant again too soon… to give my body the best chance of recovering… I'm not sure if this is a common feeling for other women or not… Thank you for showing an interest in this area and conducting research. Anything that helps women make an informed choice about future deliveries following a tear is incredibly valuable. I feel extremely lucky with my recovery and really appreciate the incredible care I have received but still really struggle when considering future pregnancies and births. This is something I know I will need to approach if I am lucky enough to have further babies. Thank you again."

OVD

"I haven't told anyone about [symptoms of anal incontinence] and I don't suppose there is anything that can be done about it. I wish I'd had a caesarean the first time around – then I might have been more inclined to have a 2nd child. As it is, one child will do nicely and is worth the problems!"

"I am dreading having a second child" (In relation to the struggles associated with PFD)

"I don't feel that I was made aware of the seriousness of third degree tears and the long term effects of having this kind of tear. I was given an information sheet after the birth and I was advised to attend physio, but I didn't go because I thought it was a fact of life that women tear during childbirth… I do feel that it should have been stressed to me that there are long term implications, the importance of physio, pelvic floor exercises etc, and that recovery can be slow and painful. It really has put me off having another baby in the future. In hindsight, perhaps I was naïve to brush off the seriousness of a third degree tear (clue in the name!) but I don't know anyone else who has

suffered this kind of tear and so there is no one to share this experience with. It really does upset me when I think back to the months after giving birth and how painful and sore I was even though I healed well, and how scared I was that my bodily functions may never go back to normal."

NVD-NVD

"I expressed concerns about tearing again with second labour. Midwife advised use of gas and air when delivering the head to minimise the risk of a tear. This was written in my birth plan and reassured me."

"I can't remember the outcome [of the EAUS] but I remember the Consultant saying he would back me if I opted for a C-section, but when I came to having my youngest the Consultant I saw said I couldn't have a C-section…"

"I feel follow-up was poor. It seems, as a woman, that these things are the sorts of things that we experience, but to keep quiet about it."

"I asked [at EAUS] whether I would be likely to have another 3rd degree tear with subsequent deliveries – they said it was very unlikely and the chance of that happening was no higher than anyone who hadn't suffered a 3rd degree tear."

"They said [at EAUS] … that I shouldn't be any more likely to tear a second time."

"I was told [at EAUS] that I had made a good recovery. I also had [the Consultant] make me a promise that I could be allowed to have a C-section if I wanted on. I was traumatised by the entire experience!"

OVD-NVD

"I felt the way the doctors spoke to me was very frank and upsetting. I definitely needed reassurance and didn't get much."

"…I did suffer from faecal urgency. I was embarrassed and anxious about this and did avoid social situations… This consequence was not discussed with me as a possibility after my surgical repair…"

"I was so terrified of my second birth. I asked to be induced early, which initially I was told 'no' to until I got really upset… I felt like I was just being an inconvenience."

NVD-CS

"After my first child sex was very painful for several years… it's slowly got better and is nearly back to normal. This pain was a big factor in being unsure about how to deliver my second child. It turned out he was transverse so the choice of how to deliver was made for me. However, before this I was strongly pushed towards a vaginal birth, even though at times I was very obviously upset by this thought… people were very dismissive of my very genuine fear of things being made worse by another vaginal delivery. I was wondering whether if this study would also provide guidance on the emotional consequence of tears and how important it is for doctors to show compassion about the longer-term emotional effects of them."

"When I left hospital after my first birth, I knew I'd had surgery, but didn't know it would affect me for the next 5 years. I think more should be explained before you leave hospital. I didn't know exactly what happened to me until I went to me scan."

"When talking to pregnant women, please can incontinence be covered (both wee and poo)? I didn't know how to bring up my [symptoms]… This prevented me from being considered for C-section until I had a second consultation and broke down in shame…"

"After the tear I suffered from postnatal depression, in my opinion, the physical symptoms (pain and stress incontinence) had a significant impact on bonding with my daughter. I remain on anti-depressants now. No mental health history before the tear. It took 5 years for me to have another child due to the effect of childbirth on my physical and mental health. I had to argue my case in order to be allowed to have an elective C-section. I kept being told I would be fine having a natural delivery. After having such a significant history, it would have been good not to have had this discussion in such a manner. If this study addresses this, I would be grateful as it will help women in this situation in the future."

"I really had to push for an elective C-section. I was terrified after No.1. If I hadn't had a fantastic Consultant who agreed after the degree of my tear it was necessary, I would probably experience all of the symptoms. Luckily, I am middle-class and educated. I dread to think what would happen if we didn't have the awareness of what could go wrong."

OVD-CS

"In my experience, it took nearly 3 years to be taken seriously about the pain and problems that resulted from my tear and slow healing. I was told to 'give it time'… it was very discouraging and frustrating. I think there should be more support for those who have had significant tears. I would have found this very valuable."

"I feel that if someone has had a traumatic birth i.e. a tear, then when you go on to have another baby, it would be nice if there was more support and understanding as to why you don't feel happy to try for a natural birth. All everyone asked when I had my second daughter was why I was having an elective C-section."

"Since the birth of my second child, my incontinence problems have increased despite having a C-section. I was very upset that when meeting my Obstetrician for the first time and was in floods of tears when [the doctor] told me it was the Obstetrician's decision not [Consultant at EAUS]. I would not have risked a second pregnancy if there had been any doubt that I could not have a C-section, so I was very distressed."

"Since the birth of my firstborn my life changed and never got better. I live in fear of wee/poo leakage. I live around the toilet. Even my sacral nerve stimulation box has not improved things as much as I hoped for."

"I can recall extreme problems when a new mum – not able to go out, difficulties looking after a baby and getting to the loo as a matter of urgency. It took a considerable amount of time to improve and a high level of anxiety. At that time, I was invited to a group session to discuss problems – not an easy subject in front of other 'non-medical' strangers. I really didn't feel this was appropriate.

Appendix H Participant paperwork – Postnatal pelvic floor symptoms questionnaire

University Hospital Southampton NHS
NHS Foundation Trust

Portsmouth Hospitals NHS
NHS Trust

Postnatal Pelvic Floor Questionnaire Study

A questionnaire based study to establish women's knowledge of pelvic floor problems associated with childbirth

Congratulations again on the birth of your little one!
We understand time is precious, so don't want to take up too much of yours!

Many thanks for your interest in taking part in this questionnaire study.
Your participation should only take 10 minutes and all you need to do is complete this questionnaire.

With your help, we will find out what women know about the effect of pregnancy and childbirth on the pelvic floor. We hope that this information will help improve the service we provide for future women giving birth in Southampton.
Your participation is greatly appreciated.

If you'd prefer to complete the online version, please visit: https://www.surveymonkey.co.uk/r/PPFQStudy

Name of the Doctor inviting you to participate: .....

Bleep No.: .....

pg. 1

PPFQ Study Pack v.1.0 13.12.18

University Hospital Southampton NHS
NHS Foundation Trust

Portsmouth Hospitals NHS
NHS Trust

Participant Information Sheet

Postnatal Pelvic Floor Questionnaire Study

A questionnaire based study to establish women's knowledge of pelvic floor problems associated with childbirth

Name of Lead Researcher: Mr. Ash Monga, Consultant Urogynaecologist
Location of Research: Urogynaecology Dept. Princess Anne Hospital, Southampton SO16 5YA

Introduction:

You are being invited to take part in a research project. If you decide to take part you will only need to complete one questionnaire. Nothing further will be asked of you.

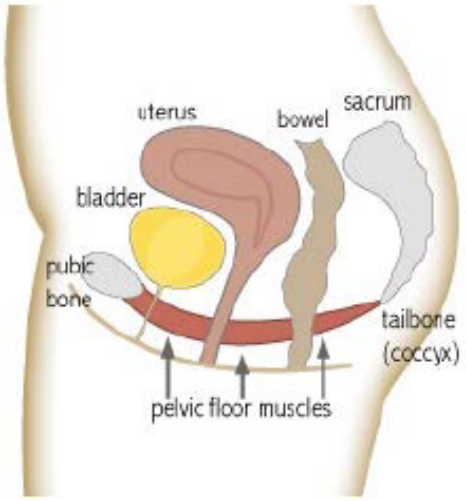
This sheet will tell you about the research and why we are doing it. If you do not understand, or would like more information, then please ask us. One of our team can go through this information sheet with you and answer any questions you have.

What is the purpose of this study?

During pregnancy, women are given information on various topics about pregnancy and birth. This information can come in many forms and from a variety of sources such as their midwife, doctor or antenatal classes, the NCT as well as leaflets, books, internet websites and forums, and friends or family.

This study aims to give us an insight into how much information is understood and retained by women. This study will focus on the effect birth has on the pelvic floor (a hammock of muscles in your pelvis, which support the bladder, womb and bowel. (See the picture).

Our hope is that this questionnaire will give us an idea of the level of knowledge women have. This will then enable us to gauge how we might develop the information, support and counselling we offer. We hope this will help women to make informed decisions about their care, in consultation with midwives and doctors and enhance their overall experience.



Why have you been invited?

You have been invited to take part in this research because you are 18 years old or over, and you have given birth in the past 12 weeks

The small print...

Do I have to take part?

It is up to you whether or not you wish to take part. The standard of care you receive will not be affected if you decide not to take part.

What are the possible disadvantages and risks of taking part?

There are no health or safety risks associated with taking part. The questionnaire may leave you with some unanswered questions. If this is the case, you can contact your midwife or GP.

What are the possible benefits of taking part?

Although you will not receive any direct personal benefit from taking part, your participation will help improve the service provided in the future to women giving birth at this hospital.

Will my participation in the study be kept confidential?

Yes. Any information used in the study will not have your details on it, so it will not be possible for you to be identified.

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NHS Trust

What will happen to the results of the research?
Only the researcher and medical personnel involved in your treatment will have access to any results of the research. These results will be kept for up to one year to ensure enough time for analysis of the data produced. We hope to publish the data from this research in medical journals and as part of a research thesis in affiliation with the University of Southampton. You may contact the Chief Investigator (details below) if you would like to know the results of the study.

What if something goes wrong?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Please raise your concerns in the first instance with the Chief Investigator Mr. Ash Monga. If you wish to make a more formal complaint, please contact the hospital's Patient Support Services. All contact details are at the end of this information sheet.

Which insurance provisions are in place?
In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the Sponsor, Southampton University Hospitals NHS Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanism will still be available to you.

Contact details:

Mr. Ash Monga
Consultant Urogynaecologist
Urogynaecology Secretary: 023 8120 8504

Contacts for further information:
If you would like to speak to someone independent about taking part in the study you can contact the Patient Support services:

Portsmouth Hospital NHS Trust
Patient Advice and Liaison Service
Health Information Office
Queen Alexandra Hospital
Cosham, Portsmouth
PO6 3LY

Email: PHT.Pals@porthosp.nhs.uk
Tel: 023 9288 6309

Thank you for taking the time to read this information sheet.
If you are happy to take part, please proceed to complete the questionnaire. Thank you!

Once you've finished please hand it to the midwives who will make sure it comes back to the research team.

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Postnatal Pelvic Floor Questionnaire

Please complete this questionnaire to the best of your ability and without asking anyone else for their help or advice. It is your own opinion that is most important to us. It will help us understand whether clear advice is given to all mum's consistently before birth, and help show us where we could do better.

There are no wrong answers. Any information you provide will be helpful. Thank you!

Information about you

Age: What is your age?

[ ] 18-24 years old
[ ] 25-29 years old
[ ] 30-34 years old
[ ] 35-39 years old
[ ] 40+ years old
[ ] Prefer not to answer

Education:
Please indicate the highest level of education you have completed:

[ ] No schooling completed
[ ] Primary school
[ ] Secondary school to GCSEs/O-levels
[ ] A-levels, Diploma, Trade/Vocational training
[ ] Degree
[ ] Postgraduate qualification
[ ] Prefer not to answer

Professional or Employment Status
Please indicate your employment status prior to commencing maternity leave:

[ ] Employed full-time
[ ] Employed part-time
[ ] Self-employed
[ ] Currently unemployed and looking for work
[ ] Not currently employed or seeking work
[ ] Stay-at-home mother
[ ] Student
[ ] Military
[ ] Prefer not to answer
[ ] Other (Please specify) .....

Ethnicity origin (or Race):
Please specify your ethnicity.

[ ] Prefer not to answer

A White
- ☐ English / Welsh / Scottish / Northern Irish / British
- ☐ Irish
- ☐ Gypsy or Irish Traveller
- ☐ Any other White background, write in

B Mixed / multiple ethnic groups
- ☐ White and Black Caribbean
- ☐ White and Black African
- ☐ White and Asian
- ☐ Any other Mixed/multiple ethnic background, write in

C Asian / Asian British
- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi
- ☐ Chinese
- ☐ Any other Asian background, write in

D Black / African / Caribbean / Black British
- ☐ African
- ☐ Caribbean
- ☐ Any other Black / African / Caribbean background, write in

E Other ethnic group
- ☐ Arab
- ☐ Any other ethnic group, write in

Your child(ren)

Please fill in the dates of birth of your child(ren), how old you were at that birth and if the birth was a normal vaginal birth, instrumental (Forceps or Ventouse) or a planned or unplanned Caesarean section.

Child 1: --/--/---- Your age: ..... Birth: .....

Child 2: --/--/---- Your age: ..... Birth: .....

Child 3: --/--/---- Your age: ..... Birth: .....

Child 4: --/--/---- Your age: ..... Birth: .....

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Q1: In this section we are interested in finding out what kind of information you received during your pregnancy and where this information came from.

a) Did you receive any information on the following topics? If so, where from?

b) For topics which you would have liked some/more information please put a '*' where you would have liked to receive the information. **See example in the box below.**

E.g. *I did not receive information about 'Episiotomy' so I have put a '✓' in the 'No information received box'. I would have liked information from my Midwife, so I have put '*' in the 'midwife' box.*
My friends told me about 'Caesarean birth' but I would have liked the information from my Doctor.

Topics about pregnancy and birth		Where did you gain knowledge about the topics?							
	No information received	Midwife	Doctor	NCT / Antenatal classes	NHS Leaflet/ Booklet	Internet forum/ Website	Book	Family/ Friends	I knew about it prior to this pregnancy
Episiotomy	✓	*							
Caesarean birth (C-section)			*					✓	

Please now fill in the table below

Topics about pregnancy and birth		Where did you gain knowledge about the topics?							
	No information received	Midwife	Doctor	NCT / Antenatal classes	NHS Leaflet/ Booklet	Internet forum/ Website	Book	Family/ Friends	I knew about it prior to this pregnancy
Pelvic floor muscle training exercises (Kegel exercises)									
Vaginal tears during birth									
Episiotomy									
Instrumental birth (Forceps/Ventouse)									
Caesarean birth (C-section)									
Damage to sensation / nerves (down below)									
Sexual function (after childbirth)									
Pain down below (after childbirth)									
Leakage of flatus (wind), stool (poo) after childbirth									
Leakage of urine (wee) after childbirth									

Q2: **a)** Do you think that pelvic floor muscle training exercises help with the following: (tick **any** that apply)

[ ] To prevent urine (wee) leaking (e.g. when coughing/sneezing/exercising)
[ ] To prevent prolapse (bulging of the womb into the vagina)
[ ] To prevent leakage of faeces (poo)
[ ] With physical recovery after birth
[ ] Improve sex life for women
[ ] Not sure

b) In which of the following situations do you think pelvic floor muscle training exercises are particularly important? (tick **any** that apply)

[ ] If a woman leaked urine when coughing/sneezing/exercising before she was pregnant
[ ] If a woman leaks urine after she has given birth
[ ] If her baby was delivered by forceps or ventouse
[ ] If her baby was delivered by caesarean section
[ ] If a woman was overweight before she fell pregnant
[ ] If a woman was underweight before she fell pregnant
[ ] Not sure

c) Have you been taught these exercises? [ ] Yes [ ] No (If 'No', skip to Q3:)

d) If you were taught pelvic floor exercises:

- Who taught you these exercises? .....
- How were you taught these exercises? (Please tick all that apply)

  [ ] I was shown when I had a vaginal examination
  [ ] I was given an instruction sheet
  [ ] I watched a video
  [ ] Other .....

- Did you do these exercises during your pregnancy? [ ] Yes [ ] No
- Are you planning to do these exercises now your baby is born? [ ] Yes [ ] No

Q3:

During childbirth the entrance to the vagina and the perineum (the skin between the vagina and the anus) need to stretch to allow the baby to emerge. When the baby stretches the vagina during birth the skin of the perineum strains, which can lead to a perineal tear. A lot of women will tear to some extent and most of these tears do not lead to long-term problems.

Occasionally a tear can be more serious leading to problems such as leakage of flatus (wind) and faeces (poo). This is more likely to happen when a tear affects the muscles of the back passage. These are referred to as 3rd and 4th degree tears.

a) Would you think the following make having a severe tear more or less likely?

(Please tick one box per row)

	More likely	Less likely	Not sure
Having the support of a known and trusted midwife			
Having an instrumental delivery (e.g. forceps or ventouse)			
Having an epidural for pain relief			
Pelvic floor muscle training (Kegel) exercises during pregnancy			

(Continuation... Please tick one box per row)

	More likely	Less likely	Not sure
Having your first baby at a young age			
If you have a tear before			
Having a baby weighing less than 4kg (8lb 13oz)			
Perineal massage from 34 weeks of pregnancy			
If it's your first vaginal delivery			
If you have had a baby before but not had a previous tear			

b) This question will tell us about how knowing more about tears might make you feel.

Mark an 'x' to indicate the level (%) of the emotion felt

I think being given information about tears during my pregnancy would have made me feel...

Prepared	0 ..... 100%
Anxious	0 ..... 100%
Empowered	0 ..... 100%
Upset	0 ..... 100%

I would have benefitted from knowing more about tears ('Circle' one option)

	Strongly disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Strongly agree
	1	2	3	4	5

I would rather only know about tears in the event of me having one ('Circle' one option)

	Strongly disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Strongly agree
	1	2	3	4	5

Q4:

An episiotomy is a cut in the perineum, made by a doctor or midwife, in order to make the opening wider to help deliver baby. They are not carried out routinely, but in special circumstances, such as:

- when baby needs to be born without delay
- if baby is in a difficult position or is big
- if a woman is getting too exhausted to continue pushing
- in a forceps or ventouse delivery.

Some research has shown that episiotomy can help to prevent a serious tear. However, they require stitching and they take time to heal which can be painful.

a) If you were told that it would prevent a serious tear but there was no other reason to need it, would you request an episiotomy?

[ ] Yes [ ] No [ ] Not sure

b) If you were told that tears heal better than episiotomies would you choose to tear rather than have an episiotomy?

[ ] Yes [ ] No [ ] Not sure

Q5:

Sometimes the safest option for mum and baby is to have a Caesarean section. This is an operation to deliver baby by making a surgical cut through the tummy wall into the womb. Caesarean sections carry the risk of increased hospital stay, longer time to heal, blood clots, infection to the tummy wound, and an increased risk of complications in a future pregnancy.

a) In the UK, what percentage of births do you think are by Caesarean section?
(Please mark 'X' on line to indicate the % you think)

---

0 10 20 30 40 50 60% of births

b) Do you think that a Caesarean will prevent problems with leakage of flatus (gas), faeces (poo) or urine (wee) later in life?

[ ] Yes [ ] No [ ] Not sure

c) If Caesarean Section was shown to reduce the risk of leakage (of flatus, faeces or urine) later in life, would you want to deliver by Caesarean Section despite the risks of surgery, even if there was no other medical reason for needing one?

[ ] Yes [ ] No [ ] Not sure

Q6:

a) Would knowing about potential complications of giving birth naturally (vaginally) make you more likely to want a Caesarean Section if you had the choice?

[ ] Yes [ ] No [ ] Not sure

b) Would knowing about potential complications of giving birth by Caesarean section make you less likely to want a Caesarean Section if you had the choice?

[ ] Yes [ ] No [ ] Not sure

Thank you for taking to the time to complete this questionnaire.

Please return your completed questionnaire to the midwives who will hand it back to the research team.

(Ward use: Bleep No. .....)

If completing this questionnaire has raised any worries or concerns, you may wish to talk these through with your midwife or GP.

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