Variation in availability and use of surgical care for female urinary incontinence: a mixed-methods study

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This report should be referenced as follows:

Geary RS, Gurol-Urganci I, Mamza JB, Lynch R, El-Hamamsy D, Wilson A, *et al.* Variation in availability and use of surgical care for female urinary incontinence: a mixed-methods study. *Health Serv Deliv Res* 2021;**9**(7).

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HS&DR programme

This report

Abstract

Variation in availability and use of surgical care for female urinary incontinence: a mixed-methods study

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Background: Urinary incontinence affects between 25% and 45% of women. The availability and quality of services is variable and inequitable, but our understanding of the drivers is incomplete.

Objectives: The objectives of the study were to model patient, specialist clinician, primary and secondary care, and geographical factors associated with referral and surgery for urinary incontinence, and to explore women's experiences of urinary incontinence and expectations of treatments.

Design: This was a mixed-methods study.

Setting: The setting was NHS England.

Participants: Data were collected from all women with a urinary incontinence diagnosis in primary care data, and all women undergoing mid-urethral mesh tape surgery for stress urinary incontinence were included. Interviews were also carried out with 28 women from four urogynaecology clinics who were deciding whether or not to have surgery, and surveys were completed by 245 members of the Royal College of Obstetricians and Gynaecologists with a specialist interest in urinary incontinence.

Data sources: The sources were patient-level data from Hospital Episode Statistics, the Clinical Practice Research Datalink and the Office for National Statistics mortality data linked to Hospital Episode Statistics. Interviews were conducted with women. An online vignette survey was conducted with members of the Royal College of Obstetricians and Gynaecologists.

Main outcome measures: The main outcome measures were the rates of referral from primary to secondary care and surgery after referral, the rates of stress urinary incontinence surgery by geographical area, the risk of mid-urethral mesh tape removal and reoperation after mid-urethral mesh tape insertion.

Results: Almost half (45.8%) of women with a new urinary incontinence diagnosis in primary care were referred to a urinary incontinence specialist: 59.5% of these referrals were within 30 days of diagnosis. In total, 14.2% of women referred to a specialist underwent a urinary incontinence procedure (94.5% of women underwent a stress urinary incontinence procedure and 5.5% underwent an urgency urinary incontinence procedure) during a follow-up period of up to 10 years. Not all women were equally likely to be referred or receive surgery. Both referral and surgery were less likely for older women,

those who were obese and those from minority ethnic backgrounds. The stress urinary incontinence surgery rate was 40 procedures per 100,000 women per year, with substantial geographical variation. Among women undergoing mid-urethral mesh tape insertion for stress urinary incontinence, the 9-year mesh tape removal rate was 3.3%. Women's decision-making about urinary incontinence surgery centred on perceptions of their urinary incontinence severity and the seriousness/risk of surgery. Women judged urinary incontinence severity in relation to their daily lives and other women's experiences, rather than frequency or quantity of leakage, as is often recorded and used by clinicians. Five groups of UK gynaecologists could be distinguished who differed mainly in their average inclination to recommend surgery to hypothetical urinary incontinence patients. The gynaecologists' recommendations were also influenced by urinary incontinence subtype and the patient's history of previous surgery.

Limitations: The primary and secondary care data lacked information on the severity of urinary incontinence.

Conclusions: There was substantial variation in rates of referrals, surgery, and mesh tape removals, both geographically and between women of different ages and women from different ethnic backgrounds. The variation persisted after adjustment for factors that were likely to affect women's preferences. Growing safety concerns over mid-urethral mesh tape surgery for stress urinary incontinence during the period from which the data are drawn are likely to have introduced more uncertainty to women's and clinicians' treatment decision-making.

Future work: Future work should capture outcomes relevant to women, including ongoing urinary incontinence and pain that is reported by women themselves, both before and after mesh and non-mesh procedures, as well as following conservative treatments. Future research should examine long-term patient-reported outcomes of treatment, including for women who do not seek further health care or surgery, and the extent to which urinary incontinence severity explains observed variation in referrals and surgery.

Funding: This project was funded by the National Institute for Health Research (NIHR) Health Services and Delivery Research programme and will be published in full in *Health Services and Delivery Research*; Vol. 9, No. 7. See the NIHR Journals Library website for further project information.

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AIC	Akaike information criterion	LSOA	lower-layer super output area
aOR	adjusted odds ratio	MUI	mixed urinary incontinence
APC	admitted patient care	MUT	mid-urethral mesh tape
ASA	American Society of Anesthesiologists	NICE	National Institute for Health and Care Excellence
BAME	black, Asian and minority ethnic	OPCS-4	Office of Population, Censuses and Surveys Classification of Interventions and Procedures, version 4
BIC	Bayesian information criterion		
BMI	body mass index		
BSUG	British Society of Urogynaecology	POP	pelvic organ prolapse
		PPI	patient and public involvement
CCG	Clinical Commissioning Group	RCOG	Royal College of Obstetricians and Gynaecologists
CI	confidence interval		
COPD	chronic obstructive pulmonary disease	RCS	Royal College of Surgeons
		SD	standard deviation
CPRD	Clinical Practice Research Datalink	sdHR	subdistribution hazard ratio
		STP	Sustainability and Transformation Partnership
CVD	cardiovascular disease		
GP	general practitioner	SUI	stress urinary incontinence
HES	Hospital Episode Statistics	T2DM	type 2 diabetes mellitus
ICD-10	*International Classification of Diseases,* Tenth Revision	UI	urinary incontinence
		UTI	urinary tract infection
IMD	Index of Multiple Deprivation	UTS	up to standard
IQR	interquartile range	UUI	urgency urinary incontinence
IRR	incidence rate ratio	WP	work package
LSHTM	London School of Hygiene & Tropical Medicine		

Plain English summary

Urinary incontinence is the involuntary loss of urine. It affects between 25% and 45% of adult women, and for many has a negative impact on their quality of life. Stress urinary incontinence is leaking of urine when coughing, laughing or sneezing, and urgency urinary incontinence is a sudden strong urge to urinate that is hard to stop. Despite major national initiatives in the last decade, the quality and availability of urinary incontinence services remain variable.

Using existing NHS databases, interviews with women who have urinary incontinence, and a survey of gynaecologists, we investigated which factors determine whether or not urinary incontinence services are used.

We found that women assess the severity of their urinary incontinence based on more factors than just those considered by doctors. Women's understanding of urinary incontinence and their decisions about surgery are influenced by their daily lives and their own and other women's experiences.

The results of the study suggest that women were less likely to be referred to a urinary incontinence specialist or to receive surgery if they were older, obese or from a minority ethnic background.

We found considerable differences between particular areas of England in how likely women were to be referred to a specialist or receive surgery. This mirrors findings from our survey that there were large differences between gynaecologists in how likely they were to recommend surgery to women.

During the final year of the study, in response to safety concerns about the most common surgical treatment for stress urinary incontinence in women ('mesh surgery'), NHS England suspended the use of these treatments. We conducted supplementary analyses using existing NHS data to provide evidence on the longer-term risks of these 'mesh' treatments. We found that about 1 in 30 women who received mesh had it removed within 9 years.

Future research could focus on how better assessment of a woman's history of urinary incontinence and quality of life, as well as early provision of lifestyle interventions and pelvic floor muscle training in primary care, could reduce the number of women referred to secondary care and improve their urinary incontinence symptoms. Another research priority is to identify the types of problems that women experience after surgery, ideally using information reported by women themselves.

Scientific summary

Background

Urinary incontinence is the involuntary loss of urine and includes subtypes with different underlying aetiologies. Stress urinary incontinence is defined as the loss of urine on physical exertion, sneezing or coughing. Other subtypes of urinary incontinence are associated with urgency to urinate (i.e. urgency urinary incontinence) or symptoms such as increased frequency and nocturia (i.e. overactive bladder). Between 25% and 45% of adult women are affected by urinary incontinence, which has a negative impact on their quality of life. Over the last two decades there has been an aspiration to shift services for women with urinary incontinence from secondary to primary care. At the same time, it is unclear whether or not the current level of provision of surgical services for urinary incontinence is appropriate.

This project started in June 2016, just after discussions began about problems that some women had experienced after insertion of a mid-urethral mesh tape for stress urinary incontinence, including pain, dyspareunia, persistent urinary incontinence and mesh exposure or erosion. During the first 2 years of the project, mid-urethral mesh tape surgery, then the most common surgical treatment for stress urinary incontinence, continued in the English NHS, but the need for a multidisciplinary approach and better information for women considering whether or not to undergo stress urinary incontinence surgery was highlighted. In response to this, an additional objective was added to this project, that is, to explore long-term removal and reoperation rates after mid-urethral mesh tape insertion for stress urinary incontinence. The routine use of mid-urethral mesh tape surgery as a treatment for stress urinary incontinence was then 'paused' by NHS England in July 2018, following recommendations by an independent review [*The Independent Medicines and Medical Devices Safety Review*. 2018. URL: www.immdsreview.org.uk (accessed 19 May 2020)] that had engaged with patients and patient groups about long-term complications. For some patients, mid-urethral mesh tape procedures may remain the only viable treatment option, but the review recommends that they should be used only in selected patients who fully understand the risks and have given informed consent.

Aim and objectives

The aim of the project was to inform and improve the delivery and organisation of surgical services for women with urinary incontinence. The project assessed the availability and use of surgical services for urinary incontinence across England and identified factors that explained the observed variation in use of surgery (including the impact of patients' experiences and expectations, clinicians' judgement, and organisational and contextual factors).

The project analysed existing primary and secondary care administrative data sets and additional data collected from women with urinary incontinence (in interviews) and from clinicians (using an online case vignette survey).

The four objectives of the project were captured in five work packages:

- Objective 1: methods development –

  - to develop a coding framework for urinary incontinence diagnoses and treatments allowing for divergent coding practices among providers (work package 1).

- Objective 2: availability and delivery of services –

  - to assess determinants of geographical variation in the rate of surgery for urinary incontinence (work package 2).

- Objective 3: understanding patients' experiences and expectations –

  - to collect women's own accounts of the impact of urinary incontinence on their lives, and their experiences and expectations of surgical and non-surgical treatments and outcomes, including the many different values that women draw on (work package 3).

- Objective 4: understanding the determinants of referral and surgical treatment –

  - to identify determinants of outpatient referrals and surgery, using a linked primary–secondary care data set (work package 4).
  - to explore the relative importance of specific patient characteristics for clinicians in their decisions about recommending surgery, using case vignettes (work package 5).

Given the changing context of stress urinary incontinence surgery, which eventually led to a 'pause' in mid-urethral mesh tape surgery in the English NHS, additional research was conducted on long-term rates of mesh tape removal and reoperation (work package 6).

Methods

To address work packages 1, 2, 4 and 6, existing primary and secondary care administrative data sets were used. The Hospital Episode Statistics (work packages 1, 2 and 6) database contains records of all inpatient episodes of care in English NHS hospitals (secondary care), with unique patient identifiers allowing the study of longitudinal patterns of care. Diagnostic information is captured using the *International Classification of Diseases*, Tenth Revision, codes and procedures using the Office of Population, Censuses and Surveys Classification of Interventions and Procedures, version 4, codes. The Clinical Practice Research Datalink (work packages 1 and 4) contains anonymised patient data from > 600 general practices, covering a representative sample of 9% of the UK population (primary care). Diagnostic and treatment information are captured using Read codes. A subset of the Clinical Practice Research Datalink data set has been linked to Hospital Episode Statistics; this linked data set was also used in work package 4.

The consistency, completeness and accuracy of diagnostic and procedure codes relevant for urinary incontinence were assessed in Hospital Episode Statistics and the Clinical Practice Research Datalink. A coding framework was developed allowing for divergent coding practices based on a stepwise 'forward' and 'backward' coding strategy (work package 1).

Multilevel poisson regression models were used to analyse Hospital Episode Statistics data to produce estimates of stress urinary incontinence surgery rates in the 209 Clinical Commissioning Groups and 44 Sustainability and Transformation Partnership areas in England, adjusted for age, socioeconomic deprivation, ethnicity and long-term illness (work package 2).

Semistructured interviews were carried out with women who had urinary incontinence (who were aged > 18 years with no previous urological surgery). The women were purposively sampled from four English urogynaecology outpatient clinics. Transcripts were analysed using a constant comparative method (work package 3).

Multivariable logistic regression and competing risk survival analysis were used to identify factors associated with referral to secondary care (using Clinical Practice Research Datalink data on their own) and surgical treatment (using Clinical Practice Research Datalink data linked to Hospital Episode Statistics) (work package 4).

An online survey of 18 clinical case vignettes (hypothetical 'paper' patients) was sent to gynaecologists in the UK with a special interest in urogynaecology. The vignettes described patients based on seven clinical characteristics. Gynaecologists indicated how likely they would be to recommend surgery on a five-point Likert scale. Latent class analysis was used to distinguish groups of gynaecologists according to their recommendations (work package 5).

A cohort study using Hospital Episode Statistics data identified all women (aged > 18 years) who had a first-ever mid-urethral mesh tape insertion for stress urinary incontinence between 2006 and 2015. Competing risk survival analysis was used to assess the risk of mid-urethral mesh tape removal (partial/total), reoperation for stress urinary incontinence and any reoperation (i.e. mid-urethral mesh tape removal or reoperation for stress urinary incontinence) (work package 6).

Results

Work package 1
The coding frameworks developed in this work package were used to define cohorts, procedures and outcomes in work packages 2, 4 and 6.

Work package 2
The study of the determinants of geographical variation in the rate of stress urinary incontinence surgery found 27,997 inpatient episodes with a first procedure for stress urinary incontinence between April 2013 and March 2016. The rate of stress urinary incontinence surgery was 40 procedures per 100,000 women per year. There was substantial geographical variation in the surgery rate. Adjusted rates varied from 20 to 106 procedures per 100,000 women per year between Clinical Commissioning Groups and from 24 to 69 procedures per 100,000 women per year between Sustainability and Transformation Partnerships. Annual stress urinary incontinence surgery rates declined from 52 per 100,000 women in 2013 to 36 per 100,000 women in 2015, but geographical variation remained stable. This evidence suggests that women with urinary incontinence in some areas are more likely to be treated surgically than women in other areas.

Work package 3
Interviews with 28 women demonstrated that women's decision-making centred on perceptions of the severity of their urinary incontinence and the seriousness, or risk, of surgery. Women assessed urinary incontinence severity according to their individual circumstances, rather than criteria such as frequency or quantity of leakage, moving the concept of 'severity' beyond commonly used medical definitions to what is important to them. Decision-making around urinary incontinence surgery appeared to be based on multiple criteria, which often changed in priority over time; decisions were rarely made conclusively. Women made sense of evidence in the light of their own experiences and those of others.

Work package 4
The study of the determinants of referral for any type of urinary incontinence identified 104,466 women who were newly diagnosed with urinary incontinence in primary care in the UK between April 2004 and March 2014 (using Clinical Practice Research Datalink data). Almost half (45.8%) of these women were referred to secondary care within 9 years after their visit and 59.5% of those women were referred within 30 days. The 30-day referral rates were lower for women who were older, from a minority ethnic background, underweight (i.e. with a body mass index of $< 20 \, \text{kg/m}^2$), or severely obese (i.e. with a body mass index of $\geq 40 \, \text{kg/m}^2$). The study of the determinants of surgery for urinary incontinence identified 30,312 women who had been referred for urinary incontinence

(using Clinical Practice Research Datalink–mid-urethral mesh tape-linked data). In total, 7.3% of women underwent a urinary incontinence procedure within 1 year of referral, 15.5% within 5 years and 18.1% within 9 years. As with rate of referrals, the surgery rate among women referred was lower for women who were older, from a minority ethnic background, underweight or severely obese.

Work package 5

The analysis of the responses to case vignettes of 245 gynaecologists with a special interest in urogynaecology showed that the type of urinary incontinence (i.e. stress urinary incontinence, stress-predominant or mixed urinary incontinence) was the most important factor in decisions to recommend surgical treatment, followed by previous stress urinary incontinence surgery (i.e. none, bladder neck injection, mid-urethral mesh tape). Five groups of gynaecologists whose practice style differed mainly with respect to their mean recommendation score could be distinguished [mean recommendation scores ranging from 1.25 to 4.04 on a scale with a minimum of 1 ('certainly yes') and a maximum of 5 ('certainly not')].

Work package 6

The cohort study of women with a first mid-urethral mesh tape insertion included 60,194 women with a retropubic insertion and 34,683 with a transobturator insertion. The 9-year removal rate was 3.6% after a retropubic insertion and 2.7% after a transobturator insertion. The 9-year rate of any reoperation, including mesh tape removal, was 4.1% after a retropubic insertion and 5.3% after a transobturator insertion.

Conclusions

First, there was substantial geographical variation in the use of surgery for stress urinary incontinence in the NHS in England, suggesting that women in some areas are more likely to have surgical treatment than women in other areas. The variation is likely to reflect differences in how national guidelines were being interpreted before the 'pause' in mid-urethral mesh tape surgery in the NHS. This geographical variation is mirrored in the finding that there are groups of gynaecologists with different practice styles; mainly their average inclination was to recommend surgery, which seems to correspond to uncertainty about safety and effectiveness of stress urinary incontinence surgery.

Second, the rate of referral from primary to secondary care of women diagnosed with urinary incontinence was high. About one-quarter of women were referred within 30 days of the first primary care record of a urinary incontinence diagnosis. Approximately one in six referred women underwent urinary incontinence surgery within 5 years of referral.

Third, many women with urinary incontinence were referred to secondary care soon after they had discussed their urinary incontinence problems with their general practitioner for the first time, which demonstrates that the involvement of primary care in providing treatment for women with urinary incontinence is limited. As a consequence, for many women, the management of their urinary incontinence is co-ordinated in a secondary care setting.

Fourth, women who had been referred to secondary care and were making decisions about whether or not to have surgery did not assess the severity of their urinary incontinence only by the quantity and frequency of leakage; they considered a broader set of criteria, informed by the impact their urinary incontinence had on their daily lives.

Fifth, within 9 years of a mid-urethral mesh tape insertion, 3.3% of women had undergone a removal procedure, 4.5% had undergone a reoperation for stress urinary incontinence and 6.9% had undergone any reoperation (mesh tape removal and/or reoperation for stress urinary incontinence). Removal rates were lower following transobturator insertions than following retropubic insertions. These findings

may guide women and surgeons when making decisions about surgical treatment of stress urinary incontinence. However, this study reported only on women who underwent a surgical intervention after mid-urethral mesh tape insertion and did not capture problems that did not lead to surgery.

In summary, the findings suggest that there are potential deficiencies along the whole care pathway for women with urinary incontinence:

- The substantial variation in the use of surgery for urinary incontinence, and in the inclination of gynaecologists to recommend surgical treatment, suggests that there is uncertainty about indications for surgical treatment.
- The high referral rate soon after urinary incontinence is first recorded in primary care indicates that the contribution of primary care in the care of women with urinary incontinence is relatively limited.
- Women's decisions about whether or not to have surgery are based on their personal circumstances and can change over time under the influence of a wide range of factors, whereas clinicians may often focus on more objective measures of severity, such as the quantity and frequency of leakage, which may not reflect women's priorities.

Recommendations for future research

Our research highlights a number of unanswered questions.

First, a national registry of mesh and non-mesh urinary incontinence procedures is being established [National Institute for Health and Care Excellence (NICE). *Collecting Data on Surgery and Surgical Complications*. London: NICE; 2019. URL: www.nice.org.uk/guidance/ng123/chapter/Recommendations#collecting-data-on-surgery-and-surgical-complications (accessed 19 May 2020)]. However, it is important that this registry collects information from women that reflects their concerns, both before and after treatment. This will allow a comparison of all available treatment options using measures that are meaningful to women. These data would also allow future research to explore whether or not patient-reported urinary incontinence severity explains observed variation in referrals and surgery.

Second, research on outcomes of mid-urethral mesh tape surgery has been limited by the procedure codes available; those available for this research (i.e. Office of Population, Censuses and Surveys Classification of Interventions and Procedures, version 4.7) do not distinguish between partial and total mesh tape removals after transobturator mid-urethral mesh tape insertions. Future research using Office of Population, Censuses and Surveys Classification of Interventions and Procedures, version 4.8, procedure codes (which have been in use since August 2017) can compare total and partial removal rates between transobturator and retropubic mid-urethral mesh tape insertions.

Third, the observed geographic variation in stress urinary incontinence surgery rates and in gynaecologists' average inclination to recommend surgery, need further exploration. A first step will be to understand for which patients the benefits of surgical treatment outweigh the risks. The national registry described above may be able to provide parameters for modelling quality-adjusted life-years following the available treatment options for women with specific clinical profiles, if the registry collects patient-reported data on urinary incontinence severity and outcomes.

Fourth, our research demonstrates that a relatively large proportion of women were referred to secondary care soon after their urinary incontinence was first recorded. Future research should focus on how better assessment (e.g. history taking, symptom scoring, quality-of-life assessment and physical examination), as well as conservative management (e.g. lifestyle interventions and pelvic floor muscle training) in primary care could reduce the number of women referred to secondary care without negatively affecting outcomes.

Fifth, the National Institute for Health and Care Excellence has recently produced a patient decision aid for women considering stress urinary incontinence surgery [National Institute for Health and Care Excellence (NICE). *Urinary Incontinence and Pelvic Organ Prolapse in Women: Management (NG123)*. London: NICE; 2019. https://doi.org/10.1111/bju.14763]. This patient decision aid provides descriptions of the surgical options, information about short- and long-term outcomes, graphical representations of risk and a chart to help women explore their feelings about the options. However, our interviews with women demonstrated that their decisions are informed not only by quantitative information about possible outcomes but also by their individual circumstances. Future research should explore how decision aids can best support women, acknowledging that decisions are rarely conclusive and that women's priorities can change over time.

Funding

Chapter 1 Background

Urinary incontinence (UI), the involuntary loss of urine, affects between 25% and 45% of women at some point in their lives,[1] which has a substantial impact on their quality of life.[2–5] Prevalence increases with age, affecting an estimated 17% of women aged > 20 years and 38% of women aged > 60 years.[6–8] However, despite this high prevalence and the impact on quality of life, there is evidence that UI is underdiagnosed and undertreated. Only 25% of women affected by UI seek care and, of those, fewer than half receive treatment, suggesting that there is a high unmet need for care.[9–11] If left untreated, UI is associated with falls and fractures, depression, sleep disturbance and urinary tract infections (UTIs).[12–14] Unplanned admissions for UTIs cost the NHS > £400M per year.[15]

Types of urinary incontinence

Female urinary incontinence can be classified into subtypes. Stress urinary incontinence (SUI) is the involuntary loss of urine with increases in abdominal pressure, such as when exercising or coughing. Urgency urinary incontinence (UUI) is characterised by a sudden and compelling desire to pass urine that is difficult to defer. Overactive bladder syndrome, which can include UUI, is usually accompanied by frequency and nocturia. Many women experience coexisting stress and urgency UI symptoms, a subtype often called mixed urinary incontinence (MUI). However, women do not require extensive preliminary evaluation of the subtype of urinary incontinence before beginning initial non-invasive treatments as symptoms may commence without clear differentiation between the two most common subtypes: stress and urgency UI. Stress UI appears to be the most common subtype of UI. Epidemiological evidence suggests that about 50% of women with UI indicate that they have solely SUI symptoms and about 40% indicate symptoms suggesting that they have MUI.[16,17]

Treatment

Non-invasive treatment
General practices are the gatekeepers of health care in the English NHS, acting as the first point of contact for non-emergency health issues, which may then be managed in primary care and/or referred to secondary care. In the UK, UI is initially managed at the primary care level.[11] Lifestyle changes may be recommended in primary care when women with UI also smoke cigarettes, report excessive fluid or caffeine consumption, or are overweight or obese.[18] Referral to a urinary incontinence specialist is available when non-surgical treatments do not improve symptoms or are not acceptable to women. Urgent referral (i.e. within 2 weeks) is recommended if there are concerns about conditions, such as cancer.[19]

Surgical treatment
For women whose UI symptoms are predominantly SUI, the standard surgical treatments have been colposuspension (a major abdominal surgery) or a sling, with autologous fascia, or synthetic mesh. Women with SUI can also undergo urethral bulking injections to increase outflow resistance. Mid-urethral mesh tapes (MUTs) or slings were introduced in 1998 as a minimally invasive surgical treatment for female SUI.[2] The use of MUTs or slings rose precipitously in the decade following their introduction, with a corresponding decline in the use of colposuspension.[20] Their use has since rapidly declined with a change in patient choice and surgical practice that is likely to reflect growing publicity of concerns about longer-term complications after MUT procedures.[21–26] For women with UI symptoms that are predominantly UUI, invasive but predominantly outpatient/day case procedures include percutaneous tibial nerve stimulation (electrical stimulation via an acupuncture needle weekly for 3 months and monthly thereafter), OnabotulinumtoxinA (Botox, Allergan) injections and sacral neuromodulation (with an implanted electrode placed along the third sacral nerve root).

The project began in June 2016, immediately after discussions began about problems that some women experience after MUT insertion, such as pain, dyspareunia, persistent UI and mesh exposure or erosion. During the first 2 years of the project, the use of MUTs, then the most common surgical treatment for SUI, continued in the NHS England; however, the need for a multidisciplinary approach and better information for women considering surgery was highlighted. In response to this, we added an additional work package (WP) to the study to explore long-term removal and reoperation rates after MUT insertion. The routine use of MUTs for SUI was then 'paused' by NHS England in July 2018 following recommendations by the Independent Medicines and Medical Devices Safety Review[27] that had engaged with patients and patient groups about complications.[28]

In the UK, despite major national initiatives in the last decade, the quality and availability of continence services remains poor, variable and inequitable. The burden on secondary care resources is increasing because of demographic changes and higher referral rates. For women with SUI, rates of surgery have increased in the decade following the introduction of new procedures (i.e. MUTs) in 1998, but there is evidence of inequity in access and service provision, with concerns of underprovision in vulnerable groups. For example, although it has been shown that the minimally invasive procedures are as safe and effective in older women[29] and can often be performed as a day-case procedure, these procedures are less frequently used in older patients than in younger patients.[30,31] It is likely that there is also suboptimal care for women from minority ethnic and different socioeconomic backgrounds.[32,33]

There is considerable uncertainty about whether or not the level of provision for surgical services for women with SUI is uniform across regions and providers in England. Variations in care provision may also depend on the availability of UI services. A recent survey of the availability of specialist UI services has demonstrated that there is variable distribution of urogynaecologists with subspecialty training, dedicated teams to manage repeat surgery and availability of various surgical care treatments across the UK.[34] Information on variation in practice is important for examining relationships between policy decisions and clinical decisions and raises questions concerning the efficiency and effectiveness of health care.[35]

There are also unanswered questions about assessment and treatment of women before referral, the duplication of treatment in each care environment and the appropriate delivery of secondary care interventions.[36] More than 50% of patients referred to secondary care are reported not to have received any treatment in primary care.[34]

Patient perspectives

There is limited research on which treatments women with UI want themselves and which factors have an impact on their preferences. Moreover, to the best of our knowledge, there is no research to date on how general practitioners (GPs) decide when women need to be referred and how clinicians decide whether or not surgery is helpful. Although UI can have a substantial impact on the quality of life, there is evidence that many women with UI under-report or delay seeking treatment for several years after the problem has become bothersome,[37] leading to high levels of unmet need for incontinence services.[38] For example, in the UK, only about one-quarter of women consult a doctor about their symptoms.[39] Delayed health-seeking behaviour and under-reporting might be caused by the belief that these symptoms are normal after childbirth or in old age and by a lack of awareness of available treatment options.[40,41]

Clinical coding

It is recognised that UI and related procedures are poorly coded in electronic clinical records. Therefore, before existing administrative health-care databases can be used to study service provision in primary and secondary care, a detailed coding framework needs to be developed to overcome these deficiencies. This methodological work not only is an essential preparation for data analysis, but will also guide recommendations on how diagnoses and procedures related to UI can be better recorded in electronic databases in the future.

The structure of this report is as follows:

- In *Chapter 2*, we outline the project's aim and objectives and the corresponding six WPs.
- In *Chapter 3*, we describe the data and methods used in each WP.
- In *Chapter 4*, we summarise geographic variation in rates of surgery for SUI.
- In *Chapter 5*, we describe the determinants of referral and surgery for UI.
- In *Chapter 6*, we summarise long-term rates of mesh tape removal after MUT surgery for SUI.
- In *Chapter 7*, we explore the impact of UI on women's lives and when surgery is perceived to be a treatment option.
- In *Chapter 8*, we explore gynaecologists' approaches to recommending surgical treatment for women with UI.
- In *Chapter 9*, we bring together the findings from each WP in terms of how they relate to the scientific literature and discuss their implications for future research.

Chapter 2 Aim and objectives

Overall aims

The aim of the project was to improve the delivery and organisation of surgical services for women with UI in England. We assessed the availability and use of surgical services for UI across NHS England and identified factors that explain observed variation in use, including the impact of administrative data issues, patients' experiences and expectations, clinicians' judgement, and organisational and contextual factors. During the first 2 years of the project, an additional objective was added to this project (i.e. WP 6) to explore the long-term removal and reoperation rates after MUT insertion for SUI.

Objectives

The objectives were captured in five WPs. We analysed existing primary and secondary care data sets and collected data from patients (using in-depth interviews) and clinicians (using case vignettes or 'paper patients').

- Objective 1: methods development –

  o assesses the consistency, completeness and accuracy of diagnostic and procedure coding for UI in existing electronic data sets (WP 1)
  o develops a coding framework for UI allowing for divergent coding practices among providers (WP 1).

- Objective 2: availability and delivery of services –

  o assesses variation between NHS Clinical Commissioning Groups (CCGs), Local Area Teams and Clinical Senates (or other relevant regional units) in rate of surgery for UI (WP 2)
  o examines the impact of supply-side factors (e.g. primary care characteristics and availability and delivery of secondary care services) on local surgical rates (WP 2).

- Objective 3: understanding patients' experiences and expectations –

  o explores the impact of UI on women's lives and if and when it is perceived to be a medical problem (WP 3)
  o collects women's own accounts of experiences and expectations of surgical and non-surgical treatments and outcomes, including the many different values that women draw on (WP 3).

- Objective 4: understanding the determinants of referral and surgical treatment –

  o identifies determinants of outpatient referrals and surgery, using a linked primary–secondary care data set (WP 4)
  o explores the relative importance of specific patient characteristics for clinicians in their treatment decisions, using case vignettes (WP 5).

An additional objective was to explore the long-term removal and reoperation rates after MUT insertion for SUI (WP 6).

Within most WPs, further work was carried out to evaluate how findings vary according to age, economic deprivation, ethnicity and type of procedure.

Chapter 3 Overview of methods

A mixed-methods study was undertaken to assess the availability and use of surgical services for UI across England and to identify factors that could explain observed variation in practice, including the impact caused by data issues, patients' experiences and expectations, clinicians' judgement, and organisational and contextual factors.

Data sources

The Hospital Episode Statistics (HES) database contains information on each episode of admitted patient care (APC) in English NHS hospital trusts. These data are extracted from local patient administration systems as part of the Commissioning Data Set. This data set is submitted to NHS Digital for processing and made available for audit and research as the HES data set.[42] Each record contains data on patient demographics (e.g. age, sex, ethnicity and area of residence), the episode of care (e.g. hospital name, date of admission and discharge) and clinical information. Diagnoses are recorded using the *International Classification of Diseases*, Tenth Revision (ICD-10),[43] and procedures using the Office of Population, Censuses and Surveys Classification of Interventions and Procedures, version 4 (OPCS-4).[44] Each patient is assigned a unique identifier, making it possible to study longitudinal patterns of care, including tracking any future admission or procedure in the same or a different NHS hospital.

The Clinical Practice Research Datalink (CPRD) (formerly the General Practice Research Database) collates routinely collected anonymised patient data from general practices that have agreed at a practice level to provide data. All patients registered with participating practices are included in the data set, unless they have individually requested to opt out of data sharing at their GP practice. CPRD uses Read codes (used to record symptoms, diagnoses, processes of care) and *British National Formulary* codes to record information on prescriptions. More than 600 GP practices contribute data to CPRD, covering 9% of the population. CPRD linkage data include patients from 411 practices, covering approximately 75% of contributing CPRD practices in England.[45] Compared with the 2011 UK census, CPRD patients are broadly representative of the UK population in terms of age, sex and ethnicity, and comparable for body mass index (BMI) distribution to the Health Survey for England.[46] CPRD is deemed 'up to standard' (UTS) for research purposes and widely used in epidemiological and health services research. CPRD data have been linked to HES APC and HES Outpatient data by the trusted third party, NHS Digital. Three distinct administrative health-care data sets were used in this project: HES APC, CPRD and CPRD-linked to HES APC and HES Outpatient. We indicate throughout this report which data were used by each WP.

In addition to using the administrative health-care databases HES and CPRD, we conducted primary data collection. This data collection comprised interviews with women who had been referred to secondary care and were considering surgical treatment, and an online survey of gynaecologists using clinical case vignettes (i.e. hypothetical patients). The primary data collection is described in detail in the sections below for WPs 3 and 5.

Methods for work package 1

Work package 1 aimed to assess the consistency, completeness and accuracy of diagnostic and procedure coding for UI in the HES and the CPRD databases, and to develop a coding framework for UI allowing for divergent coding practices among providers.

In the HES database, we first used a 'forward and backward' searching strategy. The forward searching step began with a list of ICD-10 and OPCS-4 codes that were compiled iteratively by the clinical and

methodological members of the research team. The backwards strategy then explored whether or not records found on the basis of the prespecified ICD-10 codes contain additional relevant OPCS-4 codes that were not prespecified. A similar exercise considers additional ICD-10 codes in records found on the basis of the prespecified OPCS-4 codes. Second, we assessed the frequency with which all of these potentially relevant codes have been used and explore the consistency of diagnosis and procedure codes within the records of individual patients. Third, the variation in consistency of diagnosis and procedure codes among providers was explored to identify providers that have divergent coding practices. We have previously demonstrated that this strategy for using HES data has the potential to produce a coding framework creating groups of patients who are homogeneous with respect to diagnosis, prognosis and treatment.[47]

In the CPRD database, we started with a previously published code list.[48] We tested this existing code list by evaluating the consistency between diagnostic and treatment codes and the temporal consistency of coding within records of the same patient. Next, additional relevant keywords, synonyms and possible codes were identified by searching additional published literature and code list repositories. Finally, the clinicians on the research team manually reviewed the code list (individually and collectively). Recommendations made by each clinician were collated and collectively discussed with the aim of reaching a consensus on the codes that would be regarded as UI diagnosis or treatment codes. The coding work conducted for WP 1 fed directly into the analyses conducted for WPs 2, 4 and 6.

Methods for work package 2

Work package 2 aimed to assess variation in rates of surgery for SUI using HES APC (inpatient) data. We examined variation in rates of SUI surgery between NHS CCGs and other relevant regional units, and the impact of supply-side factors (e.g. primary care characteristics and availability and organisation of secondary care services) on local rates. WP 2 focused on variation in surgery for SUI specifically because SUI symptoms are the most common subtype of UI symptoms; 50% of women with UI indicate solely SUI symptoms and approximately 40% indicate MUI symptoms, where SUI and UUI symptoms coexist.[16,17]

The cohort comprised women aged $\geq$ 20 years who had received surgical treatment for SUI between 1 April 2013 and 31 March 2016 and had a SUI diagnosis recorded at the time of the procedure. SUI surgery was defined using UK OPCS-4 codes (*Table 1*) based on coding work conducted for WP 1.[44] SUI diagnosis was defined using the ICD-10 code N39.3 Stress urinary incontinence.[43]

The outcome measure was rate of surgery for SUI per 100,000 women per year at two geographic levels: 209 CCGs and 44 Sustainability and Transformation Partnership (STP) areas. CCGs are statutory NHS bodies responsible for the planning and commissioning of health care services in a local area (with an average population size of about 104,000 adult females). CCG areas are grouped into 44 STP areas (with an average population size of about 493,000 adult females), which were set up to co-ordinate improvements in the delivery of NHS services.[49] Reference denominator populations were derived by aggregating the 2011 census population counts for women aged $\geq$ 20 years in lower-layer super output areas (LSOAs) that are within the respective boundaries of the CCG and STP areas. There are 32,844 LSOAs (postcode-based geographic units) in England (with an average population of approximately 1700 people).[50] Women may have had repeat procedures in the study period, but only the first procedure was counted in calculating the surgery rate.

Sociodemographic factors may explain variations in the rates of surgery for SUI. We adjusted for age, socioeconomic deprivation, ethnicity and limiting long-term illness in our regression models. We handled age as a patient-level characteristic grouped into five categories (i.e. 20–39, 40–49, 50–59, 60–69 and $\geq$ 70 years). Socioeconomic deprivation, ethnicity and limiting long-term illness were

TABLE 1 The OPCS-4 codes used to define SUI surgery

OPSC-4	Description
Mid-urethral mesh tape insertions	
M53.3	Introduction of tension-free vaginal tape
M53.6	Introduction of transobturator tape
Injection of urethral bulking agents	
M56.3	Endoscopic injection of inert substance into the outlet of the female bladder
Other abdominal/vaginal operations	
M51.1	Abdominoperineal suspension of the urethra
M51.2	Endoscopic suspension of the neck of the bladder
M51.8	Other specified combined abdominal and vaginal operations to support the outlet of the female bladder
M51.9	Unspecified combined abdominal and vaginal operations to support the outlet of the female bladder
M52.1	Suprapubic sling operation
M52.2	Retropubic suspension of the neck of the bladder
M52.3	Colposuspension of the neck of the bladder
M52.8	Other specified abdominal operations to support the outlet of the female bladder
M52.9	Unspecified abdominal operations to support the outlet of the female bladder
M53.1	Vaginal buttressing of the urethra
M53.8	Other specified vaginal operations to support the outlet of the female bladder
M53.9	Unspecified vaginal operations to support the outlet of the female bladder
M55.2	Implantation of artificial urinary sphincter into the outlet of the female bladder
M55.6	Insertion of a retropubic device for female SUI NEC
M55.8	Other specified – other open operations on the outlet of the female bladder
M55.9	Unspecified other – open operations on the outlet of the female bladder
M58.8	Other specified – other operations on the outlet of the female bladder
M58.9	Unspecified other operations on the outlet of the female bladder

NEC, not elsewhere classified.

CCG-level characteristics derived from 2011 census data.[50] For socioeconomic deprivation, we used the averages of the national ranking of the Index of Multiple Deprivation (IMD) of LSOAs within each CCG, and grouped the CCG averages into national quintiles ranging from 1 (most deprived CCGs) to 5 (least deprived CCGs).[51] For ethnicity, we used the percentage of the population reporting a black, Asian and minority ethnic (BAME) background, and for long-term illness we used the percentage of the population who reported that their day-to-day activities were limited because of a health problem or disability that had lasted, or was expected to last, at least 12 months. For each CCG, we took the averages of these percentages for LSOAs and grouped these CCG averages into national quintiles (range: 1 corresponds to CCGs with average percentages in the lowest quintile to 5 the highest quintile).

We calculated the number and the unadjusted and adjusted rates per 100,000 women per year of SUI procedures overall, and according to patient and regional characteristics. Incidence rate ratios (IRRs) were used to represent associations between the procedure rate and regional characteristics. Multilevel Poisson regression models were used to produce empirical Bayes' estimates of the unadjusted and adjusted incidence rates for each CCG and STP area. In addition, risk-adjusted regression models were

used to assess geographic variation in the rates of surgery by year. The empirical Bayes' estimator produces more precise results by 'pulling' estimates for small outlier regions towards the mean.[52] For each geographic area level (CCG/STP), we illustrated the amount of variation in adjusted surgery rates using maps and range plots with 99.8% credibility intervals. CCGs and STPs were marked as 'outliers' where the national average rate of surgery was not within the 99.8% credibility interval of their rates. All statistical analyses were performed using Stata, version 15 (StataCorp LP, College Station, TX, USA).

Methods for work package 3

Work package 3 aimed to explore the impact of UI on women's lives and if and when surgery is perceived to be a treatment option, collecting women's own accounts of expectations of surgical and non-surgical treatments, experiences and outcomes through semistructured interviews. WP 3 used primary data collected from interviews with women. All women considering surgery for their UI could participate in the interviews. We did not restrict the interviews to women with a specific subtype of UI (e.g. SUI or UUI).

A broad narrative review of the patient experience social sciences literature was conducted to map out the issues female UI raises that are in common with other conditions, including those related to shame; embarrassment and stigma; gender, identity and sexuality; social relationships, work and mobility; experiences of care; and medicalisation of the female body. These higher-order topics informed the development of the semistructured interview topic guide and generated the analytical themes that were later used to complement the more descriptive codes derived from the content analysis of the interviews. The topic guide (see *Appendix 6*) was also informed by discussion with the research team, especially drawing on the input from the public and patient representatives. The topic guide was designed so that interviews would be sufficiently open and flexible to ensure that participants are able to talk at length about issues that most concern them.

Women were recruited from four urogynaecology outpatient clinics in different parts of England: Birmingham, Gillingham (in Kent), Leicester and Southampton. Recruitment was limited to women being treated in England for practical reasons. Between May and December 2017, women who had been referred to these clinics, were aged ≥ 18 years, had not previously had urology surgery (for UI or a related condition) and were now considering surgery for their UI were approached about the project by members of the clinic teams (which included physiotherapists, nurses, surgical consultants and specialist registrars) as part of the patient's routine appointments. Women who were potentially interested in participating were given an information sheet and form to complete and return directly to the qualitative members of the research team at the London School of Hygiene & Tropical Medicine if they wished to participate. Those women who completed the form were contacted by telephone or e-mail (depending on their preference) and given further information about the study and what the interview would involve. Interviews were then scheduled and conducted either face to face or by telephone (also according to the women's preferences). Women were given the opportunity to ask further questions about the research before agreeing to participate. Written consent was obtained from all interviewees and women were also informed that they could withdraw their consent at any time, during or after the interviews. Women were reassured that the interviewer was not part of the clinic staff and that their decision to participate or not would have no influence on their care. Ethics approval for the study was granted by the NHS Health Research Authority (Research Ethics Committee reference number 16/IEC08/0044).

Interviewees were initially purposively sampled by region (clinic) and age. The geographical location of those women interviewed did not appear to influence their responses, whereas ageing emerged as a strong theme through the interviews. Interviewees were therefore then sampled by age alone, to ensure that women of a wide range of ages were included. Interviews lasted between 40 and 130 minutes, were audio-recorded and transcribed verbatim. Transcription was undertaken by an external company

experienced in dealing with confidential data. Transcripts were imported and coded in NVivo 10 (QSR International, Warrington, UK). Initial coding was undertaken by the interviewer while recruitment and interviews were under way. Following a constant comparative method[53,54] emerging themes from the interviews were followed up in more depth in subsequent interviews such that the topic guide became more refined and focused on areas that were most important to the participants themselves.

The codes, drawn both deductively from the interview topic guide and literature review and inductively through early analysis, were augmented and refined through the process of analysis and through discussion with the WP 3 lead. Codes were then ordered into higher-level themes and hierarchies, with codes that were similar collapsed together. These codes were then discussed with the rest of the research team, which included clinicians, leading to further refinement.

Methods for work package 4

Work package 4 aimed to identify determinants of gynaecology outpatient referrals and surgery for women with UI.

Analysis cohorts

Initial non-invasive treatments can be started in primary care without extensive evaluation of the main subtype of UI indicated by a woman's symptoms. Subtype-specific diagnoses may therefore not be present in primary care (CPRD) data. We therefore defined the cohorts for the analysis of both determinants of referral and determinants of surgery after referral on the basis of a diagnosis of UI, not restricted by UI subtype.

Diagnoses of UI were defined using Read codes and MedCODES identified in WP 1 (*Table 2*). Referral to a specialist was defined using a combination of Read codes and referral specialty codes developed in WP 1 (see *Appendix 4, Tables 18* and *19*). Surgery for UI was defined using OPCS-4 codes (see *Appendix 1, Tables 13–15*).

TABLE 2 Read codes and MedCODES used to define UI diagnosis for cohort selection in WP 4

Read code	Read code chapter	MedCODES	Read code definition
1593	1 – history and symptoms	15918	H/O: stress incontinence
1A23.00	1 – history and symptoms	6161	Incontinence of urine
1A24.00	1 – history and symptoms	1929	Stress incontinence
1A24.11	1 – history and symptoms	5844	Stress incontinence – symptom
1A26.00	1 – history and symptoms	3887	Urge incontinence of urine
K198.00	K – genitourinary system diseases	3182	Stress incontinence
K586.00	K – genitourinary system diseases	17620	Stress incontinence – female
Kyu5A00	K – genitourinary system diseases	52763	[X] Other specified urinary incontinence
R083.00	R – symptoms, signs and ill-defined conditions	3283	[D] Incontinence of urine
R083000	R – symptoms, signs and ill-defined conditions	4375	[D] Enuresis – NOS
R083100	R – symptoms, signs and ill-defined conditions	31220	[D] Urethral sphincter incontinence
R083200	R – symptoms, signs and ill-defined conditions	17320	[D] Urge incontinence
R083z00	R – symptoms, signs and ill-defined conditions	15400	[D] Incontinence of urine – NOS

H/O, history of; NOS, not otherwise specified.

Determinants of referrals analysis

The cohort for identifying determinants of referrals was derived from the CPRD data set and comprised women aged ≥ 18 years who had an index diagnosis of UI between 1 April 2004 and 31 March 2014. An index diagnosis of UI was defined among women who had no earlier record of a UI symptom/ diagnosis (see *Appendix 2, Table 16*) or treatment (see *Appendix 3, Table 17*) within the 12 months prior to the date of first diagnosis in the study period. For the referral analyses, women were followed up until the date of the GP visit that they were referred to a UI specialist, transfer out of practice, death or to 1 April 2014. Women with < 12 months of UTS data prior to index diagnosis were excluded. Women were also excluded if the follow-up period was < 30 days.

Determinants of surgery analysis

The cohort for identifying determinants of surgery after referral comprised women aged ≥ 18 years who had an index UI diagnosis (defined as described above) and a referral to a urinary incontinence specialist in secondary care between 1 April 2004 and 31 March 2014. The cohort of women for surgery after referral was derived from the CPRD linked to HES APC data set and was therefore restricted to women registered in primary care practices that had linked CPRD–HES data. Women were followed up from the date of referral until the date of surgery, transfer out of practice, death or to 1 April 2014.

Outcome measures

Determinants of referrals analysis

For the determinants of referrals analysis, the outcome measure was referral to a UI specialist within 30 days of diagnosis.

Determinants of surgery analysis

For the determinants of surgery analysis, the primary outcome measure was risk of any UI surgery. (The codes for SUI surgery are shown in *Table 1* and the codes for UUI surgery are shown in *Appendix 1, Table 14*.)

Potential determinants of referral and surgery

Potential determinants of both referral and surgery (defined a priori with the project team clinicians) were age at index diagnosis (analysed as 18–39, 40–49, 50–59, 60–69, 70–79, ≥ 80 years), BMI (< 20 kg/m^2 = underweight, 20–24 kg/m^2 = normal, 25–29 kg/m^2 = overweight, 30–39 kg/m^2 = obese, ≥ 40 kg/m^2 = severely obese), smoking (non-, current or former smoker) and ethnic background (white, Asian/Asian-British, black/black-British, mixed or other ethnic group, or missing) and comorbidities. The comorbidities included were pelvic organ prolapse (POP), UTI, type 2 diabetes mellitus (T2DM), cardiovascular disease (CVD) (as defined as any cardiovascular or ischaemic heart disease, heart failure or hypertension), renal disease, respiratory disease [asthma or chronic obstructive pulmonary disease (COPD)], anxiety or depression and cancer. Comorbidities were defined using Read codes (from the clinical codes repository www.clinicalcodes.org; accessed 6 April 2020) in the 12 months before the start of follow-up ('index date'), apart from UTI (defined as in the 30 days before). The 'index date' was the date of UI diagnosis for the referrals analysis and the referral date for the surgery analysis. A clinical code repository list was not available for POP, so this code list was developed for this project by the research team, including the clinicians (see *Appendix 5, Table 20*). BMI and smoking status were defined using the value recorded closest to the index date. To reduce the number of missing data, and given the more fixed nature of ethnic background, no time-restrictions were placed on ethnicity codes. Practice-level characteristics were IMD (quintiles: 1 = most deprived, 5 = least deprived), practice country for the referrals analysis (England, Northern Ireland, Scotland and Wales) and English region [for the surgery analysis, 10 strategic health authorities (SHAs): North East, North West, Yorkshire and The Humber, East Midlands, West Midlands, East of England, South West, South Central, London and South East Coast].

Statistical analyses

For the determinants of both referrals and surgery analyses, patient and practice characteristics were summarised using descriptive statistics. In both analyses, multiple imputation was used to impute

missing values for BMI (missing for 5% of women) and smoking status (missing for 0.1% of women), with statistical coefficients obtained from imputed data sets, pooled using Rubin's rules.[55] In the determinants of referral analysis, ethnicity data were available from the CPRD database only and were missing for 55% of women. A separate 'missing' category was therefore included in the models. In the determinants of surgery analysis, ethnicity data were available from both the CPRD and the HES databases and were missing for just 5% of women, allowing multiple imputation to be used to impute missing values. All statistical calculations were performed using Stata.

Determinants of referrals analysis

For the determinants of referrals analysis we used multivariate logistic regression, with cluster standard error estimands to account for clustering within general practices, to identify factors associated with referral within 30 days.

Determinants of surgery analysis

For the determinants of surgery analysis we used the cumulative incidence function to estimate surgery risk as a function of time from the initial referral to first surgical procedure. Death was considered as a competing event and patients reaching the end of the follow-up period were censored.[56] We used a multivariable Fine–Gray model to estimate subdistribution hazard ratios (sdHRs) to assess the association between patient and provider characteristics and the risk of surgery, with robust standard errors to account for within-hospital homogeneity.[57]

Methods for work package 5

Work package 5 used primary data collected from an online survey. The survey used hypothetical simulated patients described by clinical case vignettes to measure variation in clinicians' approaches to recommending surgical treatment for female SUI. This method has been used to measure variation in clinicians' approaches to the diagnosis and treatment of patients with a range of similar health problems and is considered to be a cost-effective way of studying how clinicians respond to specific characteristics of their patients when making decisions rather than using medical records or standardised patients.[58–62]

Survey

We conducted an online survey of all members of the British Society of Urogynaecology (BSUG) and members of the Royal College of Obstetricians and Gynaecologists (RCOG) who indicated that they had specialist interest in urogynaecology at the time of their RCOG registration ($n = 1139$). Data collection was carried out using the online survey platform, SurveyMonkey® (Palo Alto, CA, USA). In June 2017, a link to the online survey was e-mailed to the participants, with information about the survey and how to complete it. Three reminder e-mails were sent in the 1-month period following the initial e-mail. The survey included an information screen providing a brief description of the project, questions on the clinicians' demographic characteristics, a page providing additional information and a number of clinical assumptions we asked the clinicians to make when responding to the survey (see *Box 1*). This was followed by the 18 case vignettes and response options.

Case vignette development

We used a three-stage approach to select the patient characteristics and their levels to be included in the clinical case vignettes. The first stage involved 'item identification'. A targeted non-systematic literature search of English-language studies including female patients only was carried out to identify patient characteristics associated with surgical treatment for UI. We also drew on national guidelines and four senior clinical experts from the project team.

The second stage was 'item reduction'. Each of the clinical experts reviewed the patient characteristics and selected those patients that they considered most likely to influence clinicians' decisions about surgery for UI to be included in the vignettes. The recommendations made were collated and

collectively discussed by the clinicians, reaching consensus on the most important characteristics for inclusion in the case vignette profiles. Seven potential characteristics were selected: age, BMI, type of SUI (pure SUI, stress predominant or MUI), previous SUI surgery, leakage, bother and physical status. Further discussions were held to decide on the relevant levels for these characteristics. Here the aim was to create maximum difference between the levels for each characteristic while ensuring that the clinical profiles captured in the vignettes were relevant and realistic. The seven patient characteristics and their levels (six characteristics with three levels and one with two) that were used in the case vignettes are presented in *Table 3*. Physical status was described according to categories recognised by the classification of the American Society of Anesthesiologists (ASA) at levels 2 (i.e. 'a patient with mild systemic disease') and 3 (i.e. 'a patient with severe systemic disease').

The third stage involved creating the 'experimental design'. The total number of possible different cases using these seven patient characteristics is 1458 ($= 3^6 \times 2^1$) in a full factorial design. We used an orthogonal fractional factorial design [using SPSS software version 25 (SPSS Inc., Chicago, IL, USA)], which reduced the number of clinical case vignettes to 18.[63] This design reduces the number of vignettes while maximising the amount of information collected and retaining the absence of correlation between patient characteristics.[64] In addition to the 18 case profiles generated, we included two extra case profiles ('holdout profiles') to test our model specification.

TABLE 3 Patient characteristics included in the case vignette profiles

Characteristic	Level
Age (years)	55
	68
	79
BMI (kg/m^2)	23
	30
	36
Urinary incontinence conditions	Stress urinary incontinence
	Stress-predominant mixed incontinence
	Mixed incontinence
Previous SUI surgery	None
	MIU (any route)
	Bladder neck injection
Frequency of leakage	About two or three times a week
	About once a day
	Several times a day
Bother	A bit of a problem
	Quite a problem
	A serious problem
Physical status	ASA grade 2
	ASA grade 3

The case vignettes described the clinical profile of women referred to secondary care for further assessment and management of their SUI. Each case profile comprised a short patient description according to the seven characteristics followed by one question: 'Would you recommend that this patient has surgical treatment now?'. The clinicians were asked to score their recommendation on a five-point Likert scale ranging from 'certainly yes' to 'certainly not'. A pilot study was undertaken among eight clinicians to optimise the clarity of the vignettes. An example of one of the 18 clinical case vignettes is presented in *Box 1*.

Statistical analyses

We used descriptive statistics to summarise the characteristics of the responding clinicians. We calculated the means of the response scores and the 25th and 75th percentiles to describe the recommendations of the clinicians for each of the 18 case vignettes.

To assess the relative influence of the patients' characteristics (i.e. 'weight') on the clinicians' recommendations, we calculated the means of the recommendation score by level of each of the characteristics. The weight of a patient characteristic was defined as the difference between the lowest and the highest mean recommendation score for that characteristic, divided by the sum of these differences for all seven clinical characteristics.[65] In other words, the weights express as a percentage the influence of each characteristic on the clinicians' recommendations relative to the total overall weight of all patient characteristics. We used a mixed-effects analysis of variance model to test the statistical significance of differences in the clinicians' recommendation scores according to level of the patient characteristics. This mixed-effects model recognised that the recommendation scores for the 18 case vignettes were nested within clinicians. The same mixed-effects model was used to analyse the impact of the clinicians' own characteristics (subspecialty, gender and age group) on their recommendations. This was carried out by modelling the interaction between the patient characteristics and clinicians' characteristics with a likelihood ratio test for composite models.

Latent class analysis was used to determine if mutually exclusive groups of clinicians ('latent classes') could be identified whose recommendations suggested a similar practice style.[66] Clinicians classed within the same group are expected to be more homogeneous with respect to their recommendation scores than gynaecologists classed in different groups. We used the Akaike information criterion (AIC) and the Bayesian information criterion (BIC) to determine the optimal number of latent classes. For both the AIC and BIC, a smaller value represents a better balance between the number of classes and the fit of the statistical model. The predicted posterior probabilities of latent class membership were used to assign each clinician to a group. Where a clinician did not have a posterior probability > 50% for one particular group, group membership was considered to be unknown. Statistical analyses were performed using Stata.

Methods for additional work package: work package 6

With growing concerns about the long-term outcomes of MUT procedures (of a subset of SUI procedures) changing the context of surgery for SUI, we also conducted additional research. The objective of this additional WP (WP 6) was to estimate the long-term rates of mesh tape removal and reoperation in women who had a MUT inserted for SUI.

Analysis cohort

The cohort for the additional work on mesh tape removal and reoperation comprised women aged ≥ 18 years who underwent a MUT insertion procedure for SUI for the first time between 1 April 2006 and 31 December 2015 in the HES APC data set. SUI was defined by the ICD-10 code N39.3. MUT insertions were defined with the OPCS-4 codes M53.3 (introduction of tension-free vaginal tape) and M53.6 (introduction of transobturator tape). The procedure was considered to be the 'initial' MUT insertion procedure in which there was no record of a MUT insertion in the preceding 3 years.

BOX 1 Example of a clinical case vignette

A **55-year**-old woman presents with symptoms of **mixed incontinence**.

She leaks **several times a day**. She says that her UI condition is affecting her daily activities and is **a serious problem** for her. Her BMI is **36 kg/m²**.

Previous gynaecological history includes **mid-urethral tape**. She is **ASA grade 2**.

Would you recommend that this patient has surgical treatment now?

☐ Certainly yes

☐ Probably yes

☐ Not sure

☐ Probably not

☐ Certainly not

PLEASE ASSUME THAT:

PATIENTS

- Have been referred by their GP for further assessment.
- Have completed all conservative and behavioural treatments (e.g. frequency volume charts, pelvic floor exercises, etc.) without benefit.

RESULTS OF EXAMINATION INDICATE

- Abdominal examination – normal.
- Mid-stream urinalysis results – all negative.
- Post-void residual volume of < 100 ml.

TYPE OF URINARY INCONTINENCE

This survey focuses on the following conditions:

- stress urinary incontinence
- stress-predominant mixed urinary incontinence
- mixed urinary incontinence (urodynamic stress incontinence with detrusor overactivity).

PHYSICAL STATUS

We describe physical status by the ASA grade classification.

Examples of patients with ASA grade 2

- *Hypertension*: well controlled with one type of antihypertensive medication.
- *Diabetes*: well controlled with oral medication or insulin, without diabetic complication.
- *COPD/asthma*: with productive cough and wheeze, well controlled by inhalers with rare episode of acute chest infection, not limiting lifestyle.

Examples of patients with ASA grade 3

- *Hypertension*: requiring multiple antihypertensive medications, or not well controlled.
- *Diabetes*: diabetic complications, or not well controlled with oral medication or insulin.
- *COPD/asthma*: not well controlled, limiting lifestyle, with high dose of inhaler or oral steroids, with frequent episodes of acute chest infections.

Follow-up was from the date of the initial procedure to the date of a MUT removal, the date of reoperation or 31 March 2016, whichever was earliest. The minimum follow-up period was therefore 3 months and the maximum was 10 years.

Outcome measures

The outcomes were risk of MUT removal, reoperation for SUI and any reoperation (MUT removal and/or reoperation for SUI) (the codes are in *Appendix 1, Table 13*).

Potential determinants of mesh tape removal and reoperation

Potential determinants were age at initial procedure (analysed as 18–39, 40–49, 50–59, 60–69, ≥ 70 years); patient-level IMD, an area-based measure of economic deprivation (quintiles of the national distribution: 1 = most deprived, 5 = least deprived); ethnic background (white, Asian/Asian-British, black/black-British or other); number of comorbidities [as defined using the Royal College of Surgeons (RCS)'s Charlson Comorbidity Index, grouped as 0 or 1 or more]; route of MUT insertion (retropubic or transobturator); previous non-mesh SUI procedures in the 3 years prior to the initial MUT insertion; and concurrent prolapse repair procedures in the same episode of care as the initial MUT insertion. In a retropubic insertion, the mesh tape supporting the urethra is passed through two small incisions just above the pubic area. In a transobturator insertion it is passed through two small incisions on the inside of both thighs. The potential determinants at the organisational level that were related to the hospital where the initial procedure was performed were number of MUT insertions performed in the same year as the initial operation and the hospitals' status as a specialist urogyneacology unit (according to accreditation by the BSUG unit) at any point in the study period.

Statistical analyses

The cumulative incidence function was used to estimate the risk of MUT removal and of reoperation as a function of time from the initial MUT insertion procedure. Death was considered as a competing event and patients reaching the end of the follow-up period were censored.[56] We used a multivariable Fine–Gray model to estimate sdHRs to assess the association between patient and provider characteristics and the risk of surgery, with robust standard errors to account for within-hospital homogeneity.[57] Multiple imputation was used to impute missing values for ethnic background (missing for 8.3% of women), with statistical coefficients obtained from 10 imputed data sets, pooled using Rubin's rules.[55]

Patient and public involvement

All WPs benefited from the input from two patient and public involvement (PPI) representatives who were members of the Project Advisory Group. They shared their experience of the NHS as patients, which guided the project's overall design as well as the specific design of the qualitative and quantitative WPs. They also commented on all results and contributed to their interpretation.

Further PPI input was provided by the co-vice chairperson of the RCOG's Women's Network who was a member of the Project Steering Committee. In this capacity, she was able to comment on the results of the project from the perspective of the wider and diverse group of women represented by this network.

Chapter 4 Work package 2: geographic variation in surgery for female stress urinary incontinence

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In this chapter, we present evidence from WP 2 on how the rates of surgery for female SUI vary across England. This addresses the second objective of the project that was to assess variation between NHS CCGs and other regional units in the rate of surgery for UI and to examine the impact of the supply-side factors on local surgical rates.

The methods are described in detail in *Chapter 3*. In summary, we used the HES database to identify women aged ≥ 20 years who had surgical treatment for SUI between 1 April 2013 and 31 March 2016 in NHS England. The outcome measure was the rate of surgery for SUI per 100,000 women per year at two geographic levels across 209 CCG areas with an average population size of 104,000 adult women and 44 STP areas with an average population size of about 493,000 adult women. Multilevel Poisson regression models were used to produce empirical Bayes' estimates of the SUI surgery rates for each CCG and STP area, adjusted for age, socioeconomic deprivation, ethnicity and limiting long-term illness.

There were 33,708 inpatient episodes with a surgical procedure for SUI between April 2013 and March 2016. In total, 4996 episodes were excluded because, for example, they did not have a SUI diagnosis recorded at the time of the procedure. We focused on the first SUI procedure in the study period, which equated to 27,997 procedures, capturing > 97% of all SUI procedures in the study period. In total, 90% of procedures were MUT insertions and this did not vary between the first and later procedures.

The national annual rate of surgery was 40 procedures per 100,000 women. The adjusted SUI procedure rates for CCGs ranged from 20 to 106 procedures per 100,000 women per year [unadjusted rates ranged from 11 to 120 procedures per 100,000 women per year (*Figure 1*)]. Risk adjustment reduced the number of CCGs marked as 'outliers' (in which the national average was not within the 99.8% credibility interval of their rate) from 99 (47.4%) to 75 (36%), with the standard deviation (SD) of the CCG-level variation in adjusted rates [SD 0.27, 95% confidence interval (CI) 0.24 to 0.30] 16% lower than the SD of the unadjusted rates (SD 0.32, 95% CI 0.29 to 0.36).

The adjusted SUI procedure rates for the STPs ranged from 24 to 69 procedures [unadjusted rates ranged from 20 to 77 procedures per 100,000 women per year (*Figure 2*)]. Risk adjustment reduced the number of STPs identified as outliers from 23 (52%) to 22 (50%). The amount of variation observed declined by 35% after risk adjustment, that is, unadjusted (SD 0.23, 95% CI 0.17 to 0.31) and adjusted (SD 0.15, 95% CI 0.11 to 0.22).

Annual SUI procedure rates declined over the study period from 52 per 100,000 women in 2013 to 36 per 100,000 women in 2015. However, there was no evidence that CCG- or STP-level variation changed over time. In separate (adjusted) regression models run by year, the SD of CCG-level variation was 0.26 (95% CI 0.23 to 0.30) in 2013, 0.27 (95% CI 0.23 to 0.31) in 2014 and 0.29 (95% CI 0.25 to 0.34) in 2015. For STP-level variation (adjusted) the SD was 0.13 (95% CI 0.08 to 0.20) in 2013, 0.17 (95% CI 0.11 to 0.25) in 2014 and 0.18 (95% CI 0.12 to 0.26) in 2015.

(a)
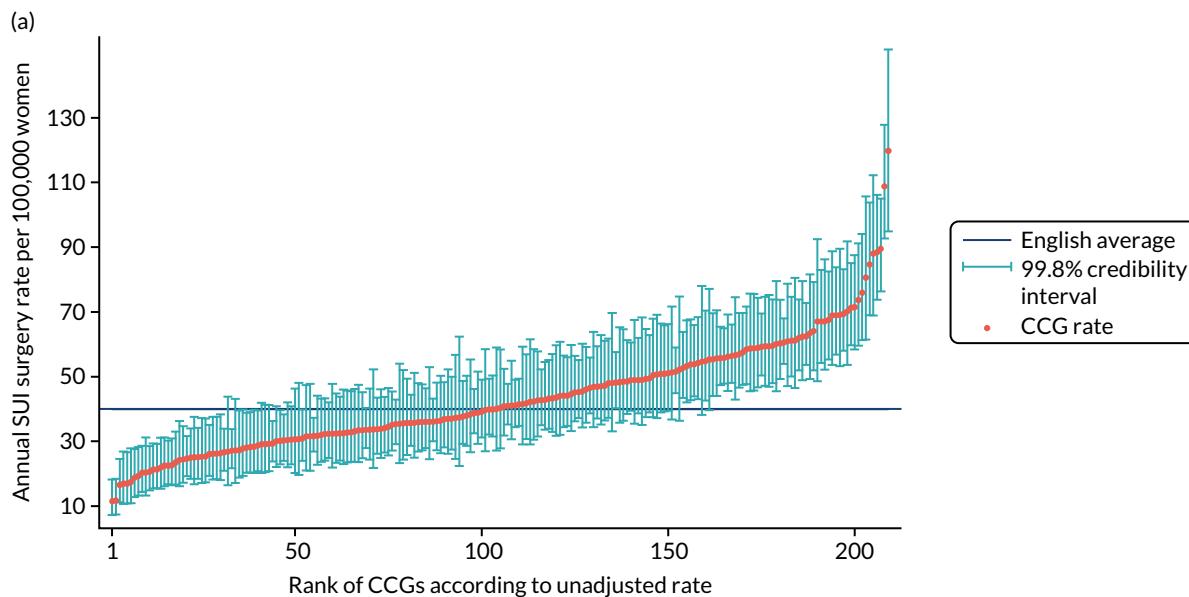
National rate: 40 per 100,000 women per year; range: 11–120 per 100,000 women per year
47% outliers: 56 above and 43 below

(b)
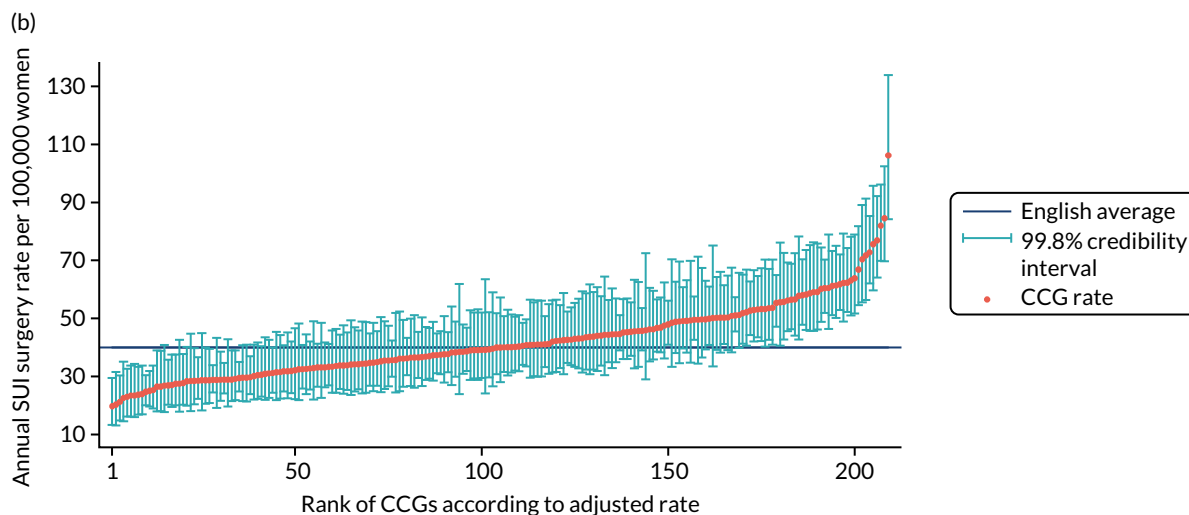
National rate: 40 per 100,000 women per year; range: 20–106 per 100,000 women per year
36% outliers: 45 above and 30 below

FIGURE 1 Variation in SUI surgery rates by CCG. (a) Variation in the unadjusted empirical Bayes' estimates of SUI procedure rates across CCGs; (b) adjusted for patients' age and the CCG-level characteristics: IMD, percentage of the population reporting BAME background and percentage with a long-term illness; and (c) map of variation in SUI surgery rates by CCG. Reproduced with permission from Mamza et al.[67] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/. (continued)

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(c)

FIGURE 1 Variation in SUI surgery rates by CCG. (a) Variation in the unadjusted empirical Bayes' estimates of SUI procedure rates across CCGs; (b) adjusted for patients' age and the CCG-level characteristics: IMD, percentage of the population reporting BAME background and percentage with a long-term illness; and (c) map of variation in SUI surgery rates by CCG. Reproduced with permission from Mamza *et al.*[67] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/.

Stress UI surgery rates were lowest for those women aged 20–39 years (16 per 100,000 women per year) and highest for those women aged 40–49 years (84 per 100,000 women per year), declining with age (beyond 50 years). Compared with the rate among women aged 40–49 years, the surgery rate for women aged 50–59 years was 20% lower (IRR 0.80, 95% CI 0.78 to 0.83) and 46% lower for women aged 60–69 years (IRR 0.54, 95% CI 0.52 to 0.56). Rates were lower in areas with higher proportions of BAME populations (highest vs. lowest quintile IRR 0.63, 95% CI 0.49 to 0.81). There were no differences in surgery rates according to the proportion of people with long-term limiting illness or CCG-level socioeconomic deprivation.

Key findings

- The rate of surgery for SUI was 40 procedures per 100,000 women per year.
- Risk-adjusted rates ranged from 20 to 106 procedures per 100,000 women per year across CCGs and from 24 to 69 procedures per 100,000 women per year across the STP areas.
- These regional differences were only partially explained by demographic characteristics, as adjustment reduced variance of surgery rates by 16% among the CCGs and 35% among the STPs.

Table 4 describes the distribution of regional characteristics and the association between these factors and SUI procedure rates.

(a)

National rate: 40 per 100,000 women per year; range: 20–77
52% outliers: 14 above and 9 below

(b)

National rate: 40 per 100,000 women per year; range: 24–69
50% outliers: 12 above and 10 below

FIGURE 2 Variation in SUI surgery rates by STP. (a) Variation in the unadjusted empirical Bayes' estimates of SUI procedure rates across STPs; (b) adjusted for patients' age and the CCG-level characteristics: IMD, percentage of the population reporting BAME background and percentage with a long-term illness; and (c) map of variation in SUI surgery rates by STP. 1, Somerset; 2, Gloucestershire; 3, Lincolnshire; 4, Norfolk and Waveney; 5, Cambridgeshire and Peterborough; 6, North Central London; 7, Cheshire and Merseyside; 8, Shropshire and Telford and Wrekin; 9, Northamptonshire; 10, Cornwall and the Isles of Scilly; 11, Suffolk and North East Essex; 12, Bristol, North Somerset and Sough Gloucestershire; 13, Staffordshire; 14, Nottinghamshire; 15, Hampshire and the Isle of Wight; 16, Coast, Humber and the Vale; 17, Bath, Swindon and Wiltshire; 18, North East London; 19, Sough Yorkshire and Bassetlaw; 20, Coventry and Warwickshire; 21, Leicester, Leicestershire and Rutland; 22, Greater Manchester; 23, Dorset; 24, The Black Country; 25, Derbyshire; 26, Durham, Darlington, Teesside, Hambleton, Richmondshire and Whitby; 27, North West London; 28, Mid and South Essex; 29, West, North and East Cumbria; 30, Herefordshire and Worcestershire; 31, South East London; 32, Sussex and East Surrey; 33, South West London; 34, Surrey Heartlands; 35, Devon; 36, Buckinghamshire, Oxfordshire and Berkshire West; 37, Milton Keynes, Bedfordshire and Luton; 38, Lancashire and South Cumbria; 39, Birmingham and Solihull; 40, West Yorkshire; 41, Frimley Health; 42, Hertfordshire and West Essex; 43, Northumberland, Tyne and Wear and North Durham; and 44, Kent and Medway. Reproduced with permission from Mamza *et al.*[67] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/. (*continued*)

(c)

FIGURE 2 Variation in SUI surgery rates by STP. (a) Variation in the unadjusted empirical Bayes' estimates of SUI procedure rates across STPs; (b) adjusted for patients' age and the CCG-level characteristics: IMD, percentage of the population reporting BAME background and percentage with a long-term illness; and (c) map of variation in SUI surgery rates by STP. 1, Somerset; 2, Gloucestershire; 3, Lincolnshire; 4, Norfolk and Waveney; 5, Cambridgeshire and Peterborough; 6, North Central London; 7, Cheshire and Merseyside; 8, Shropshire and Telford and Wrekin; 9, Northamptonshire; 10, Cornwall and the Isles of Scilly; 11, Suffolk and North East Essex; 12, Bristol, North Somerset and Sough Gloucestershire; 13, Staffordshire; 14, Nottinghamshire; 15, Hampshire and the Isle of Wight; 16, Coast, Humber and the Vale; 17, Bath, Swindon and Wiltshire; 18, North East London; 19, Sough Yorkshire and Bassetlaw; 20, Coventry and Warwickshire; 21, Leicester, Leicestershire and Rutland; 22, Greater Manchester; 23, Dorset; 24, The Black Country; 25, Derbyshire; 26, Durham, Darlington, Teesside, Hambleton, Richmondshire and Whitby; 27, North West London; 28, Mid and South Essex; 29, West, North and East Cumbria; 30, Herefordshire and Worcestershire; 31, South East London; 32, Sussex and East Surrey; 33, South West London; 34, Surrey Heartlands; 35, Devon; 36, Buckinghamshire, Oxfordshire and Berkshire West; 37, Milton Keynes, Bedfordshire and Luton; 38, Lancashire and South Cumbria; 39, Birmingham and Solihull; 40, West Yorkshire; 41, Frimley Health; 42, Hertfordshire and West Essex; 43, Northumberland, Tyne and Wear and North Durham; and 44, Kent and Medway. Reproduced with permission from Mamza *et al.*[67] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/.

TABLE 4 Patient and regional characteristics associated with SUI surgery rates

Regional factor	Scale of factor (1 unit)	Procedures, *n* (%)	Crude rate per 100,000 women per year	Procedure rate ratio (95% CI)	*p*-value[a]
Age category (years)					
20–39	Age group in years	3253 (11.6)	15.9	0.18 (0.17 to 0.19)	
40–49		9761 (34.9)	84.4	Reference	< 0.001
50–59		7496 (26.8)	67.5	0.80 (0.78 to 0.83)	
60–69		4352 (15.5)	46.2	0.54 (0.52 to 0.56)	
≥ 70		3135 (11.2)	26.8	0.31 (0.30 to 0.33)	

TABLE 4 Patient and regional characteristics associated with SUI surgery rates (*continued*)

Regional factor	Scale of factor (1 unit)	Procedures, n (%)	Crude rate per 100,000 women per year	Procedure rate ratio (95% CI)	p-value[a]
Socioeconomic status					
1: most deprived	Quintile category of IMD ranking	5838 (20.9)	43.0	Reference	0.84
2: more deprived		6315 (22.6)	47.5	1.08 (0.93 to 1.25)	
3: average		6371 (22.8)	47.9	1.05 (0.89 to 1.25)	
4: less deprived		5001 (17.9)	39.9	1.02 (0.85 to 1.21)	
5: least deprived		4472 (15.1)	36.3	1.05 (0.85 to 1.29)	
BAME population					
1: CCGs with lowest proportion	Ranked category of proportion of BAME population	5579 (19.9)	48.8	Reference	0.001
2		6867 (24.5)	49.8	1.02 (0.89 to 1.17)	
3		6326 (22.6)	45.7	1.00 (0.86 to 1.17)	
4		5725 (20.4)	41.5	0.89 (0.75 to 1.06)	
5: CCGs with highest proportion		3500 (12.5)	27.2	0.63 (0.49 to 0.81)	
Limiting long-term illness					
1: CCGs with lowest proportion	Ranked category of proportion of people with limiting illness	4433 (15.8)	32.8	Reference	0.46
2		6328 (22.6)	44.4	1.16 (0.99 to 1.36)	
3		4882 (17.4)	43.7	1.11 (0.91 to 1.34)	
4		6896 (24.6)	46.1	1.12 (0.91 to 1.39)	
5: CCGs with highest proportion		5458 (19.5)	48.9	1.16 (0.91 to 1.49)	
Random-effects estimates		**SD (95% CI)[b]**		**SD (95% CI)[c]**	
STP-level variation (level 2)		0.23 (0.17 to 0.31)		0.15 (0.11 to 0.22)	
CCG-level variation (level 1)		0.32 (0.29 to 0.36)		0.27 (0.24 to 0.30)	

a The *p*-value was obtained from the likelihood ratio test.
b Unadjusted estimates.
c Adjusted for all regional factors (age, IMD, ethnicity and long-term illness).
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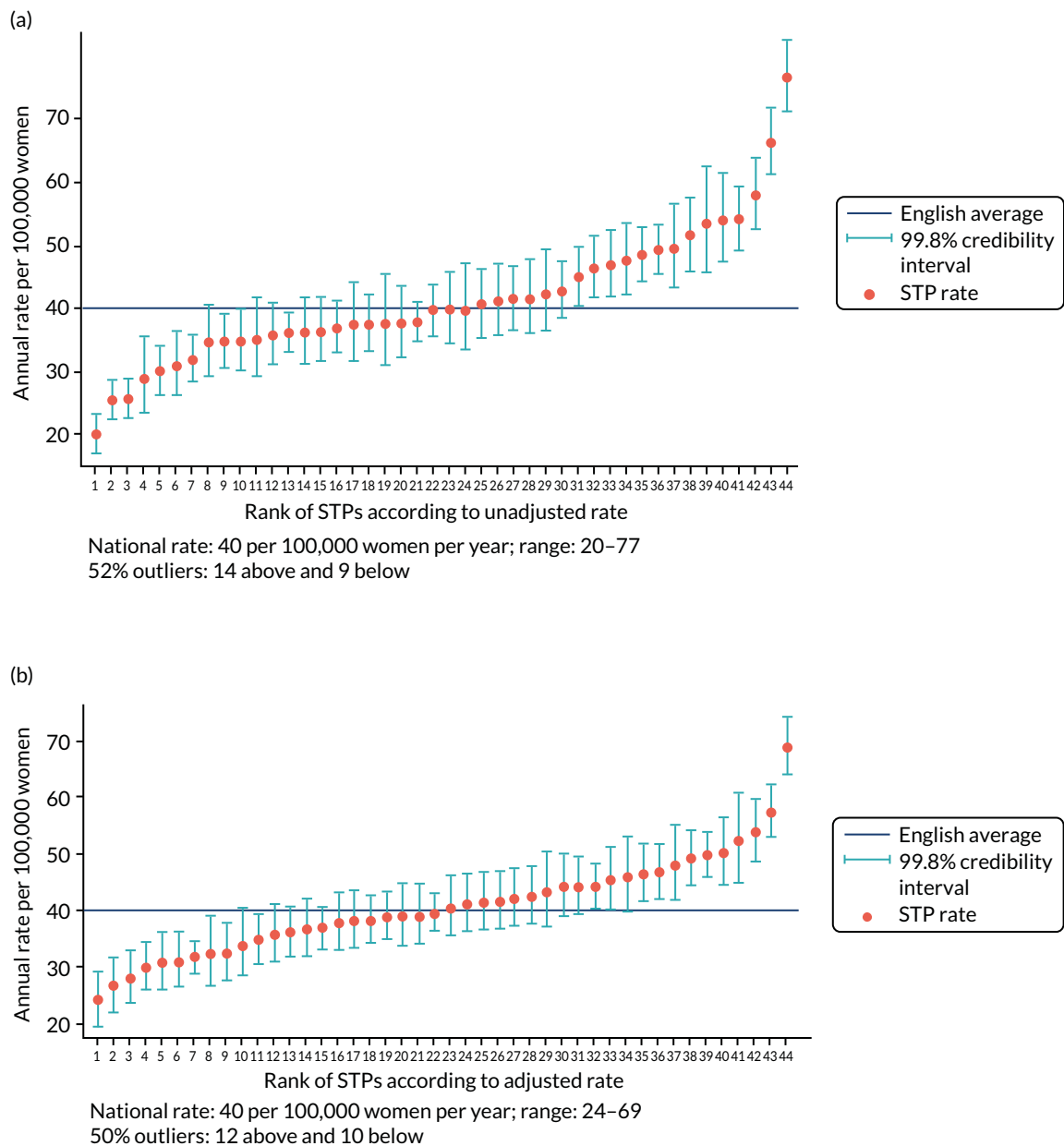
Chapter 5 Work package 4: determinants of referral and surgery for female urinary incontinence

I n this chapter we present findings from WP 4, addressing the first element of the fourth project objective, which was to identify determinants of referrals and surgical treatment for UI.

The methods are described in detail in *Chapter 3*. Briefly, the cohort for identifying determinants of referral to a UI specialist was derived from the CPRD data set[45] and comprised women aged ≥ 18 years who had an index diagnosis of UI between 1 April 2004 and 31 March 2014. An index diagnosis of UI was defined among women who had no earlier record of UI diagnosis or treatment within the 12 months prior to the date of their first diagnosis in the study period. Women with < 12 months of UTS data prior to index diagnosis or with a follow-up period of < 30 days were excluded. Women were followed up until the date of a referral to a UI specialist, transfer out of the practice, death or 1 April 2014, whichever was earliest. The primary outcome measure was referral to a UI specialist within 30 days of diagnosis.

The cohort for identifying determinants of surgery comprised women aged ≥ 18 years who had an index UI diagnosis (defined as above) and a referral to a UI specialist in secondary care between 1 April 2004 and 31 March 2014. This cohort for surgery after referral was derived from the CPRD linked to HES (APC and Outpatient) data set and was therefore restricted to women registered in primary care practices that had linked CPRD–HES data (England only). Women were followed up until the date of surgery, transfer out of the practice, death or 1 April 2014, whichever was earliest. The primary outcome measure was time to first UI surgery after referral.

Diagnoses of UI were defined using Read codes (see *Appendix 2, Table 16*). Referral to a UI specialist was defined using a combination of Read codes and referral specialty codes (see *Appendix 4, Tables 18* and *19*). UI surgery was defined using OPCS-4 codes (see *Appendix 1, Tables 13–15*).

Referrals

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Between April 2004 and March 2014, 104,466 women had at least one UI diagnosis code and met the cohort criteria. The median age of women in the cohort was 58 years [interquartile range (IQR) 45–73 years]. Almost one-third of women (32%) were overweight (i.e. with a BMI of 25–29 kg/m^2) and 29% were obese (i.e. with a BMI of 30–39 kg/m^2). Ethnicity data were missing for over half (55%) of the referrals cohort; 92% were white, 4% were Asian/Asian British and 2% were black/black British. Of the comorbidities considered, CVD and anxiety or depression were the most common, each recorded for approximately 12% of women (*Table 5*).

TABLE 5 Patient and practice characteristics associated with referral within 30 days

	Total, n (%)	Referred, n (%)	30-day referral rate (%)	Unadjusted OR (95% CI)	p-value	aOR (95% CI)	p-value
Overall	104,466	28,476	27.3				
Patient-level characteristics							
Age group (years)							
18–39	14,599 (14)	4696 (16.5)	32.2	0.91 (0.87 to 0.96)		0.91 (0.87 to 0.96)	
40–49	21,642 (20.7)	7411 (26)	34.2	Reference	< 0.001	Reference	< 0.001
50–59	19,654 (18.8)	5964 (20.9)	30.3	0.84 (0.80 to 0.87)		0.84 (0.80 to 0.88)	
60–69	17,468 (16.7)	4687 (16.5)	26.8	0.70 (0.67 to 0.74)		0.70 (0.66 to 0.73)	
70–79	15,834 (15.2)	3372 (11.8)	21.3	0.52 (0.49 to 0.55)		0.51 (0.49 to 0.54)	
≥ 80	15,269 (14.6)	2346 (8.2)	15.4	0.35 (0.32 to 0.38)		0.34 (0.31 to 0.37)	
BMI (kg/m²)							
Underweight (< 20)	5224 (5.3)	1190 (4.4)	22.8	0.75 (0.70 to 0.81)		0.85 (0.79 to 0.91)	
Normal (20–24)	28,044 (28.3)	7966 (29.2)	28.4	Reference	< 0.001	Reference	< 0.001
Overweight (25–29)	31,580 (31.8)	8748 (32.1)	27.7	0.98 (0.94 to 1.01)		0.99 (0.95 to 1.03)	
Obese (30–39)	28,873 (29.1)	7922 (29.1)	27.4	0.97 (0.93 to 1.01)		0.95 (0.91 to 0.99)	
Severely obese (≥ 40)	5474 (5.5)	1439 (5.3)	26.3	0.91 (0.85 to 0.98)		0.84 (0.78 to 0.90)	
Missing (imputed, n = 5271, 5.0%)							
Smoking status							
Non-smoker	61,109 (58.6)	16,471 (57.9)	27.0	Reference	0.02	Reference	< 0.001
Current	18,827 (18)	5350 (18.8)	28.4	1.08 (1.02 to 1.13)		0.94 (0.90 to 0.98)	
Ex-smoker	24,395 (23.4)	6632 (23.3)	27.2	1.01 (0.98 to 1.05)		1.04 (1.01 to 1.08)	
Missing (imputed, n = 135, 0.1%)							
Ethnicity							
White	43,015 (92.4)	11,398 (92.9)	26.5	Reference	0.04	Reference	0.001
Asian/Asian British	1722 (3.7)	416 (3.4)	24.2	0.88 (0.76 to 1.03)		0.76 (0.65 to 0.89)	
Black/black British	930 (2)	221 (1.8)	23.8	0.86 (0.71 to 1.05)		0.76 (0.62 to 0.92)	
Mixed/other	888 (1.9)	233 (1.9)	26.2	0.99 (0.80 to 1.22)		0.85 (0.69 to 1.05)	
Missing (category, n = 57,991, 55.4%)	–	–	28.0	1.08 (1.00 to 1.16)		1.04 (0.97 to 1.11)	

	Total, n (%)	Referred, n (%)	30-day referral rate (%)	Unadjusted OR (95% CI)	p-value	aOR (95% CI)	p-value
Comorbidities							
UTI	2503 (2.4)	659 (2.3)	26.3	0.95 (0.86 to 1.05)	0.33	1.10 (1.00 to 1.21)	0.06
POP	3230 (3.1)	720 (2.5)	22.3	0.76 (0.67 to 0.85)	< 0.001	0.77 (0.68 to 0.87)	0.00
T2DM	5639 (5.4)	1221 (4.3)	21.7	0.73 (0.67 to 0.78)	< 0.001	0.92 (0.85 to 0.99)	0.02
CVD	12,034 (11.5)	2632 (9.2)	21.9	0.72 (0.68 to 0.76)	< 0.001	0.95 (0.90 to 1.00)	0.07
Renal disease	2507 (2.4)	491 (1.7)	19.6	0.64 (0.57 to 0.73)	< 0.001	0.97 (0.86 to 1.09)	0.59
Respiratory disease	9396 (9)	2590 (9.1)	27.6	1.02 (0.97 to 1.07)	0.51	1.01 (0.96 to 1.06)	0.68
Anxiety or depression	12,101 (11.6)	3358 (11.8)	27.7	1.03 (0.97 to 1.09)	0.33	0.95 (0.90 to 1.00)	0.05
Cancer	1785 (1.7)	365 (1.3)	27.3	0.68 (0.61 to 0.77)	< 0.001	0.84 (0.75 to 0.94)	0.00
Practice-level characteristics **Country**							
England	80,751 (77.3)	22,189 (77.9)	27.5	Reference	< 0.001	Reference	< 0.001
Northern Ireland	4187 (4.0)	1774 (6.2)	42.4	1.94 (1.50 to 2.52)		1.83 (1.40 to 2.39)	
Scotland	10,908 (10.4)	2049 (7.2)	18.8	0.61 (0.47 to 0.79)		0.60 (0.46 to 0.78)	
Wales	8620 (8.3)	2464 (8.7)	28.6	1.06 (0.90 to 1.23)		1.05 (0.89 to 1.24)	
IMD (quintiles)							
1 (most deprived)	19,485 (18.7)	5486 (19.3)	28.2		0.19	Reference	0.16
2	20,782 (19.9)	6024 (21.2)	29.0	1.04 (0.89 to 1.22)		1.02 (0.88 to 1.19)	
3	20,576 (19.7)	5706 (20)	27.7	0.98 (0.84 to 1.14)		1.00 (0.86 to 1.16)	
4	21,960 (21)	5750 (20.2)	26.2	0.91 (0.78 to 1.05)		0.90 (0.77 to 1.04)	
5 (least deprived)	21,663 (20.7)	5510 (19.3)	25.4	0.87 (0.73 to 1.03)		0.88 (0.74 to 1.05)	

OR, odds ratio.

Of the 104,466 women with UI, 47,838 (45.8%) had a referral to a UI specialist (*Figure 3*). Of these, 28,476 women (27.3% of the 104,466 women with UI, 59.5% of the 47,838 women referred) were referred within 30 days of their index UI diagnosis. The cumulative incidence of referral (with death as a competing risk) at 30 days, 1 year and 9 years was 25.5% (95% CI 25.3% to 25.8%), 34.0% (95% CI 33.7% to 34.3%) and 54.5% (95% CI 53.9% to 55.2%), respectively (*Figure 4*).

Patient/practice characteristics associated with referral within 30 days

The likelihood of being referred within 30 days declined with increasing age. Women in all age groups ≥ 50 years (i.e. 50–59, 60–69, 70–79 and ≥ 80 years) were less likely to have been referred than those aged 40–49 years. Compared with those women aged 40–49 years, women aged ≥ 80 years were 66%
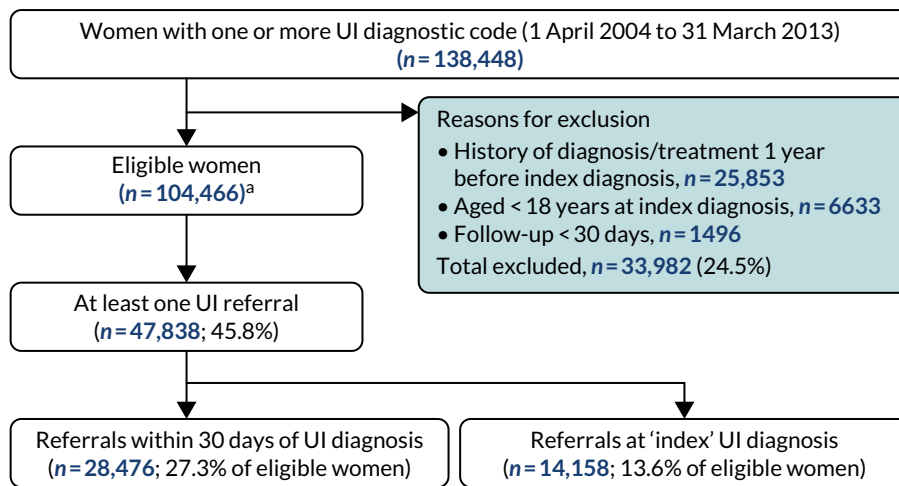
FIGURE 3 Referrals analysis cohort. Parts of this figure have been reproduced with permission from Gurol-Urganci *et al.*[68] This article is licensed under a Creative Commons Attribution 4.0 International License, which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if changes were made. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit http://creativecommons.org/licenses/by/4.0/. The Creative Commons Public Domain Dedication waiver (https://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated in a credit line to the data. The figure includes minor additions and formatting changes to the original figure.
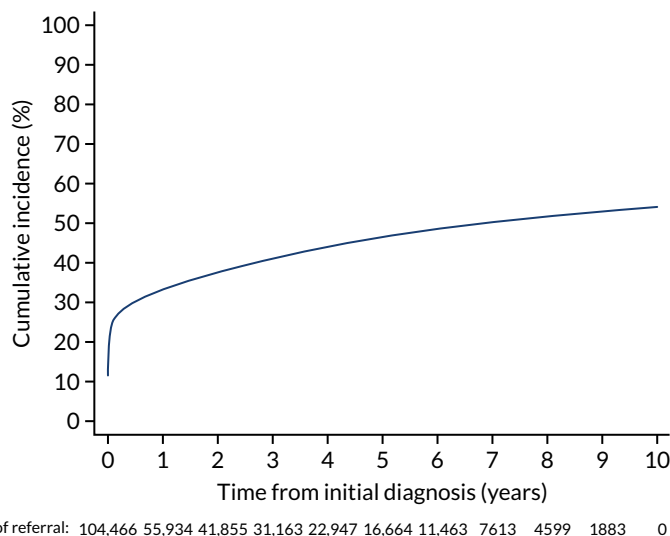
FIGURE 4 Cumulative incidence of any referral within the study period.

less likely to have been referred within 30 days [adjusted odds ratio (aOR) 0.34, 95% CI 0.31 to 0.37] and women aged 70–79 years were 49% less likely to have been referred within 30 days (aOR 0.51, 95% CI 0.49 to 0.54). Women from an Asian/Asian British and black/black British minority ethnic background were less likely to have been referred than white women (aOR 0.76, 95% CI 0.65 to 0.89 for Asian vs. white women; aOR 0.76, 95% CI 0.62 to 0.92 for black vs. white women).

Women with a BMI indicating that they were underweight (aOR 0.85, 95% CI 0.79 to 0.91) or severely obese (aOR 0.84, 95% CI 0.78 to 0.90) were less likely to have been referred than women with a normal range BMI. Current smokers were less likely to have been referred than non-smokers (aOR 0.94, 95% CI 0.90 to 0.98). Three comorbidities were associated with the likelihood of referral within 30 days. Women with a POP diagnosis were 23% less likely to have been referred for UI than women without a diagnosis of POP (aOR 0.77, 95% CI 0.68 to 0.87). Women with T2DM were slightly less likely to have been referred than those without (aOR 0.92, 95% CI 0.85 to 0.99). Finally, women with any type of cancer recorded in the previous 12 months were less likely to have been referred within 30 days (aOR 0.84, 95% CI 0.75 to 0.94). Other comorbidities were not associated with referral.

The country in which women accessed primary care for their 'index' UI diagnosis was also associated with the likelihood of referral within 30 days. Women in Scotland were 40% less likely to be referred than those accessing care in England (aOR 0.60, 95% CI 0.46 to 0.78), whereas women in Northern Ireland were 83% more likely to have been referred than those in England (aOR 1.83, 95% CI 1.40 to 2.39).

Surgical treatment

A total of 30,312 women in the linked CPRD–HES data set were identified as having been referred for UI between 1 April 2004 and 31 March 2014 (see *Box 1*). The median follow-up time was 4.6 years for women alive at the end of follow-up (IQR 2.4–6.9 years). The median age of women in the 'determinants of surgery' cohort was 53.6 years (IQR 43.4–67.6 years) and > 90% had a white ethnicity recorded. As in the referrals cohort, two-thirds of women (66.4%) were overweight, obese or severely obese and less than one-fifth (17%) were current smokers. Of the comorbidities considered, anxiety or depression and CVD were the most common, recorded for approximately 8.4% and 6.8% of women, respectively (*Table 6*).

Of the 30,312 women in the CPRD–HES 'determinants of surgery' cohort, 4307 (14.2%) underwent a UI procedure (*Figure 5*), of which 4050 (94.5%) were SUI procedures and 257 (5.5%) were UUI procedures. Of the SUI procedures, 89% ($n = 3606$) were MUT insertions.

The rate of UI surgery was 7.3% (95% CI 7.0% to 7.6%) at 1 year, 13.4% (95% CI 13.0% to 13.8%) at 3 years, 15.5% (95% CI 15.0% to 15.9%) at 5 years, and 18.1% of the women (95% CI 17.5% to 18.7%) at 9 years after the initial referral (with death as a competing risk; *Figure 6*, see *Table 6*).

Patient/practice characteristics associated with surgery

As in the findings with respect to referrals, age and ethnicity were associated with being less likely to have received surgical treatment. The rate of surgery was lower among older women (aged ≥ 50 years) than among those aged 40–49 years. The rate of surgery was lowest among those women aged 70–79 years [11.7% at 9 years after referral compared with 26.7% among women aged 40–49 years (sdHR 0.42, 95% CI 0.37 to 0.48); see *Table 6*] and ≥ 80 years [3.4% at 9 years after referral compared with 26.7% among women aged 40–49 years (sdHR 0.12, 95% CI 0.10 to 0.16); see *Table 6*]. Asian/Asian British and black/black British women had a lower rate of surgery than white women [Asian/Asian British women: 9.4% at 9 years after referral compared with 19.2% for white women (sdHR 0.50, 95% CI 0.38 to 0.67); black/black British women: 11.5% at 9 years compared with 17.8% for white women (sdHR 0.57, 95% CI 0.43 to 0.76)].

TABLE 6 Rate of SUI surgery following initial referral from primary care

	Total, n (%)	Had a UI operation, n (%)	9-year cumulative incidence of surgery (95% CI)	Unadjusted sdHR (95% CI)	p-value	Adjusted sdHR (95% CI)	p-value
Overall	30,312	4307 (14.2)	18.1 (17.5 to 18.7)				
Patient-level characteristics							
Age group (years)							
18–39	4505 (14.9)	592 (13.7)	19 (17.4 to 20.8)	0.6 (0.54 to 0.66)		0.63 (0.57 to 0.69)	
40–49	7360 (24.3)	1541 (35.8)	26.7 (25.3 to 28.2)	Reference	< 0.001	Reference	< 0.001
50–59	6251 (20.6)	973 (22.6)	19.3 (18.1 to 20.6)	0.71 (0.66 to 0.78)		0.70 (0.64 to 0.76)	
60–69	5071 (16.7)	701 (16.3)	17 (15.7 to 18.3)	0.62 (0.56 to 0.68)		0.59 (0.54 to 0.65)	
70–79	4098 (13.5)	409 (9.5)	11.7 (10.6 to 13)	0.43 (0.38 to 0.49)		0.42 (0.37 to 0.48)	
≥ 80	3027 (10)	91 (2.1)	3.4 (2.6 to 4.3)	0.12 (0.09 to 0.15)		0.12 (0.10 to 0.16)	
BMI (kg/m²)							
Underweight (< 20)	1286 (4.4)	108 (2.6)	11.1 (9 to 13.4)	0.56 (0.46 to 0.69)		0.63 (0.51 to 0.78)	
Normal (20–24)	8507 (29.2)	1214 (29.1)	18.5 (17.4 to 19.6)	Reference	< 0.001	Reference	< 0.001
Overweight (25–29)	9277 (31.9)	1453 (34.9)	20.1 (18.9 to 21.2)	1.1 (1.02 to 1.19)		1.13 (1.05 to 1.22)	
Obese (30–39)	8484 (29.2)	1248 (29.9)	18.2 (17.1 to 19.2)	1.04 (0.96 to 1.13)		1.05 (0.97 to 1.14)	
Severely obese (≥ 40)	1540 (5.3)	145 (3.5)	12.4 (10.4 to 14.5)	0.67 (0.55 to 0.8)		0.64 (0.53 to 0.77)	
Missing (imputed, n = 1218, 4.0%)							
Smoking status							
Non-smoker	17,746 (58.6)	2416 (56.1)	17.7 (16.9 to 18.4)	Reference	0.004	Reference	0.001
Current	5143 (17)	748 (17.4)	18.1 (16.8 to 19.5)	1.06 (0.97 to 1.15)		0.91 (0.83 to 1.00)	
Ex-smoker	7405 (24.4)	1142 (26.5)	19.3 (18.1 to 20.5)	1.14 (1.05 to 1.23)		1.10 (1.02 to 1.19)	

	Total, *n* (%)	Had a UI operation, *n* (%)	9-year cumulative incidence of surgery (95% CI)	Unadjusted sdHR (95% CI)	*p*-value	Adjusted sdHR (95% CI)	*p*-value
***Missing** (imputed, n = 18, 0.1%) Ethnicity*							
White	26,598 (92.5)	4007 (95.4)	19.2 (18.6 to 19.8)	Reference	< 0.001	Reference	< 0.001
Asian/Asian British	842 (2.9)	60 (1.4)	9.4 (7.2 to 11.9)	0.48 (0.36 to 0.63)		0.50 (0.38 to 0.67)	
Black/Black British	430 (1.5)	35 (0.8)	11.5 (7.6 to 16.3)	0.53 (0.4 to 0.7)		0.57 (0.43 to 0.76)	
Mixed/Other	876 (3)	98 (2.3)	17.1 (13.5 to 21)	0.78 (0.65 to 0.95)		0.76 (0.63 to 0.92)	
***Missing** (imputed, n = 1566, 5.2%) Comorbidities*							
UTI	946 (3.1)	90 (2.1)	12.7 (10.1 to 15.6)	0.66 (0.54 to 0.81)	< 0.001	0.82 (0.67 to 1.01)	0.07
POP	1063 (3.5)	185 (4.3)	18.7 (16.2 to 21.4)	1.26 (1.08 to 1.48)	0.003	1.30 (1.11 to 1.52)	0.001
T2DM	1027 (3.4)	81 (1.9)	9.9 (7.7 to 12.5)	0.5 (0.39 to 0.63)	< 0.001	0.62 (0.50 to 0.79)	< 0.001
CVD	2078 (6.9)	243 (5.6)	12.7 (11.2 to 14.3)	0.75 (0.66 to 0.86)	< 0.001	0.95 (0.83 to 1.09)	0.49
Renal disease	431 (1.4)	40 (0.9)	9.7 (7.1 to 12.9)	0.57 (0.41 to 0.79)	0.001	0.89 (0.66 to 1.22)	0.48
Respiratory disease	2058 (6.8)	297 (6.9)	19 (16.6 to 21.6)	0.98 (0.87 to 1.11)	0.74	0.93 (0.83 to 1.06)	0.29
Anxiety or depression	2561 (8.4)	372 (8.6)	17.7 (15.8 to 19.6)	0.95 (0.85 to 1.06)	0.36	0.84 (0.76 to 0.94)	0.003
Cancer	293 (1)	28 (0.7)	14.9 (8 to 23.9)	0.62 (0.43 to 0.9)	0.01	0.71 (0.49 to 1.04)	0.08
IMD (quintiles)							
1 (most deprived)	7260 (24.6)	1069 (24.8)	18.6 (17.4 to 19.8)	Reference	0.08	Reference	0.20
2	6906 (23.4)	1057 (24.6)	19.9 (18.6 to 21.3)	1.05 (0.95 to 1.16)		1.11 (1.01 to 1.22)	
3	5685 (19.2)	854 (19.8)	18.8 (17.4 to 20.2)	1.03 (0.93 to 1.14)		1.09 (0.99 to 1.21)	
4	5388 (18.2)	774 (18)	18.6 (17.3 to 20.1)	0.99 (0.88 to 1.11)		1.09 (0.98 to 1.22)	
5 (least deprived)	4307 (14.6)	549 (12.8)	16.9 (15.4 to 18.5)	0.87 (0.76 to 0.99)		1.03 (0.90 to 1.16)	

TABLE 6 Rate of SUI surgery following initial referral from primary care (*continued*)

	Total, *n* (%)	Had a UI operation, *n* (%)	9-year cumulative incidence of surgery (95% CI)	Unadjusted sdHR (95% CI)	*p*-value	Adjusted sdHR (95% CI)	*p*-value
Missing (imputed, n = 776, 2.5%) Region							
North East	712 (2.3)	90 (2.1)	15.1 (12.2 to 18.3)	Reference	< 0.001	Reference	< 0.001
North West	5133 (16.9)	629 (14.6)	16.4 (15.1 to 17.9)	0.96 (0.72 to 1.27)		0.95 (0.72 to 1.25)	
Yorkshire and The Humber	1213 (4)	200 (4.6)	20.7 (17.8 to 23.8)	1.22 (0.90 to 1.67)		1.17 (0.87 to 1.58)	
East Midlands	808 (2.7)	138 (3.2)	18.6 (15.8 to 21.6)	1.23 (0.85 to 1.77)		1.17 (0.79 to 1.72)	
West Midlands	3478 (11.5)	455 (10.6)	17.4 (15.8 to 19.2)	1.04 (0.79 to 1.38)		1.07 (0.82 to 1.41)	
East of England	4042 (13.3)	555 (12.9)	16.8 (15.4 to 18.3)	1.04 (0.78 to 1.39)		1.05 (0.79 to 1.39)	
South West	3574 (11.8)	542 (12.6)	19.2 (17.4 to 21.1)	1.17 (0.89 to 1.53)		1.18 (0.91 to 1.54)	
South Central	3586 (11.8)	611 (14.2)	21.1 (19.4 to 22.9)	1.33 (1.01 to 1.75)		1.28 (0.98 to 1.67)	
London	3836 (12.7)	397 (9.2)	14.4 (12.8 to 16)	0.82 (0.62 to 1.09)		0.86 (0.65 to 1.14)	
South East Coast	3930 (13)	690 (16)	21.7 (20 to 23.5)	1.42 (1.08 to 1.87)		1.35 (1.04 to 1.75)	

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┌─────────────────────────────────────────────────────────────────┐
│  Women with one or more UI diagnostic codes and associated        │
│  referral to secondary care                                       │
│  (1 April 2004 to 31 March 2013)                                  │
│  (n = 47,838)                                                     │
└─────────────────────────────────────────────────────────────────┘
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Eligible women
(n = 30,312)[a]

Reasons for exclusion
- Referring practice not in England (n = 10,614) or region missing (n = 171)
- CPRD–HES linkage not available, n = 6733
- Patient referred on study end date, n = 8
Total excluded, n = 17,526 (36.6%)

At least one SUI surgery
(n = 4307; 14.2%)

FIGURE 5 Surgery analysis cohort.

Number at risk
All UI operations   30,312 25,082 20,787 17,343 14,137 11,072 8172 5704 3551 1533 0
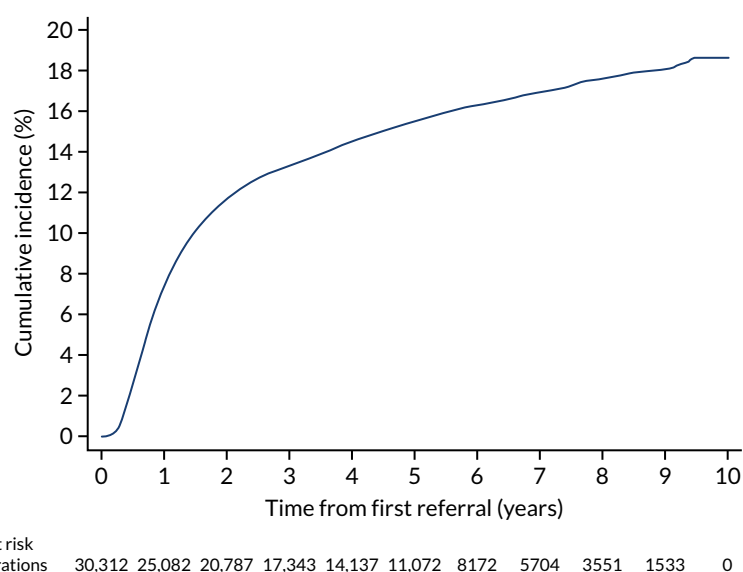
FIGURE 6 Cumulative incidence of any UI operation after referral within the study period.

Similar associations between BMI and surgery were observed as between BMI and referral. Women whose BMI placed them in the severely obese group had a lower rate of surgical treatment than women with a BMI in the normal range [12.4% for severely obese women 9 years after referral compared with 18.5% for women with a normal BMI (sdHR 0.64, 95% CI 0.53 to 0.77)]. Women whose BMI indicated that they were underweight also had a lower rate of surgery than women with a normal range BMI [11.1% for underweight women at 9 years compared with 18.5% for women with a normal BMI (sdHR 0.63, 95% CI 0.51 to 0.78)]. Three comorbidities were associated with the rate of surgical treatment. Women with a diagnosis of POP had a higher rate of surgery than women without a POP diagnosis (sdHR 1.30, 95% CI 1.11 to 1.52). Women with T2DM or anxiety/depression had a lower rate of surgery than women without a diagnosis of these conditions (sdHR 0.62, 95% CI 0.50 to 0.79 and sdHR 0.84, 95% CI 0.76 to 0.94, respectively). There was substantial variation in the rate of surgery by region of referring general practice, ranging from 14.4% in London at 9 years after referral to 21.7% in the South East Coast region (*Figure 7*).

Figure 7 illustrates geographical variation in the rate of referral and SUI surgery in England. For this figure, we have restricted the referrals cohort to England only for comparability with the surgery cohort, which is England only as a result of the linkage of CPRD data (UK wide) with HES (English hospital data). *Figure 7* demonstrates that two regions, the South East and Yorkshire and The Humber,

(a)

Referral for UI in English SHAs
Cumulative incidence (%) of referral after new diagnosis within 9 years
- 47 - 52
- 52 - 57
- 57 - 62

(b)

Surgery for UI in English SHAs
Cumulative incidence (%) of UI surgery after referral within 9 years
- 14 - 17
- 17 - 20
- 20 - 23
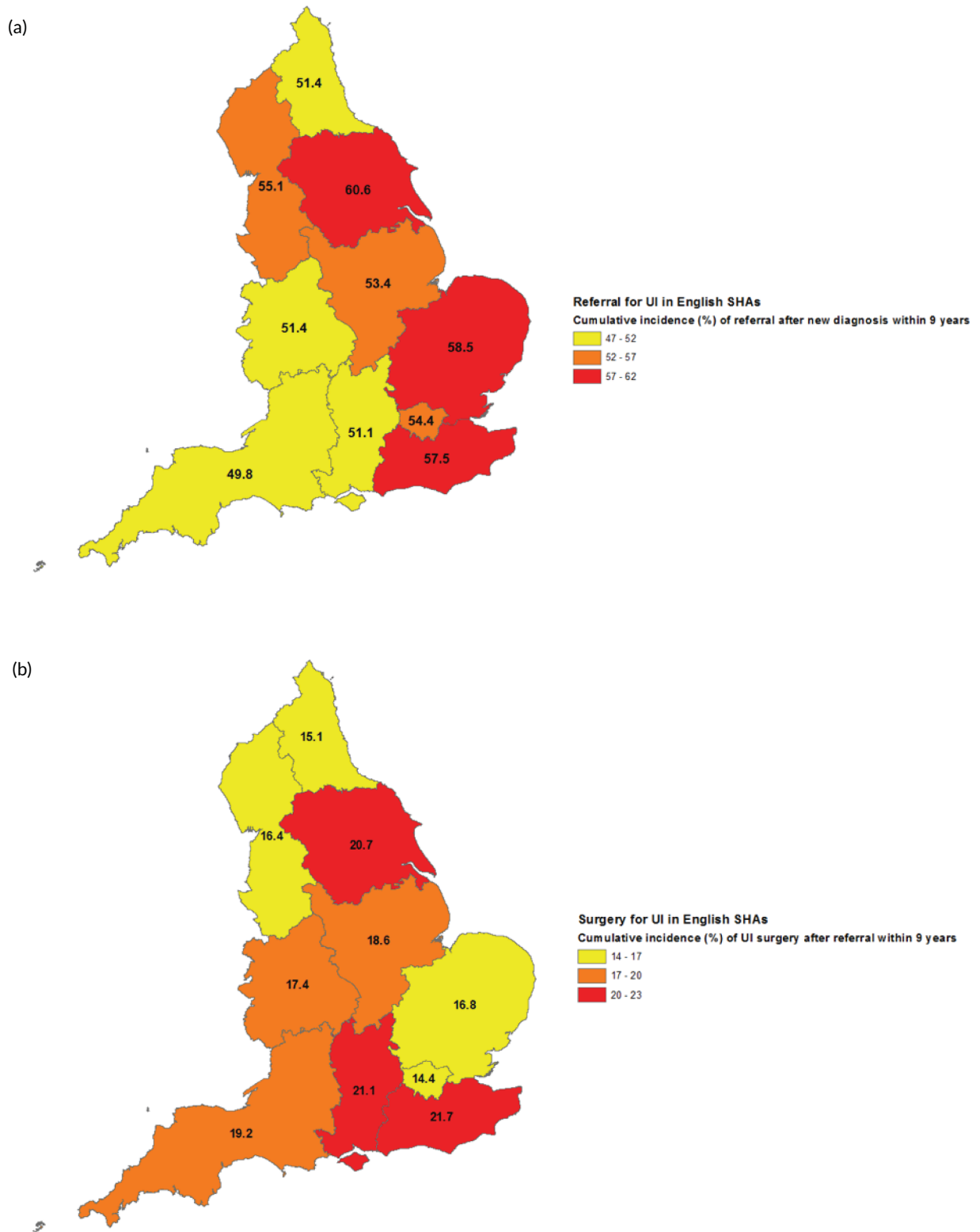
FIGURE 7 Geographical variation in rate of referral and UI surgery in England. (a) Referral after a new diagnosis; and (b) UI surgery after referral.

have high rates of both referrals and surgical treatment, whereas, in the North East, both referral and surgery rates are relatively low. *Figure 7* suggests that geographical variation in the overall rate of surgery (as demonstrated in WP 2, *Chapter 4*) is likely to arise from differences in both primary care (in terms of referrals) and secondary care.

Key findings

- Almost half of women newly diagnosed with UI in primary care in the UK between April 2004 and March 2014 were referred to secondary care within 9 years. Of those women, 59.5% were referred within 30 days.
- Referral rates were lower for older women, women from a minority ethnic background, women who were underweight (BMI of $< 20 \, kg/m^2$) and women who were severely obese (BMI of $\geq 40 \, kg/m^2$).
- Of the women who had been referred for UI, 7.3% underwent a UI procedure within 1 year of referral, 15.5% within 5 years and 18.1% within 9 years.
- Surgery rates were lower in older women, women from a minority ethnic background and women who were underweight or severely obese.

Chapter 6 Work package 6: long-term rates of mesh tape removal following mid-urethral mesh tape insertion for female stress urinary incontinence

In this chapter, we present evidence on rates of mesh tape removal after MUT insertion for female SUI in England.

The methods are described in detail in *Chapter 3*. Briefly, the cohort for identifying long-term rates of MUT removal following MUT insertion was derived from the HES APC (inpatient) data set and comprised women aged ≥ 18 years who underwent an initial MUT insertion procedure for SUI between 1 April 2006 and 31 December 2015. The procedure was considered to be the 'initial' insertion procedure in which there was no record of a MUT insertion in the preceding 3 years. Follow-up was from date of initial procedure to date of a MUT removal or reoperation or to 31 March 2016, whichever was earlier. The minimum follow-up period was, therefore, 3 months and the maximum was 10 years. SUI was defined using the ICD-10 code N39.3. MUT insertions were defined using OPCS-4 codes M53.3 and M53.6. The outcomes were risk of MUT removal, reoperation for SUI and any reoperation (MUT removal and/or reoperation for SUI) (the codes are in *Appendix 1, Table 13*).

Mid-urethral mesh tape insertions

A total of 95,057 women resident in England had a first MUT insertion between 1 April 2006 and 31 December 2015 and a diagnosis of SUI. Of these, 60,194 women (63.3%) had a retropubic and 34,863 (36.7%) had a transobturator insertion. The median follow-up time was 5.5 years for women who were alive at the end of follow-up (IQR 3.2–7.5 years). The women's median age was 51 years (IQR 44–61 years) and 19.8% had one or more comorbidity. A total of 18.1% had a concurrent prolapse operation in the same episode as their MUT insertion (*Table 7*).

TABLE 7 Risk of mesh tape removal following initial MUT insertion

		Risk of removal[a] (%)				
	Number (%)	1 year (95% CI)	5 year (95% CI)	9 year (95% CI)	sdHR[b] (95% CI)	*p*-value[c]
All: crude risk, *n/N* (%)		1275/90,215 (1.4)	1508/52,715 (2.9)	240/6981 (3.4)		
All: adjusted risk	95,057 (100)	1.4 (1.3 to 1.4)	2.7 (2.6 to 2.8)	3.3 (3.2 to 3.4)		
Age at initial surgery (years)						
18–39	10,292 (10.8)	2.0 (1.7 to 2.2)	3.6 (3.2 to 4.0)	4.4 (3.9 to 4.9)	Reference	< 0.001
40–49	33,094 (34.8)	1.5 (1.4 to 1.6)	2.9 (2.8 to 3.1)	3.7 (3.4 to 4.0)	0.83 (0.74 to 0.93)	
50–59	24,664 (26.0)	1.4 (1.2 to 1.5)	2.8 (2.6 to 3.1)	3.4 (3.1 to 3.6)	0.77 (0.68 to 0.87)	
60–69	16,877 (17.8)	1.0 (0.8 to 1.1)	2.1 (1.9 to 2.3)	2.5 (2.2 to 2.8)	0.56 (0.48 to 0.66)	
≥ 70	10,130 (10.7)	0.9 (0.8 to 1.1)	1.7 (1.5 to 2.0)	2.1 (1.7 to 2.5)	0.46 (0.38 to 0.56)	

TABLE 7 Risk of mesh tape removal following initial MUT insertion (*continued*)

	Number (%)	Risk of removal[a] (%)			sdHR[b] (95% CI)	p-value[c]
		1 year (95% CI)	5 year (95% CI)	9 year (95% CI)		
IMD (quintiles)						
1 (most deprived)	16,136 (17.0)	1.3 (1.1 to 1.5)	2.7 (2.4 to 2.9)	3.2 (2.9 to 3.5)	Reference	0.12
2	18,277 (19.2)	1.5 (1.3 to 1.7)	2.9 (2.7 to 3.2)	3.5 (3.2 to 3.8)	1.12 (0.97 to 1.30)	
3	20,468 (21.5)	1.3 (1.1 to 1.5)	2.5 (2.3 to 2.8)	3.0 (2.7 to 3.3)	0.96 (0.83 to 1.12)	
4	20,779 (21.9)	1.3 (1.1 to 1.4)	2.6 (2.4 to 2.9)	3.2 (2.9 to 3.6)	1.01 (0.87 to 1.18)	
5 (least deprived)	19,397 (20.4)	1.5 (1.3 to 1.7)	2.8 (2.5 to 3)	3.5 (3.2 to 3.9)	1.08 (0.92 to 1.25)	
Ethnic background[d]						
White	83,451 (95.8)	1.4 (1.3 to 1.5)	2.7 (2.6 to 2.8)	3.3 (3.2 to 3.4)	Reference	0.08
Asian/Asian-British	2049 (2.4)	0.9 (0.5 to 1.3)	2.1 (1.6 to 2.9)	2.9 (2.0 to 4.1)	0.73 (0.51 to 1.05)	
Black/black-British	576 (0.6)	1.7 (0.9 to 3.0)	2.3 (1.3 to 3.7)	2.3 (1.3 to 3.7)	0.71 (0.42 to 1.19)	
Other	1057 (1.2)	0.9 (0.5 to 1.6)	1.9 (1.2 to 2.9)	2.8 (1.6 to 4.5)	0.73 (0.49 to 1.09)	
Missing (n = 7924, 8.3%)						
Route of mesh tape insertion						
Retropubic	60,194 (63.3)	1.6 (1.5 to 1.7)	3.0 (2.9 to 3.2)	3.6 (3.5 to 3.8)	Reference	< 0.001
Transobturator	34,863 (36.7)	0.9 (0.8 to 1.0)	2.2 (2.0 to 2.3)	2.7 (2.4 to 2.9)	0.72 (0.62 to 0.84)	
Comorbidities[e]						
None	76,252 (80.2)	1.4 (1.3 to 1.5)	2.7 (2.6 to 2.8)	3.3 (3.2 to 3.5)	Reference	0.37
1 or more	18,805 (19.8)	1.3 (1.1 to 1.5)	2.7 (2.4 to 2.9)	3.0 (2.7 to 3.3)	1.05 (0.94 to 1.17)	
Previous bulking injection						
No	94,349 (99.2)	1.4 (1.3 to 1.5)	2.7 (2.6 to 2.8)	3.3 (3.1 to 3.4)	Reference	0.36
Yes	709 (0.8)	0.7 (0.3 to 1.6)	3.0 (1.9 to 4.6)	3.3 (2.1 to 5.0)	1.21 (0.80 to 1.83)	
Previous other SUI procedure						
No	94,710 (99.6)	1.4 (1.3 to 1.4)	2.7 (2.6 to 2.8)	3.3 (3.1 to 3.4)	Reference	0.13
Yes	347 (0.4)	2.6 (1.3 to 4.7)	4.2 (2.4 to 6.8)	4.2 (2.4 to 6.8)	1.50 (0.89 to 2.52)	
Concurrent prolapse repair						
No	77,932 (82.0)	1.4 (1.3 to 1.4)	2.7 (2.6 to 2.8)	3.3 (3.1 to 3.4)	Reference	0.09
Repair with mesh	817 (0.9)	1.7 (1.0 to 2.8)	3.4 (2.3 to 4.9)	3.9 (2.6 to 5.6)	1.43 (0.98 to 2.08)	
Repair without mesh	16,308 (17.2)	1.4 (1.2 to 1.6)	2.7 (2.5 to 3.0)	3.3 (2.9 to 3.6)	1.07 (0.93 to 1.22)	
Specialist urogynecology unit						
No	75,695 (79.6)	1.3 (1.2 to 1.4)	2.6 (2.5 to 2.7)	3.1 (3.0 to 3.3)	Reference	0.17
Yes	19,362 (20.4)	1.7 (1.6 to 1.9)	3.2 (2.9 to 3.4)	3.8 (3.5 to 4.2)	1.17 (0.94 to 1.47)	

TABLE 7 Risk of mesh tape removal following initial MUT insertion (*continued*)

		Risk of removal[a] (%)				
	Number (%)	1 year (95% CI)	5 year (95% CI)	9 year (95% CI)	sdHR[b] (95% CI)	*p*-value[c]
Annual volume of mesh tape insertions in the unit per year						
< 60	28,939 (30.3)	1.3 (1.2 to 1.4)	2.5 (2.3 to 2.7)	3.0 (2.8 to 3.3)	Reference	0.21
60–119	44,228 (46.5)	1.4 (1.3 to 1.5)	2.7 (2.6 to 2.9)	3.4 (3.2 to 3.6)	1.07 (0.92 to 1.24)	
≥ 120	21,990 (23.1)	1.5 (1.3 to 1.6)	2.8 (2.6 to 3.0)	3.4 (3.1 to 3.7)	1.02 (0.82 to 1.28)	

a Cumulative incidence function and corresponding 95% CIs according to the time after initial insertion.
b The sdHRs were calculated with competing risks regression model (as detailed in Fine and Gray[69]) and adjusted for all patient and hospital factors in the table.
c The *p*-value was obtained from the Wald test.
d Ethnicity percentages were calculated for non-missing data.
e The number of comorbidities was derived from the RCS's Charlson Comorbidity Index.
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Mid-urethral mesh tape removal

Mid-urethral mesh tape was removed in 1.4% (95% CI 1.3% to 1.4%) of the women at 1 year, in 2.7% (95% CI 2.6% to 2.8%) at 5 years and in 3.3% (95% CI 3.2% to 3.4%) at 9 years after the initial insertion, accounting for the competing risk of death (see *Table 7* and *Figure 8*). The risk of removal was higher (at all time points) in women who had a retropubic insertion than in those who had a transobturator insertion (3.6% compared with 2.7% at 9 years after insertion; see *Table 7*). This difference remained after adjusting for other risk factors (sdHR for transobturator insertion: 0.72, 95% CI 0.62 to 0.84). The risk of MUT removal decreased with age (4.4% for women aged 18–39 years compared with 2.1% for women aged ≥ 70 years at 9 years after insertion; sdHR 0.46, 95% CI 0.38 to 0.56; see *Table 7*).

FIGURE 8 Mid-urethral mesh tape removal, reoperation for SUI and any reoperation by time from insertion. Reproduced with permission from Gurol-Urganci *et al.*[70] *JAMA* 2018;**320**(16):1659–69. Copyright © 2018, American Medical Association. All rights reserved.

Reoperation for stress urinary incontinence

Risk of reoperation for SUI was 1.3% (95% CI 1.3% to 1.4%) of the women at 1 year, 3.5% (95% CI 3.4% to 3.6%) at 5 years and 4.5% (95% CI 4.3% to 4.7%) at 9 years after the initial insertion, accounting for the competing risk of death (*Table 8* and *Figure 8*). The risk of reoperation for SUI was higher (at all time points) in women who had a transobturator insertion than in those who had a retropubic insertion (5.3% compared with 4.1% at 9 years after insertion; see *Table 8*), which remained after adjusting for other risk factors (sdHR for transobturator insertion, 1.31, 95% CI 1.14 to 1.51). A higher risk of reoperation for SUI was associated with having undergone a non-mesh continence procedure prior to the initial MUT insertion in this study [8.1% for women who had a bulking injection and 4.5% for women who did not (sdHR 1.74, 95% CI 1.32 to 2.29); 11.1% for women who had another non-mesh SUI continence procedure and 4.5% for women who did not (sdHR 2.60, 95% CI 1.85 to 3.65); see *Table 8*].

TABLE 8 Risk of reoperation for SUI following initial MUT insertion

	Number (%)	Risk of reoperation for stress urinary incontinence[a] (%)			sdHR (95%CI)[b]	*p*-value[c]
		1 year (95% CI)	5 year (95% CI)	9 year (95% CI)		
All: crude risk, *n/N* (%)		1252/90,215 (1.4)	2087/52,715 (3.9)	391/6981 (5.6)		
All: adjusted risk	95,057 (100)	1.3 (1.3 to 1.4)	3.5 (3.4 to 3.6)	4.5 (4.3 to 4.7)		
Age at initial surgery (years)						
18–39	10,292 (10.8)	1.1 (1.0 to 1.3)	3.3 (3.1 to 3.5)	4.5 (4.2 to 4.8)	Reference	0.29
40–49	33,094 (34.8)	1.3 (1.1 to 1.4)	3.4 (3.2 to 3.7)	4.2 (3.9 to 4.6)	0.91 (0.80 to 1.03)	
50–59	24,664 (26.0)	1.6 (1.4 to 1.8)	3.7 (3.4 to 4.1)	4.6 (4.2 to 5.0)	0.92 (0.81 to 1.05)	
60–69	16,877 (17.8)	1.7 (1.4 to 1.9)	3.8 (3.4 to 4.2)	4.3 (3.9 to 4.8)	1.00 (0.86 to 1.16)	
70 +	10,130 (10.7)	1.1 (1.0 to 1.3)	3.3 (3.1 to 3.5)	4.5 (4.2 to 4.8)	0.99 (0.83 to 1.18)	
IMD (quintiles)						
1 (most deprived)	16,136 (17.0)	1.3 (1.1 to 1.5)	3.5 (3.2 to 3.8)	4.2 (3.9 to 4.6)	Reference	
2	18,277 (19.2)	1.4 (1.2 to 1.5)	3.7 (3.4 to 4.0)	4.9 (4.5 to 5.4)	1.08 (0.96 to 1.23)	
3	20,468 (21.5)	1.3 (1.2 to 1.5)	3.5 (3.2 to 3.7)	4.3 (4.0 to 4.7)	0.99 (0.87 to 1.13)	
4	20,779 (21.9)	1.4 (1.2 to 1.5)	3.8 (3.5 to 4.1)	4.9 (4.5 to 5.3)	1.09 (0.94 to 1.26)	
5 (least deprived)	19,397 (20.4)	1.3 (1.1 to 1.4)	3.1 (2.8 to 3.3)	4.1 (3.8 to 4.5)	0.92 (0.78 to 1.09)	
Ethnic background[d]						
White	83,451 (95.8)	1.4 (1.3 to 1.4)	3.5 (3.4 to 3.7)	4.6 (4.4 to 4.8)	Reference	
Asian/ Asian-British	2049 (2.4)	0.8 (0.5 to 1.2)	2.5 (1.9 to 3.3)	3.1 (2.3 to 4.0)	0.74 (0.54 to 1.01)	
Black/ black-British	576 (0.6)	1.0 (0.4 to 2.1)	3.1 (1.8 to 4.9)	3.4 (2.0 to 5.3)	0.71 (0.46 to 1.10)	
Other	1057 (1.2)	0.8 (0.4 to 1.5)	2.4 (1.5 to 3.5)	2.8 (1.7 to 4.2)	0.70 (0.45 to 1.07)	

TABLE 8 Risk of reoperation for SUI following initial MUT insertion (*continued*)

	Number (%)	Risk of reoperation for stress urinary incontinence[a] (%)			sdHR (95%CI)[b]	p-value[c]
		1 year (95% CI)	5 year (95% CI)	9 year (95% CI)		
Missing (n = 7924, 8.3%)						
Route of mesh tape insertion						
Retropubic	60,194 (63.3)	1.2 (1.1 to 1.3)	3.1 (3.0 to 3.3)	4.1 (3.8 to 4.3)	Reference	< 0.001
Transobturator	34,863 (36.7)	1.5 (1.4 to 1.6)	4.1 (3.9 to 4.4)	5.3 (5.0 to 5.7)	1.31 (1.14 to 1.51)	
Comorbidities[e]						
None	76,252 (80.2)	1.3 (1.2 to 1.4)	3.4 (3.3 to 3.6)	4.5 (4.3 to 4.7)	Reference	0.35
1 or more	18,805 (19.8)	1.5 (1.3 to 1.7)	3.8 (3.5 to 4.1)	4.4 (4.0 to 4.8)	1.04 (0.95 to 1.14)	
Previous bulking injection						
No	94,349 (99.2)	1.3 (1.2 to 1.4)	3.5 (3.3 to 3.6)	4.5 (4.3 to 4.7)	Reference	< 0.001
Yes	709 (0.8)	2.9 (1.8 to 4.3)	6.9 (5.1 to 9.1)	8.1 (5.9 to 10.6)	1.74 (1.32 to 2.29)	
Previous other SUI procedure						
No	94,710 (99.6)	1.3 (1.2 to 1.4)	3.5 (3.3 to 3.6)	4.5 (4.3 to 4.7)	Reference	< 0.001
Yes	347 (0.4)	4.9 (3.0 to 7.6)	9.1 (6.3 to 12.6)	11.1 (7.8 to 15.1)	2.60 (1.85 to 3.65)	
Concurrent prolapse repair						
No	77,932 (82.0)	1.4 (1.3 to 1.4)	3.6 (3.5 to 3.7)	4.7 (4.5 to 4.9)	Reference	0.001
Repair with mesh	817 (0.9)	2.8 (1.9 to 4.2)	4.9 (3.5 to 6.6)	6.2 (3.9 to 9.3)	1.32 (0.94 to 1.84)	
Repair without mesh	16,308 (17.2)	1.1 (0.9 to 1.3)	3.0 (2.7 to 3.3)	3.7 (3.3 to 4.1)	0.80 (0.69 to 0.93)	
Specialist urogynecology unit						
No	75,695 (79.6)	1.3 (1.2 to 1.4)	3.5 (3.4 to 3.6)	4.5 (4.3 to 4.8)	Reference	0.84
Yes	19,362 (20.4)	1.4 (1.2 to 1.5)	3.5 (3.2 to 3.8)	4.4 (4.0 to 4.8)	1.02 (0.81 to 1.29)	
Annual volume of mesh tape insertions						
< 60	28,939 (30.3)	1.2 (1.1 to 1.4)	3.4 (3.2 to 3.6)	4.4 (4.1 to 4.8)	Reference	0.37
60–119	44,228 (46.5)	1.4 (1.3 to 1.5)	3.6 (3.5 to 3.8)	4.7 (4.4 to 4.9)	1.09 (0.96 to 1.24)	
≥ 120	21,990 (23.1)	1.3 (1.1 to 1.4)	3.4 (3.1 to 3.6)	4.3 (4.0 to 4.7)	1.03 (0.83 to 1.28)	

a Cumulative incidence function and corresponding 95% CIs according to the time after initial insertion.
b The sdHRs were calculated with competing risks regression model (as detailed in Fine and Gray[69]) and adjusted for all patient and hospital factors in the table.
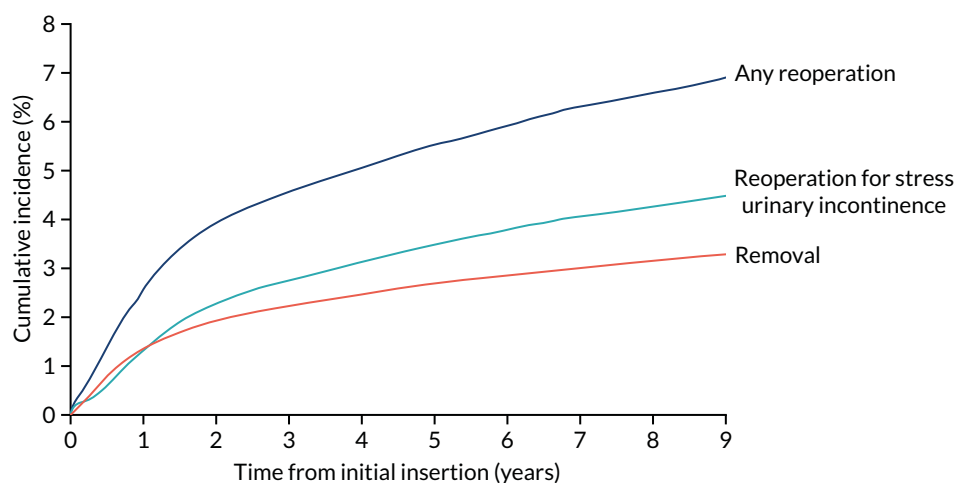c The *p*-value was obtained from the Wald test.
d Ethnicity percentages were calculated for non-missing data.
e The number of comorbidities was derived from the RCS's Charlson Comorbidity Index.

Any reoperation

The risk of any reoperation (i.e. mesh tape removal and/or reoperation for SUI) following the initial MUT insertion was 2.6% (95% CI 2.5% to 2.7%) at 1 year, 5.5% (95% CI 5.4% to 5.7%) at 5 years and 6.9% (95% CI 6.7% to 7.1%) at 9 years (*Table 9*). The risk of any reoperation was not statistically significantly different between initial retropubic or transobturator insertions (see *Table 9*).

TABLE 9 Risk of mesh tape removal or reoperation for SUI following initial MUT insertion

	Number (%)	Risk of any reoperation[a] (%)			sdHR (95%CI)[b]	p-value[c]
		1 year (95% CI)	5 year (95% CI)	9 year (95% CI)		
All: crude risk, n/N (%)		2415//90,215 (2.7)	3216/52,715 (6.1)	553/6981 (7.9)		
All: adjusted risk		2.6 (2.5 to 2.7)	5.5 (5.4 to 5.7)	6.9 (6.7 to 7.1)		
Age at initial surgery (years)						
18–39	10,292 (10.8)	3.1 (2.8 to 3.4)	6.3 (5.8 to 6.9)	8.3 (7.6 to 9.2)	Reference	0.01
40–49	33,094 (34.8)	2.5 (2.3 to 2.7)	5.4 (5.2 to 5.7)	7.1 (6.7 to 7.4)	0.86 (0.79 to 0.94)	
50–59	24,664 (26.0)	2.5 (2.3 to 2.7)	5.6 (5.3 to 5.9)	6.8 (6.4 to 7.2)	0.86 (0.78 to 0.95)	
60–69	16,877 (17.8)	2.5 (2.3 to 2.7)	5.4 (5.1 to 5.8)	6.6 (6.1 to 7.1)	0.83 (0.74 to 0.94)	
70 +	10,130 (10.7)	2.5 (2.2 to 2.9)	5.3 (4.9 to 5.8)	6.1 (5.5 to 6.7)	0.79 (0.68 to 0.91)	
IMD (quintiles)						
1 (most deprived)	16,136 (17.0)	2.5 (2.2 to 2.7)	5.5 (5.1 to 5.9)	6.6 (6.1 to 7.1)	Reference	0.13
2	18,277 (19.2)	2.7 (2.4 to 2.9)	5.8 (5.5 to 6.2)	7.3 (6.8 to 7.8)	1.08 (0.97 to 1.20)	
3	20,468 (21.5)	2.5 (2.3 to 2.7)	5.4 (5.0 to 5.7)	6.5 (6.1 to 7.0)	0.98 (0.88 to 1.08)	
4	20,779 (21.9)	2.6 (2.3 to 2.8)	5.7 (5.3 to 6.0)	7.2 (6.8 to 7.7)	1.05 (0.94 to 1.17)	
5 (least deprived)	19,397 (20.4)	2.6 (2.4 to 2.9)	5.3 (5.0 to 5.7)	6.9 (6.4 to 7.4)	1.00 (0.88 to 1.13)	
Ethnic background[d]						
White	83,451 (95.8)	2.6 (2.5 to 2.7)	5.6 (5.4 to 5.8)	7.0 (6.8 to 7.2)	Reference	0.01
Asian/ Asian-British	2049 (2.4)	1.5 (1.1 to 2.1)	4.3 (3.5 to 5.3)	5.4 (4.2 to 6.8)	0.75 (0.59 to 0.96)	
Black/ black-British	576 (0.6)	2.7 (1.6 to 4.2)	5.0 (3.4 to 7.1)	5.0 (3.4 to 7.1)	0.73 (0.51 to 1.05)	
Other	1057 (1.2)	1.7 (1.1 to 2.6)	3.9 (2.8 to 5.2)	5.2 (3.6 to 7.3)	0.74 (0.54 to 1.01)	
Missing (n = 7924, 8.3%) *Route of mesh tape insertion*						
Retropubic	60,194 (63.3)	2.7 (2.6 to 2.9)	5.5 (5.3 to 5.7)	6.8 (6.5 to 7.0)	Reference	0.61
Transobturator	34,863 (36.7)	2.3 (2.1 to 2.4)	5.7 (5.4 to 5.9)	7.2 (6.8 to 7.5)	1.03 (0.92 to 1.16)	
Comorbidities[e]						
None	76,252 (80.2)	2.5 (2.4 to 2.6)	5.5 (5.3 to 5.7)	7.0 (6.7 to 7.2)	Reference	0.22
1 or more	18,805 (19.8)	2.7 (2.5 to 2.9)	5.8 (5.4 to 6.1)	6.6 (6.2 to 7.1)	1.05 (0.97 to 1.13)	
Previous bulking injection						
No	94,349 (99.2)	2.6 (2.5 to 2.7)	5.5 (5.4 to 5.7)	6.9 (6.7 to 7.1)	Reference	0.001
Yes	709 (0.8)	3.6 (2.4 to 5.2)	8.9 (6.8 to 11.4)	10.3 (7.9 to 13.2)	1.55 (1.20 to 1.99)	
Previous other SUi procedure						
No	94,710 (99.6)	2.6 (2.5 to 2.7)	5.5 (5.4 to 5.7)	6.9 (6.7 to 7.1)	Reference	< 0.001
Yes	347 (0.4)	7.0 (4.6 to 10.0)	12.5 (9.2 to 16.3)	14.5 (10.7 to 18.8)	2.29 (1.66 to 3.14)	

TABLE 9 Risk of mesh tape removal or reoperation for SUI following initial MUT insertion (*continued*)

		Risk of any reoperation[a] (%)				
	Number (%)	**1 year (95% CI)**	**5 year (95% CI)**	**9 year (95% CI)**	**sdHR (95%CI)[b]**	***p*-value[c]**
Concurrent prolapse repair						
No	77,932 (82.0)	2.6 (2.5 to 2.7)	5.6 (5.4 to 5.8)	7.0 (6.8 to 7.3)	Reference	0.001
Repair with mesh	817 (0.9)	4.3 (3.1 to 5.9)	7.8 (6.0 to 9.8)	9.6 (6.9 to 12.8)	1.43 (1.09 to 1.87)	
Repair without mesh	16,308 (17.2)	2.4 (2.2 to 2.7)	5.2 (4.8 to 5.6)	6.3 (5.8 to 6.8)	0.92 (0.83 to 1.01)	
Specialist urogynecology unit						
No	75,695 (79.6)	2.5 (2.4 to 2.6)	5.5 (5.3 to 5.6)	6.8 (6.6 to 7.1)	Reference	0.37
Yes	19,362 (20.4)	3.0 (2.8 to 3.2)	5.9 (5.6 to 6.3)	7.2 (6.7 to 7.7)	1.08 (0.91 to 1.29)	
Annual volume of mesh tape insertions						
< 60	28,939 (30.3)	2.4 (2.2 to 2.6)	5.3 (5.0 to 5.6)	6.7 (6.3 to 7.1)	Reference	0.4
60–119	44,228 (46.5)	2.7 (2.5 to 2.8)	5.7 (5.5 to 6.0)	7.1 (6.8 to 7.4)	1.07 (0.96 to 1.20)	
≥ 120	21,990 (23.1)	2.6 (2.4 to 2.8)	5.5 (5.2 to 5.8)	6.8 (6.4 to 7.3)	1.02 (0.86 to 1.20)	

a Cumulative incidence function and corresponding 95% CIs according to the time after initial insertion.
b The sdHRs were calculated with competing risks regression model (as detailed in Fine and Gray[69]) and adjusted for all patient and hospital factors in the table.
c The *p*-value was obtained from the Wald test.
d Ethnicity percentages were calculated for non-missing data.
e The number of comorbidities was derived from the RCS's Charlson Comorbidity Index.
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Key findings

- The rate of MUT removal was 1.4% at 1 year, 2.7% at 5 years and 3.3% at 9 years.
- The 9-year removal risk after transobturator insertion (2.7%) was lower than the risk after retropubic insertion (3.6%).
- The rate of any reoperation, including mesh tape removal, was 2.6% at 1 year, 5.5% at 5 years and 6.9% at 9 years.
- The 9-year risk of any reoperation was not statistically significantly different after transobturator insertion (7.2%) or retropubic insertion (6.8%).

Chapter 7 Work package 3: women's perspectives on urinary incontinence and its treatment

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In this chapter, we explore the impact that UI has on women's lives and their expectations when surgery is perceived to be a treatment option.

The methods are described in detail in *Chapter 3*. Briefly, we collected women's own accounts of their experiences of UI and their expectation of surgical and non-surgical treatments in semistructured interviews. Women who were aged ≥ 18 years and had not had previous urological surgery were purposively sampled from four English urogynaecology outpatient clinics. We did not restrict the interviews to women with a specific subtype of UI. The semistructured interviews lasted approximately between 60 and 90 minutes. Transcripts of the interviews were analysed following a constant comparative method. Emerging themes from the interviews were followed up in more depth in subsequent interviews. Themes were then ordered into higher-level themes and hierarchies.

Twenty-eight women were interviewed from four urogynaecology outpatient clinics in different parts of England. They were categorised by age group and the overall age range was between 26 and 74 years (*Table 10*).

Women of similar ages drew on similar ideas and understanding of their bodies, their UI and the possibilities that surgery may bring. Women's decision-making around surgery at the time we interviewed them revolved around two key areas: their perceptions of the severity of their condition and their perception of the seriousness, or risk, of surgery. Both of these areas drew on common themes that spoke to women's wider experiences, values and concerns around their bodies: first, how their UI competed with other demands they needed to deal with in their everyday lives and, second, that surgery was regarded as a major intervention and perhaps unnecessary. Issues of age and ageing ran through these subthemes, cutting across the two fields of concerns around seriousness and resulting in arguments for and against surgical intervention in both fields.

How serious is my condition?

Women placed their management of UI symptoms and their contemplation of having surgery in relation to the competing demands on their time as mothers, daughters, partners, siblings and/or employees. To continue these roles and responsibilities as far as possible, all of the women interviewed had made substantial changes to their lives such as taking (and hiding) incontinence pads as they went about their day (sometimes having supplies at the houses of other family members); keeping changes of clothes at work or in their car; wearing loose, dark trousers or flowing skirts to hide any leaking;

TABLE 10 Characteristics of women interviewed

Characteristic	Number of women
Age group (years)	
20–39	6
40–49	4
50–59	7
60–69	6
≥ 70	5
Clinic attended	
Birmingham	14
Gillingham (Kent)	7
Leicester	7
Southampton	1

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and avoiding activities that might trigger urine loss (e.g. running or going on the trampoline with their children). As the circumstances of daily life changed, UI symptoms could also become more or less obvious:

> I feel like it's got worse, I feel like my bladder has got weaker, that I haven't been able to retain it as much. But I don't know whether that's because I'm more aware of it now because [name of daughter]'s that much older . . . Whereas when they're younger you're at home, you can go to the toilet that much easier.
>
> *Interviewee 26, 32 years old*

The management of UI in relation to everyday life also had an impact on how women regarded the pragmatics of having a potential operation. Timing both the surgery and the recovery time around childcare, caring for others and work (along with their sick leave options) were key concerns. Although taking time out of these roles might be seen as an investment in their future bodies, this was often hard to negotiate:

> I don't really want it [the operation]. But if I delay it, I'm getting older, whereas obviously, 40, almost 41, my youngest is 13 [years old], my oldest is 17 [years old], so at some point they're going to leave. I might as well enjoy the time now and be able to do more. Because we like to put the badminton net up in the garden. I can't play badminton, or go running, you know . . .
>
> *Interviewee 23, 40 years old*

Changes in life circumstances for some older women meant that they experienced reduced demands on their time and could now consider having surgery, which in the past they could not have done. One woman in her 60s talked about how, now that her husband's ill health had got better, she could attend to her own issues, whereas another said:

> . . . I did give up work, so it wasn't an issue to think, oh, crikey, I've got to get back to work. So, I felt that, all in all, I could cope with the operation.
>
> *Interviewee 5, 62 years old*

Finding time for surgery in relation to competing demands also depended on the extent to which women prioritised their UI and saw it as something that should be dealt with. For many women whose symptoms were very pronounced and had an impact on their lives in a dramatic way, it was easy to decide that something more intrusive than conservative treatments should be undertaken. However, for others, this step was less clear:

> . . . my problem doesn't feel bad enough to go for surgery . . . I really wanted to keep going with the physio [therapy] and try and sort it out that way. And I've been signed off physio[therapy] now because it just wasn't getting any better . . . they gave me this sheet explaining the surgery and the risks involved and things, and it feels like quite a hard decision to make, because I think if I had a really bad problem the risks would be worth taking . . . I feel the problem I've got, I've made some improvement but it's only going to get worse as I get older, and why not sort it out now rather than wait for another 10 years where it's really bad. It feels quite a difficult decision . . .
>
> *Interviewee 7, 51 years old*

Women across the age groups compared themselves with others they knew with similar symptoms, to try and contextualise the severity of their own condition. Although some women were not aware of others with similar problems, others talked about particular discussions and comparisons. Many women put their symptoms worsening as down to ageing, and comparisons were often drawn with others of a similar age:

> I've had the same peer group since I was a young girl, and my friends will go out and they don't have to take spare knickers in their bag in case they laugh on the dance floor or they trip over, or a sudden movement happens that they have an issue with incontinence. I run with my friends, and they don't have a problem, they can run for ages and ages.
>
> *Interviewee 11, 38 years old*

The cost of such surgery, not only in terms of their own bodies and time but also in terms of NHS resources, was also a concern expressed spontaneously, particularly by some older women. This led these women to question whether or not their current symptoms were worth such a major intervention, especially when this might just be part of 'normal' ageing:

> I suppose one of my issues around do I take any action around this is, is this a normal part of ageing, do I accept it, do other people accept it, is the problem I've got worse, or not as bad as other people? You don't know how to compare yourself with other people because it's not really talked about . . . I mentioned it to two people and they've both said, well they implied, that it's something you just accept with age.
>
> *Interviewee 6, 66 years old*

Drawing on the lives and experiences of others to find out what was a 'normal' amount and frequency of urine loss allowed women of different ages to make a judgement about how severe their symptoms were and, therefore, whether or not they should consider surgical interventions. However, combining this with the other demands on their time, and the extent to which they were able to deal with their symptoms in everyday life, made different types of surgery more or less possible.

How serious is surgery?

In addition to drawing on the experiences of others and their own life circumstances to evaluate the seriousness of their UI condition, women's considerations about surgery were also shaped by hearing about other people's experiences of having the procedure for the same symptoms:

> My sister and one of my best friends who I worked with, they've both had their bladders done . . . my sister now, she's back out there and doing things. And I go, I want to be like my sister . . . My mate, she paid private rather than wait. 'Cause we didn't know about this. We were all just taking tablets, didn't know you could have an operation for it.
>
> *Interviewee 16, 50 years old*

Without having experienced UI surgery themselves, women across the age groups drew on a range of different sources of information to try to anticipate the impact that such surgery would have on their bodies, on their time and in relation to their other roles and responsibilities. Mentioning the stigma associated with UI, a number of women of all ages referred to the fact that the symptoms of, and surgery for, UI were not often talked about and so because they did not know other women with the same issue directly, it was difficult to understand what was 'normal' and what surgery might be like. A few women had researched online for reports of what UI surgery might be like, or looked for news articles or radio or TV programmes that might mention this, although others made a conscious decision not to do this:

> I don't want to fill my head with what might happen . . . I don't want to be like, oh, so, if mine is different, what have I got then? I try not to, I just get the leaflets from the physio lady or from my doctors and I really try not to go on Google or research it myself.
>
> *Interviewee 10, 26 years old*

In relation to the procedure itself, it was more common for women to draw on their own previous experiences of surgery for other conditions to guess what surgery for UI might be like; some were concerned about repeating negative experiences, whereas for others recalling past surgical experiences was reassuring:

> . . . it doesn't bother me at all because I know what I'm going in to . . . it's just like when I came out of my hysterectomy they said, right, okay, you can't do anything for 6 weeks, and I'm like, what does that mean, you know? . . . from that point of view I feel more prepared almost, so, not that you ever are for surgery, but I do feel more prepared.
>
> *Interviewee 15, 36 years old*

Embedded in many of these accounts was the idea that the surgery was always a significant intervention that not only required time to recover from, but also might put the body under great strain. A number of women talked about how their body found it hard to recover from general anaesthetic or being sutured. Such thinking focused on the fact that an operation always puts the body at risk, rather than the possible longer-term outcomes or chances of success. Nonetheless, the specifics of how this particular surgery would be performed on an intimate area of their anatomy was a particular concern for some women, as one woman explained:

> I thought they will [use] keyhole [surgery] or [go] through the stomach or something. I didn't think they would actually be doing it through the vagina. So, obviously anything to do with your private area you're going to be a bit nervous about. It's something completely different that, the only person that's ever been there is when I've had children.
>
> *Interviewee 10, 26 years old*

The overall point is that risks and fears around surgery, and particularly surgery around such intimate areas, were already present for women outside any discussion around the use of mesh. As the study progressed, issues around the mesh controversy were sometimes spontaneously raised, but they never dominated the interviews. In some of the later interviews, women talked about how they, or others in their family, had heard about the mesh controversy. However, the women were rarely clear whether or not this might relate to the surgery that they were considering, and there were always many other factors to take into account:

> . . . I've got an 8-year-old, I'm busy, and I didn't want, and also I had read a bit about the controversy about the sling that's been in the papers and stuff in the last year or so, so I opted just to get the injections.
>
> *Interviewee 21, 46 years old*

Another woman balanced if she might have problems with the mesh with the necessity of the operation, and had decided not to proceed:

> . . . after reading all that in the Daily Mail [a British tabloid newspaper, London], I'm not sure how much of it is true, and whether they don't know until you have the operation if you're going to be allergic to that mesh . . . it's not life-threatening this. If it was life-threatening I wouldn't have a choice, but I have got a choice.
>
> *Interviewee 12, 74 years old*

The perception of surgery as a serious and dramatic intervention led a number of women to describe trying to find ways to avoid surgery; despite surgery being raised as a possibility, one woman wondered:

> Perhaps if I carry on with my exercises I might . . . you know, I might be OK.
>
> *Interviewee 8, 71 years old*

Given the nature of our interview cohort of women, conservative treatments, by definition, had largely not been successful. Some women were nevertheless hopeful that continuing with these approaches might eventually prove effective. This subgroup of women, therefore, found it particularly difficult to decide whether or not to have surgery, because the decision had to be made not merely on the clinical information they were given, but also the hope that they held on to that a non-surgical intervention might work in the future. Some women talked about the need to encourage younger women to start pelvic floor exercises earlier and a couple of women had mentioned this to their daughters. The idea behind this was both that muscle strength might be maintained and that early issues could be stopped from developing, particularly if they came after childbirth:

> I think I'd let it go too far . . . I think perhaps the pelvic floor exercises would have worked but I'd left it too long.
>
> *Interviewee 19, 54 years old*

Ageing, and the changes to the body and everyday life that this might bring, was a key aspect that crossed different themes from the interviews. This related not only to the ideas of the ageing body across women's accounts and where the body should be at particular ages, but also to different experiences that women of different ages had and how UI symptoms and surgery fitted into their daily lives. This resulted in greater clarity about whether or not to have surgery and what type to have for some women. However, many of the women interviewed were as yet undecided about surgery.

Key findings

- Women have two key concerns when they make decisions about whether or not to have surgical treatment for their incontinence: perceptions of the severity of their condition and perceptions of the seriousness, or risk, of surgery.
- Women assessed the severity of their UI according to their individual circumstances rather than criteria such as frequency or quantity of leakage. Women moved the concept of 'severity' beyond a medical definition of UI to include what is important to them as individuals.
- For women with UI, decision-making about surgical treatment is a distributed process based on multivariate criteria, which often shift in priority over time. As a consequence, decisions are rarely made conclusively.

Chapter 8 Work package 5: clinicians' decision-making for recommending surgical treatment for female stress urinary incontinence

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In this chapter, we present the findings from WP 5, which addresses objective 4 and explores variation in treatment advice by clinicians for women with SUI using case vignettes.

The methods are described in detail in *Chapter 3*. Briefly, we conducted an online survey of all members of the BSUG and members of the RCOG who indicated that they had specialist interest in urogynaecology at the time of their RCOG registration ($n = 1139$). The survey comprised 18 case vignettes that described the clinical profile of hypothetical women referred to secondary care for further assessment and management of their SUI. Each case profile comprised a short patient description according to seven patient characteristics. Clinicians were then asked to score their recommendation on whether or not they would recommend surgery for this patient on a five-point Likert scale ranging from 'certainly yes' to 'certainly not'. We used descriptive statistics to summarise the characteristics of the responding clinicians. We calculated the means of the response scores and the 25th and 75th percentiles to describe the recommendations of the clinicians for each of the 18 case vignettes. We used a mixed-effects analysis of variance model to test the statistical significance of differences in the clinicians' recommendation scores according to level of the patient characteristics. Latent class analysis was used to determine if mutually exclusive groups of clinicians ('latent classes') could be identified whose recommendations suggested a similar practice style.

In total, 334 gynaecologists participated in the survey, of whom 245 (73.4%) fully completed the questionnaire. Of the 245 gynaecologists, 56.7% were male and 55.9% indicated that urogynaecology was their main specialty area (*Table 11*).

Recommendations for surgery

Figure 9 shows the variation in the recommendation scores of all clinicians for the 18 case profiles. The IQR was between 2 and 4 on the 5-point scale for 11 of the 18 vignettes. The scores were most strongly in favour of recommending surgery for case 5 (a 68-year-old woman with a BMI of 30 kg/m², pure SUI and no previous SUI surgery, with leakage several times a day, for whom her incontinence is quite a problem, and ASA grade 2) and most strongly against recommending surgery for case 6 (a 68-year-old woman with a BMI of 23 kg/m², with MUI, previous SUI surgery, leakage once a day, for whom her incontinence is a bit of a problem, and ASA grade 3).

Impact of women's characteristics on gynaecologists' recommendations

Figure 10 demonstrates the impact that the patient characteristics have on the clinicians' recommendations. Overall, the impact that the patient characteristics have was relatively small. UI type had the greatest

TABLE 11 Characteristics of clinicians responding and mean recommendation scores

Characteristic	Number of clinicians responding	% of total	Mean recommendation score (SD)[a]
Total	245	100	2.87 (1.28)
Gender			
Female	106	43	2.88 (1.26)
Male	139	57	2.86 (1.30)
Age category (years)			
< 45	85	35	2.88 (1.27)
45–54	84	34	2.87 (1.30)
≥ 55	76	31	2.85 (1.27)
Clinical specialty			
Gynaecology	108	44	2.83 (1.27)
Urogynaecology	137	56	2.90 (1.29)
Trainee			
No	212	87	2.86 (1.29)
Yes	33	13	2.91 (1.24)
Country of practice			
England	212	87	2.86 (1.28)
Northern Ireland	11	4	2.75 (1.13)
Scotland	15	6	3.03 (1.34)
Wales	7	3	2.90 (1.34)

a   Mean score on a five-point scale ranging from 1 = 'certainly not' to 5 = 'certainly yes'.

impact (i.e. a mean difference in recommendation score for women with SUI and MUI of 0.8, weight = 23%; see *Chapter 3*), closely followed by the impact of previous SUI surgery (weight = 21%) and, to a lesser extent, the frequency of leakage (weight = 15%) and BMI (weight = 15%). Extent of bother (weight = 13%), physical status (as assessed via the ASA grade) (weight = 8%) and age (weight = 6%) had the least influence on the clinicians' recommendations. The mixed-effects analysis of variance indicated that all patient characteristics captured in the vignettes significantly influenced the recommendation score (i.e. the *p*-value was always < 0.001).

Impact of clinicians' characteristics on their recommendations

The average recommendation scores did not differ significantly by clinicians' gender, age, specialty or trainee status (*Table 12*). In addition, there were no statistically significant differences between the scores of clinicians in England, Scotland, Wales and Northern Ireland. Using the mixed-effects model, we did not find any evidence that the relative influence of the patient characteristics on the recommendation scores varied according to the clinician's characteristics (i.e. the *p*-value of the interaction test for specialty, gender and age was always > 0.05).

Additional analyses found that six clinicians gave a recommendation score of 1 ('certainly not') to all 18 vignettes. However, excluding the responses of these six clinicians had only a slight impact on the mean recommendation scores and weights associated with the patient characteristics.

Case	Age (years)	BMI (kg/m^2)	Nature of SUI	Previous SUI surgery	Leakage	Bother	ASA grade
1	55	36	MUI	MUT	Several times a day	A serious problem	2
2	79	36	SUI	MUT	About 2 or 3 times a week	Quite a problem	3
3	68	36	Stress-predominant MUI	BNI	About 2 or 3 times a week	A serious problem	2
4	55	23	Stress-predominant MUI	MUT	Several times a day	Quite a problem	2
5	68	30	SUI	None	Several times a day	Quite a problem	2
6	68	23	MUI	MUT	About once a day	A bit of a problem	3
7	79	23	SUI	BNI	Several times a day	A serious problem	3
8	79	36	MUI	None	About once a day	Quite a problem	2
9	55	36	SUI	BNI	About once a day	A bit of a problem	2
10	79	30	MUI	BNI	Several times a day	A bit of a problem	2
11	55	30	MUI	None	About 2 or 3 times a week	A serious problem	3
12	79	30	Stress-predominant MUI	MUT	About 2 or 3 times a week	A bit of a problem	2
13	55	23	SUI	None	About 2 or 3 times a week	A bit of a problem	2
14	68	30	SUI	MUT	About once a day	A serious problem	2
15	55	30	Stress-predominant MUI	BNI	About once a day	Quite a problem	3
16	68	36	Stress-predominant MUI	None	Several times a day	A bit of a problem	3
17	79	23	Stress-predominant MUI	None	About once a day	A serious problem	2
18	68	23	MUI	BNI	About 2 or 3 times a week	Quite a problem	2

	1	2	3	4	5
	Certainly not	Probably not	Not sure	Probably yes	Certainly yes

FIGURE 9 Surgical treatment recommendations of the clinicians for the 18 clinical case profiles. The recommendations are scored on a five-point Likert scale ranging from 'certainly not' to 'certainly yes'. The range plots (horizontal bars) represent the 25th and the 75th percentile of the mean recommendation score. BNI, bladder neck injection. Reproduced with permission from Mamza et al.[72] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/.

Characteristic	Levels		Importance weight
Age (years)	55		6% $p=0.001$
	68		
	79		
BMI (kg/m²)	23		15% $p=0.001$
	30		
	36		
Nature of SUI	SUI		23% $p=0.001$
	Stress-predominant MUI		
	MUI		
Previous SUI surgery	None		21% $p=0.001$
	Bladder neck injection		
	Mid-urethral tape		
Frequency of leakage	About 2 or 3 times a week		15% $p=0.001$
	About once a day		
	Several times a day		
Bother	A bit of a problem		13% $p=0.001$
	Quite a problem		
	A serious problem		
Physical status	ASA grade 2		8% $p=0.001$
	ASA grade 3	Overall mean = 2.87	
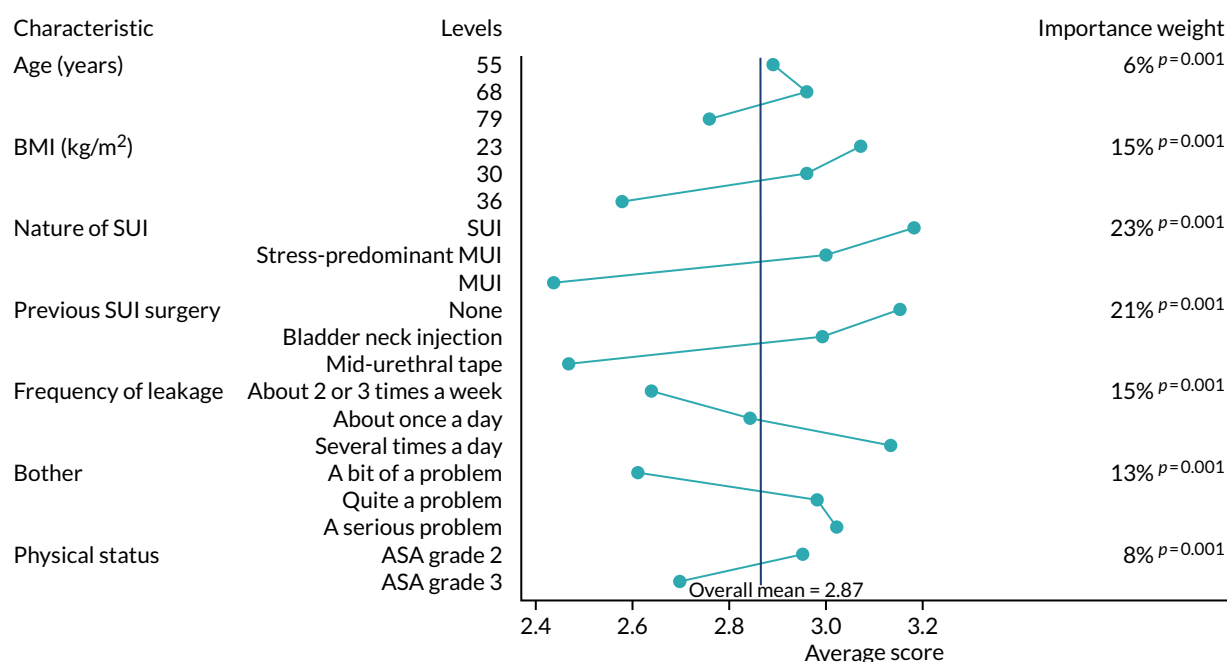
FIGURE 10 Influence of patient characteristics on clinicians' recommendation for surgical treatment. The recommendations are scored on a five-point Likert scale ranging from 'certainly not' to 'certainly yes'. Average score based on responses to a 5-point scale ranging from 1 'certainly not' to 5 'certainly yes'. Reproduced with permission from Mamza et al.[72] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/.

TABLE 12 Characteristics of clinicians according to their 'practice style group' derived from the latent class analysis

Characteristic	All	Group					p-value
		1	2	3	4	5	
Number of clinicians	244	17	85	52	69	21	
Mean recommendation score[a]	2.87	1.25	2.47	3.10	3.24	4.04	< 0.001
Gender, n (%)							0.77
Female	105 (43.0)	6 (35.3)	41 (48.2)	22 (42.3)	27 (39.1)	9 (42.9)	
Male	139 (57.0)	11 (64.7)	44 (51.8)	30 (57.7)	42 (60.9)	12 (57.1)	
Age category (years), n (%)							0.60
< 45	71 (29.1)	4 (23.5)	28 (32.9)	11 (21.2)	23 (33.3)	5 (23.8)	
45–54	97 (39.8)	10 (58.8)	30 (35.3)	24 (46.2)	24 (34.8)	9 (42.9)	
≥ 55	76 (31.1)	3 (17.7)	27 (31.8)	17 (32.7)	22 (31.9)	7 (33.3)	
Specialty, n (%)							0.14
Gynaecology	107 (43.9)	5 (29.4)	43 (50.6)	19 (36.5)	34 (49.3)	6 (28.6)	
Urogynaecology	137 (56.1)	12 (70.6)	42 (49.4)	33 (63.5)	35 (50.7)	15 (71.4)	
Trainee, n (%)							0.55
No	211 (86.5)	16 (94.1)	75 (88.2)	45 (86.5)	56 (81.2)	19 (90.5)	
Yes	33 (13.5)	1 (88.2)	10 (11.8)	7 (13.5)	13 (18.8)	2 (9.5)	

a Mean score on a 5-point Likert scale ranging from 1 = 'certainly not' to 5 = 'certainly yes'.
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Gynaecologists' practice styles

The latent class analysis identified five mutually exclusive groups of clinicians with a different practice style. The AIC and BIC decreased as more latent classes were added, but levelled off after five latent classes. In total, 244 of the 245 respondents could be assigned to a practice style group (see *Chapter 3*). The mean recommendation scores for the five practice style groups ranged from 1.25 to 4.04 ($p < 0.001$), illustrating wide variation in clinicians' inclination to recommend surgical treatment (see *Table 12*). There were no statistically significant differences in clinicians' characteristics between the five groups.

Compared with the differences in overall inclination to recommend surgical treatment between the practice style groups, the impact of the women's characteristics on clinicians' recommendation scores is small (*Figure 11*). The largest differences are observed for practice style groups 2 and 3, which appeared to give a greater weight to BMI, type of SUI and previous SUI surgery than the clinicians in the other practice style groups.

Key findings

- The type of UI (SUI, stress-predominant MUI or mixed UI) was the most important determinant of gynaecologists' decisions to recommend surgical treatment, followed by previous SUI surgery (none, bladder neck injection, MUT).
- Five groups of gynaecologists whose practice style differed mainly with respect to their mean recommendation score could be distinguished.
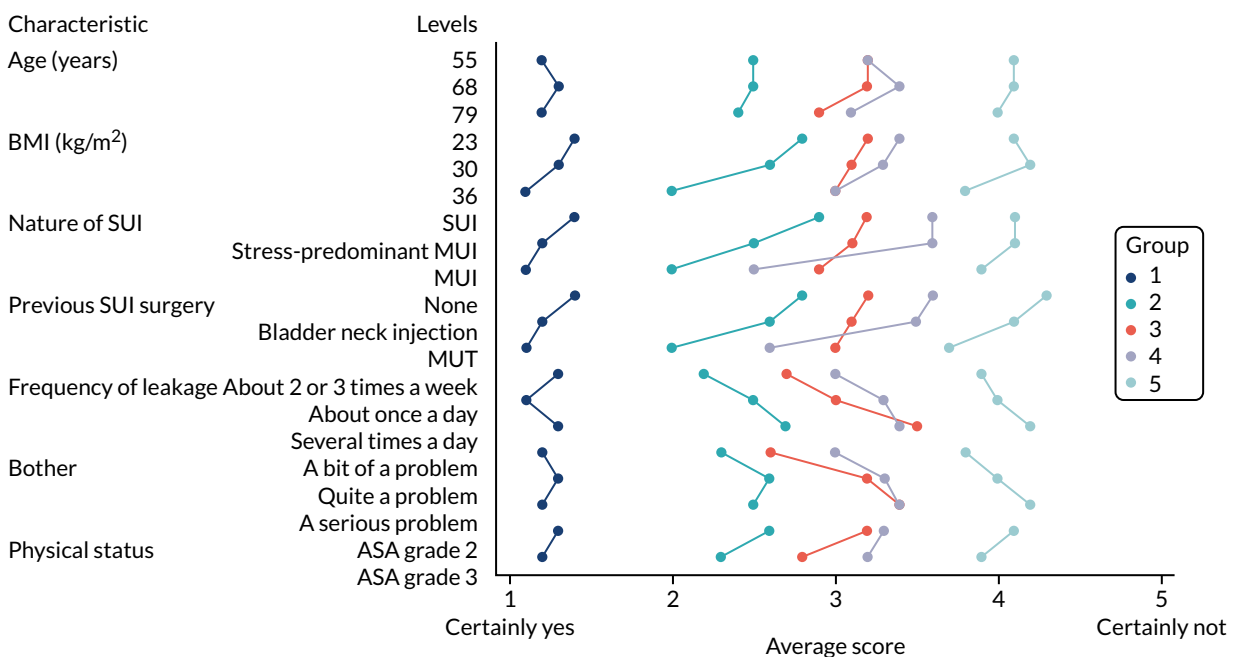
FIGURE 11 Influence of patient characteristics on clinicians' recommendations for surgical treatment according to practice style group. The recommendations are scored on a five-point Likert scale ranging from 'certainly not' to 'certainly yes'. Reproduced with permission from Mamza *et al.*[72] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/.

Chapter 9 Discussion

In this project, we set out to understand the drivers of variation in the use of surgery for women with UI in England. We combined patient-level administrative health-care databases with general practice and hospital-level information to explore women's UI care pathway. We also used information collected from women with UI and gynaecologists to understand their decision-making in relation to surgery for UI. In this chapter, we first discuss the results of each of our objectives in the context of the literature. We then describe the main limitations and suggest further research.

The aim of this project was to improve the delivery of surgical care for women with UI. Although surgical care refers to all surgical approaches and invasive procedures for all subtypes of UI, there is a focus, in some WPs, on SUI and surgical treatments with MUT insertion for this type of UI because SUI is the most common form of UI and > 95% of UI procedures conducted are SUI procedures. In our summary of the results of each WP below, we define which patient group the results relate to.

Changing context

The data used in this project capture a period of substantial change in surgical treatment for UI. MUTs were introduced in 1998 as a new, minimally invasive surgical treatment for SUI.[23] The use of MUTs rose precipitously and reached a maximum of 11,365 procedures in 2009 in England, becoming almost the sole surgical treatment conducted for SUI. At the same time, the use of the previous standard treatment for SUI, colposuspension (a major abdominal surgery), declined from > 3500 procedures per year to just 200.[20] However, the use of MUTs for SUI has since rapidly declined in the England (and elsewhere), with a 50% reduction between 2008 and 2017 (to just 6227 procedures in 2016–17).[21] This highlights a change in surgical practice that is likely to reflect growing public concerns about longer-term complications, outcomes and risk of further surgery after these MUT procedures.[21–26] In 2018, the use of MUTs as a treatment for female SUI was 'paused' in the NHS in England, following an interim recommendation of the Independent Medicines and Medical Devices Safety Review.[73,74]

Project overview

This project used five different approaches:

1. We analysed existing NHS data sets from primary care (CPRD) and secondary care (HES) to understand the determinants of referral of women with UI to secondary care as well as the determinants of the use of surgical treatment in women with UI, which were mainly SUI procedures (predominantly MUT insertions) (WPs 1 and 4).
2. We analysed an existing NHS data set from secondary care (HES) to understand geographical variation in the use of surgical treatment in women with SUI (WP 2).
3. We collected accounts from women who had been referred to an outpatient clinic in secondary care about the impact of UI on their lives and their expectations of surgical and non-surgical treatments (WP 3).
4. We carried out a national survey of gynaecologists in the UK with a special interest in urogynaecology to understand better how their decisions to recommend surgical treatment are influenced by the characteristics of women with UI (WP 5).
5. In response to the discussions about the safety of MUT insertions, we conducted supplementary work to assess long-term removal and reoperation rates after MUT insertion for SUI using the HES data set (additional WP – WP 6).

Brief overview of findings

There were a number of key findings.

With respect to WPs 2 and 4, which aimed to assess the determinants of referral to a UI specialist and surgery for women with UI (WP 4) and variation in the rate of surgery for SUI and determinants of this variation between NHS CCGs and other regional units (WP 2):

- Our analyses of primary care data demonstrated that almost 50% of women who were diagnosed with UI by their GP between 2004 and 2014 were referred to a UI specialist in the 9 years after the UI was first recorded. Almost 60% of those women who were referred were referred within the first 30 days. The referral rate was lower in older women, in women from a minority ethnic background and in women who were either underweight or severely obese. We also found considerable geographical variation.
- In addition, using primary care data linked to secondary care data we found that 7.3% of women who were referred to a UI specialist between 2004 and 2014 had surgical treatment for UI within 1 year and 18.1% within 9 years. Of the 4307 UI procedures conducted, 4050 (94.5%) were SUI procedures and 257 (5.5%) were UUI procedures. Of the SUI procedures, 89% ($n = 3606$) were MUT insertions. Again, we found that UI surgery rates were lower in older women, in women from a minority ethnic background, and in women who were either underweight or severely obese. There was also considerable regional variation in the use of surgery.
- Between 2013 and 2016, the overall rate of SUI surgery was 40 per 100,000 women per year in the NHS England (WP 2). There was substantial variation in rates between geographic regions with adjusted surgical rates ranging from 20 to 106 procedures per 100,000 women per year between CCGs and from 24 to 69 procedures per 100,000 women per year between STPs. Annual SUI surgery rates per 100,000 women per year declined over the study period from 52 in 2013 to 36 in 2015. Regional age and ethnicity distributions were associated with surgery rates.

With respect to WP 3, which aimed to explore women's experiences of UI and their expectations of surgical and non-surgical treatments and outcomes:

- The interviews demonstrated that women's decision-making centred on perceptions of the severity of their UI and the seriousness, or risk, of surgery.
- Women judged the severity of their UI according to their individual circumstances rather than criteria such as quantity and frequency of leakage, which are often used clinically. The women's accounts moved the concept of 'severity' beyond the commonly used medical definitions of UI severity to include what is important to women themselves.
- Decisions about surgery were rarely made conclusively. Decision-making about surgery is a distributed process based on multivariate criteria, which often change in priority over time.

With respect to WP 5, which aimed to explore the relative importance of specific patient characteristics for clinicians in their treatment recommendations:

- The survey of gynaecologists in the UK, asking them whether or not they would recommend surgery for women with UI described in a series of clinical case vignettes, demonstrated that the decisions of the 245 gynaecologists were most strongly determined by the subtype of UI (stress, stress-predominant or mixed UI) and whether or not a patient had undergone previous SUI surgery (none, bladder neck injection or MUT).
- Five distinct groups of gynaecologists could be distinguished whose practice style differed mainly with respect to their average inclination to recommend surgery.

With respect to the additional WP on long-term removal and reoperation rates after MUT insertion:

- The overall 9-year mesh tape removal rate was 3.3% and the reoperation rate, including mesh tape removal, was 6.9%.
- The 9-year removal rates were 3.6% after a retropubic insertion and 2.7% after a transobturator insertion.
- The 9-year reoperation rates were 6.8% after a retropubic insertion and 7.2% after a transobturator insertion.

Discussion

Variation in practice

There is considerable geographical variation in the rate of surgery for women with SUI. This variation suggests that women in some areas are more likely to be treated than women with the same condition in other areas. We found that adjusting for regional characteristics that may influence demand for treatment reduced only the observed geographical variation in rates of surgery for SUI slightly.

The rates of surgical treatment for SUI were lower in areas with older populations. This agrees with findings for other aspects of continence care that the management of UI is different in older people.[75] Although surgical treatments for SUI are considered to be safe and effective in older women,[76] these procedures are performed less frequently than in younger women.[30,77]

The overall rate of SUI surgery dropped by one-third over the 3-year study period, whereas the extent of geographic variation remained stable. The variation is likely, in part, to reflect differences in professional opinion about the appropriateness of these surgical treatments for SUI, in the context of the debate about the safety of MUT surgery, before the 'pause' in their use in 2018.

This variation in the use of surgery may partly originate in the limited involvement of primary care for some women. We found that a relatively large proportion of women, about one in two, who have a diagnosis of UI recorded in primary care were referred to secondary care and about 60% of these referrals occurred within 1 month of the diagnosis first being recorded. This demonstrates that much of the care for women with UI is provided in secondary care.

Some of the variation may reflect how physiotherapy for UI, in particular pelvic floor muscle training, is accessed in different regions, which may be through referral to urogynaecology in secondary care, or through direct referral from a GP to a physiotherapist. Updated guidelines from the National Institute for Health and Care Excellence[19] (NICE) recommend that women are offered:

> *a trial of supervised pelvic floor muscle training of at least 3 months' duration as first-line treatment . . .*
> *for stress or mixed urinary incontinence.*
>
> *© NICE 2019* Urinary Incontinence and Pelvic Organ Prolapse in Women: Management. *Available*
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This recent guideline may change referral patterns in the future because pelvic floor muscle training can be provided in primary care.

Age and ethnicity were strongly associated with both referral to a UI specialist and surgical treatment after referral. Of women seeking primary care for their UI, older women and those from minority ethnic backgrounds were much less likely to be referred to a specialist than younger women and white women.

Referral rates were also lower in women who had a POP diagnosis, possibly because they had already been referred in the past for this diagnosis.

Among women referred, older women were also much less likely to have received surgical treatment. This adds to a body of evidence that older women are less likely to receive continence care than younger women.[30,31,78] Taken together, our findings suggest that potential deficiencies in continence care occur along the whole care pathway (from primary to secondary care) for older women, the group among whom UI is most prevalent.

Lifestyle changes may be recommended in primary care for women with UI who also smoke or are obese and we observed referral rates that were correspondingly lower among these groups than for non-smokers and those with a BMI in the normal range.[19] Our findings indicate that even among those women referred, differences in surgical treatment according to smoking status and BMI persist. This may reflect lifestyle changes also being recommended in secondary care, which for some women may result in possible delays in surgical treatment.

Surgery rates varied substantially by region and these variations remained after adjustment for individual-level factors likely to affect women's preferences. However, women's preferences will also be strongly guided by the advice they receive from their clinicians, which may have varied by region, particularly in the context of the debate around the safety of MUT procedures that was ongoing at the time from which the data are drawn. Differences in referral rates between England, Scotland, Wales and North Ireland may reflect the differences in how care is being delivered, especially with respect to the threshold for referral to secondary care.

Women presenting in primary care represent the 'tip of the iceberg' in terms of those affected by UI, as it has been found that only 25% of women with UI seek care.[9] However, the women included in all our analyses had all sought care in primary care. Once they have sought primary care, these same groups of women experience differences in rates of referral and of UI surgery that may indicate clinical uncertainty among GPs and secondary care UI specialists about the appropriateness of referral or surgery, differences in women's preferences for more or less conservative treatment and expectations for improvement or cure, or inequities in the use of referral or surgery. An ageing population coupled with rising prevalence of UI with age means that the number of women who experience UI and could benefit from care is likely to increase over time, increasing the importance of addressing inequalities in continence care.

Women's own accounts

Our results demonstrate that women's decision-making in relation to surgery centred on their individual perceptions of the severity of their UI and the risk of surgery. This reflects findings of previous research; for example, it has been suggested that only around half of older people seek help for UI, commonly because of the belief that it is a 'normal' part of ageing.[40,79] Some women questioned whether or not their symptoms justified the cost of surgical treatment to the NHS.

In addition, differences in the treatment of UI received by older women and women from minority ethnic backgrounds may reflect differences their incontinence-related health beliefs, preferences and care-seeking behaviour.[33,41,80–82] It has also been reported that women from Asian backgrounds in particular are less likely to seek care because of sociocultural norms and related embarrassment, particularly in relation to discussing sensitive problems with male health-care providers.[83,84]

Clinical recommendations about treatments for UI frequently involve considering severity in terms of the quantity and frequency of leakage. However, we found that women judge the severity and impact of their UI from a much broader set of criteria, ranging from personal bodily experiences to how

extensively the condition disrupts their social roles and daily lives, as well as the ideas, opinions, and experiences of others. Two different women with the same quantity and frequency of leakage can experience UI as having very different levels of severity and impact on their daily lives. Acknowledging this in the process of shared decision-making around treatment, including surgery, provides an important opportunity to ensure that discussions and treatment decisions reflect women's own lives and experiences in personalising medicine.

Women's perceptions and decisions were open to new information and changing circumstances. The ideas, opinions and experiences of others were important to women's treatment decision-making process. The 'unfinished', flexible nature of this decision-making and the growing publicity of safety concerns relating to MUT procedures had the potential to increase uncertainty in women's decisions regarding surgery.

Recommendations of gynaecologists on surgical treatment

The study using clinical case vignettes showed that five groups of clinicians could be distinguished who differed in 'practice style', especially in their average inclination to recommend surgical treatment. These results reflect that some gynaecologists recommend surgery to many of their patients, whereas others would hardly recommend it to anyone. The recommendations for surgical treatment were only minimally influenced by patient characteristics.

In our clinical case vignettes, we included patient characteristics that can be derived only from patient-reported information (frequency of leakage and bother) and those that are derived from information determined by the clinicians (type and severity of UI, previous surgery). We found that the weights assigned to the clinician-derived characteristics had a stronger combined influence on the gynaecologists' recommendations than the patient-reported characteristics. It is important to note that the clinician-derived characteristics describe the severity and type of the UI that have a recognised impact on the effectiveness of specific surgical treatments.[85]

We found that a woman's age and BMI had relatively little impact on clinicians' recommendations for surgical treatment, which is in line with evidence that surgical treatments are effective in obese and elderly patients.[76,86–89] This finding contrasts with that from our linked primary and secondary care data study, where we observed that older women and those who were obese were less likely to have received surgical treatment. However, it is also generally accepted that clinical decision-making is more complex for these groups given that their overall health and functional status may be poorer.[89]

Removal and reoperation rates after mid-urethral mesh tape insertions

More than 95,000 women had a MUT insertion for SUI between 2006 and 2016. Within 9 years of MUT insertion, 1 in 30 women had undergone a removal procedure and 1 in 14 had undergone a reoperation, including mesh tape removal.

Risks of removal and any reoperation (mesh tape removal and/or reoperation for SUI) were lower among older women and among women from a minority ethnic background. This suggests that removal and reoperation risks may be associated with women's background. However, it is not possible to disentangle potential explanations for these differences, which could include higher morbidity, differences in the severity of the underlying UI that led to the initial surgery and women's choices about seeking further clinical advice and treatment.

The risk of a removal was about 30% lower following transobturator MUT insertions than following retropubic MUT insertions, which is in line with earlier findings from Scotland and England.[90,91]

This may be explained by the removal of transobturator sling being a more complicated procedure.[19] Recently issued NICE guidelines on the management of urinary incontinence in women[19] therefore recommend that the transobturator approach should no longer be offered:

> unless there are specific clinical circumstances (for example, previous pelvic procedures) in which the retropubic approach should be avoided.
>
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It is important to note that the risk of any reoperation, also including mesh tape removal, was not associated with the route of insertion, which confirms that the lower rate of removal after a transobturator MUT insertion is not the result of a lower complication rate.

Study strengths and limitations

A first strength of this project was the availability of comprehensive national data sets with records of referral from primary to secondary care and of the use of surgery for female UI. Second, we complemented analyses of these existing national data sets with primary data collected from women and clinicians themselves. Our interviews with women added considerably to our quantitative findings, indicating the importance of the broader values and understandings women drew on in making treatment decisions and the importance of the wider context of their lives. Our survey of gynaecologists provided an efficient and explicit approach to study the differences in the gynaecologists' practice style in terms of their average inclination to recommend surgery and the impact that patient characteristics have on their recommendations.

The main limitations of this project concern the primary and secondary care data, particularly the quality and scope of some of their data fields. Although primary diagnosis and primary procedure fields are established as highly accurate in many routinely collected data sets, the recording of comorbidities is known to be more variable, potentially introducing an unknown amount of bias.[92] Despite this, studies comparing administrative data with case note reviews have shown that administrative data are sufficiently robust to support their use for research.[93] Routinely collected administrative data, primarily collected for management and reimbursement purposes, such as HES, lack information on relevant case mix factors, in particular those relating to symptom severity. This is likely to have contributed to some of the observed variation in the referral and surgery rates between geographical regions and between specific groups of women. However, other studies[81-84,94] have also demonstrated variation in other aspects of continence care geographically and by age and ethnicity, so residual confounding is unlikely to fully explain the variation in referral and surgery rates observed in our study.

In the context of growing safety concerns about some of the surgical treatments for SUI, it is also likely that at least some of the variation observed in our project was related to this debate leading to differences in professional opinion about the appropriateness of these surgical treatments. However, although rates of SUI surgery dropped substantially over the study period, the extent of geographic variation remained stable. This, and the level of variation remaining after adjusting for regional and patient-level characteristics, suggests that residual confounding is unlikely to explain all of the geographical variation and that women in some areas and from some groups were less likely to be referred or treated surgically than women with the same condition in other areas or in other groups.

An additional complexity of using routinely collected administrative or health-care data for research is that the absence of a code for a condition in the records relating to a particular patient must be

interpreted as absence of that condition in that patient. Potential misclassification may arise from patients not presenting to the health-care provider with the condition and from variation in coding practice among health-care providers. It is also likely that the extent of such misclassification varies between conditions.[46]

Furthermore, there are often no standardised definitions for diagnoses, so we developed code lists to identify key exposures and outcomes. To avoid the use of inconsistent definitions between studies, we used published code lists as far as possible.

A further limitation inherent to studies using routinely collected data is that reasons for clinical decisions are often not available or are unspecific. For example, the reasons why MUT removals or reoperations were conducted were not available. The most common diagnostic code recorded in HES for removals was 'complications of genitourinary prosthetic devices, implants, and grafts', which cannot capture common specific problems following MUT insertion, such as mesh exposure, pain, dyspareunia and voiding difficulties. One approach to obtain better data for the reasons for removal surgery would be to collect information reported by women themselves. Patient-reported outcome measures could be included in the registry that will be established to monitor surgical procedures for UI in England, especially if these patient-reported outcome measures are collected before and after mesh and non-mesh treatments.

Where routinely collected clinical and administrative data sets are well-established, as in England, they allow consideration of outcomes in the longer term that would be prohibitively expensive and subject to loss to follow-up in prospective studies. However, those using these data to look at longer-term outcomes must consider changes in coding practices over time. For example, in our project, new OPCS-4 codes (used in the HES database) for retropubic and transobturator MUT insertions were introduced in April 2006. Before April 2006, these procedures were recorded with other non-classified procedures. We ensured that our procedure classifications took these coding standard changes into account. In addition, for the 'removals' analyses, which explicitly distinguished between route of MUT insertion, we conducted sensitivity analyses to examine the potential impact that some hospitals continuing to use the old coding standards had beyond April 2006. Our findings were robust to sensitivity analyses starting the study period 1 year later and to including the previous coding standards.

Routinely collected data provide large sample sizes of nationally representative data. In this project, this enabled us to capture the care that women received in primary and secondary care. For example, CPRD, although it covers only 7% of the UK population, has been shown to be a representative sample of primary care patients in the UK. Furthermore, HES has nearly 100% coverage of patients treated by NHS England. Therefore, our findings from these data sets can be considered generalisable to the national population of women with UI who seek care.[46,95] However, previous research has indicated that as many as 75% of women with UI do not seek care and some of those who experience complications after surgery may not seek further care. We were unable to capture the experiences of these women using these data sources.

The focus of this project was on surgical treatments for women with UI, which the routinely collected administrative data are well placed to capture. The interviews were also designed to capture women's decision-making processes around surgical treatment, recruiting women who had been referred to secondary care and were considering surgery. However, because of this we do not capture those women whose experiences of UI, and perhaps thoughts around surgery, meant that they were not referred to secondary care or were not using NHS services at all. There is also the possibility that women who were approached but did not consent to be interviewed may share characteristics that were not captured in the interviews. This may be particularly relevant given that we were unable to purposively sample for the interviews according to ethnicity.

A further limitation of administrative health-care data is that they do not capture care provided in the private sector. Although precise figures are lacking, it is likely that at least 90% of all UI procedures in England are provided by the NHS, as the total annual spending on private health care in England is about 5% of the total annual NHS spend.[96] Primary data collection also has some limitations. For example, for the case vignettes survey we invited all members of two professional bodies practising in the UK with a specialist interest in UI. However, urologists were not included, and their practice and views may be different. As a result, our case vignette findings are applicable only to gynaecological practice.

Moreover, we could include only gynaecologists in our study, using case vignettes to explore the impact of patient characteristics on recommendations about surgery. The contact details of urologists involved in treatment of female UI were simply not available. We can only speculate to what extent the results observed in gynaecologists reflect those that would have been obtained in urologists. In addition, the response of only 245 gynaecologists could be included, out of the 1139 members of the RCOG with special interest in urogynaecology. We could not explore the differences between responders and non-responders because we did not have access to the characteristics of the non-responders.

Interpretation of findings

Information on variation in practice is important for examining relationships between policy decisions and clinical decisions, and this information raises questions concerning the efficiency and effectiveness of health care.[35] In evaluating practice variation, surgical care can be considered to be 'preference sensitive' where more than one generally accepted treatment option is available. In this situation, the 'correct' rate of treatment should depend on informed patient choice, but rates may vary substantially because of the differences in the professional opinion of clinicians. International data illustrate extensive variation in elective surgery rates in many areas of practice that is much greater than can reasonably be explained by differences in condition severity.[92,97,98] Our findings suggest that this is also the case for surgery for female UI.

It is important to remember that patients in geographical areas with low rates of elective surgery, such as for UI, are not necessarily untreated; they may be treated differently. Patients' decisions regarding their treatment are understandably strongly influenced by the opinions of their clinicians. Treating patients according to their preferences requires shared decision-making and the active engagement of patients in their choice of treatment. In the context of UI surgery, it is likely that at least some of the observed variation in the use of surgery will have been related to the debate about the safety of MUTs for SUI, which would have led to differences in professional opinion about the appropriateness of these treatments for female SUI. Surgical care for UI may also be considered 'supply sensitive', with the frequency of use relating to capacity in the local health-care system. The geographic areas used in the analyses of geographical variation in SUI surgery rates (CCGs and STPs) are defined by NHS bodies that commission local hospital services. For this reason, differences in capacity of the local health-care system may have contributed to the observed variation.

The data used in this project (from the routinely collected clinical and administrative data sets and obtained from primary data collection in women and clinicians) were collected before the national 'pause' in the use of MUTs for SUI. However, the growing controversy over the use of MUTs for UI over the course of the period from which our data are drawn is likely to have played a role in our findings. Growing safety concerns around these most common surgical treatments for SUI over the study period,[99–101] with some women experiencing pain, painful sex and mesh exposure,[99,102] are likely to have introduced more uncertainty to women's and clinician's decision-making in relation to treatment and referral for female UI. This is reflected in our findings of substantial variation in rates of referrals, surgery and mesh tape removals both geographically and between groups (i.e. older women and those from minority ethnic backgrounds), which persisted after adjustment for individual-level factors likely to affect women's preferences.

Implications and recommendations for future research

Collecting and reporting patient-reported outcome measures

In April 2019, NICE published updated guidelines on the management of urinary incontinence in women.[19] This included that providers must ensure that data on surgery for SUI and surgical complications are recorded in a national registry,[103] including data for mesh and non-mesh procedures. Confirmed mesh complications must also be reported to the Medicines and Healthcare products Regulatory Agency. However, it is important that the focus on complications following surgical treatment for UI reflects women's concerns. Therefore, research in this area could benefit from a future national registry that contains patient-reported outcome measures. The current guidelines recommend that follow-up data include 'validated relevant outcome measures', 'adverse events including pain' and 'suspected and confirmed mesh-related complications'. However, it is important that outcomes are collected not only for women who have surgical treatment but also for those women who are referred back to secondary care with complications after surgical treatment. This could be achieved by conducting a national survey of women reporting on their UI, symptoms and quality of life before and after mesh and non-mesh treatments.

Future research could explore patient-reported symptom severity to examine long-term outcomes, including those that do not lead women to seek further health care or surgery, after mesh and non-mesh treatments to inform treatment decisions. Using patient-reported outcome measures, future research could also explore the extent to which patient-reported symptom severity explains observed variation in referrals and surgery. Future research could also explore barriers to seeking care among women who do not seek care for their UI, who delay seeking care or who do not seek care for complications following surgical treatment. Future research could also investigate the experiences of women who are considering a further continence procedure or mesh tape removal, whose decisions may be influenced by factors different from those that influence women considering surgery for the first time.

Utilising updates in procedure coding

During the study period, HES coded procedures using OPCS release 4.7 and it was not possible to distinguish between partial or total mesh tape removals after transobturator MUT insertions. From April 2017, procedures will be recorded using OPCS-4.8, which will distinguish between these partial and total mesh tape removals. We were not able to obtain these more recent data during the project, but future research should compare total and partial removal rates following transobturator and retropubic mesh MUT insertions to inform the use of these procedures.

Identifying best practice

This research, added to existing knowledge, has identified that there may be opportunities for GPs to initiate discussions to detect UI and to identify and treat modifiable factors such as obesity. Future research could identify best practice and promising interventions to support clinicians working in primary care to initiate discussions on these sensitive topics, particularly with women experiencing additional barriers, such as those from older age groups and minority ethnic backgrounds.

At the same time, we found that a relatively large proportion of women were referred to secondary care shortly after their UI problems were first recorded in primary care. Future research could focus on management within primary care prior to referral and for women who were not referred, especially relating to questions about how better assessment of UI (including history taking, symptom scoring and quality-of-life assessment, and physical examination), as well as conservative management (including lifestyle interventions and pelvic floor muscle training), may reduce the number of women referred to secondary care without negatively affecting outcomes.

There was wide geographical variation in the use of SUI surgery, which is also reflected in the large differences between gynaecologists in their average inclination to recommend surgery to a series of hypothetical patients. This demonstrates the need to get a better understanding of the determinants of variation and to be able to identify for whom the benefits of surgical treatment outweigh the risks.

A national registry, as mentioned above, that collects data reported by women themselves is being established. This registry will provide crucial data that could provide input parameters for a detailed modelling exercise of quality-adjusted life-years following the available treatment options for women with specific clinical profiles.

Patient decision aids on surgery for stress urinary incontinence

A patient decision aid for women thinking about a surgical procedure for SUI has recently been produced by NICE.[19] This decision aid provides information about the risks and benefits of all surgical options, including of long-term complications. The aid includes three key components: descriptions of the surgical options available, a summary of the short- and long-term outcomes with graphical representations of risk, and a chart that women can use to explore how they feel about the options. More research is needed about how these types of decisions can be best supported, acknowledging that these decisions are rarely conclusive and that the women's own prioritisation of specific criteria, which often go beyond objective measures of urine leakage, can shift over time in the light of their own experiences.

Summary of the research agenda

In summary, the proposed research agenda includes:

- a stronger emphasis on using data based on experiences and outcomes reported by women themselves
- ongoing refinement of procedure codes in HES data to ensure that partial and total removal of mesh tape can be distinguished
- initiation of studies that specifically aim to get a better understanding of the characteristics of patients for whom the benefits of surgical treatment outweigh the risks
- the development of approaches, including patient decision aids, which support women in making decisions about surgical treatment for SUI.

Acknowledgements

Project team and roles

Team member	Position	Institution	Role
Jan van der Meulen	Professor	LSHTM	Principal investigator
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Jil Mamza	Research fellow	LSHTM	WPs 1, 2 and 4–6
Simon Cohn	Professor	LSHTM	WP 3
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Publications

Gurol-Urganci I, Geary RS, Mamza JB, Duckett J, El-Hamamsy D, Dolan L, *et al.* Long-term rate of mesh sling removal following midurethral mesh sling insertion among women with stress urinary incontinence. *JAMA* 2018;**320**:1659–69.

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Data-sharing statement

The HES data were made available by NHS Digital and reused with the permission of NHS Digital. The CPRD data (including HES-linked data) were made available by the Medicines and Healthcare products Regulatory Agency and reused with the permission of the Medicines and Healthcare products Regulatory Agency. The HES and CPRD data are available on application to NHS Digital and the Medicines and Healthcare products Regulatory Agency. The data generated from the interviews with women and the survey of gynaecologists are not suitable for sharing beyond those contained within the report. Further information can be obtained from the corresponding author.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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Appendix 1 Office of Population, Census and Surveys Classification of Interventions and Procedures, version 4, codes to identify surgical procedures (Hospital Episode Statistics data)

TABLE 13 Stress UI operations

OPCS-4	Description
MUT insertions	
M53.3	Introduction of tension-free vaginal tape
M53.6	Introduction of transobturator tape
MUT removals	
M53.4	Total removal of tension-free vaginal tape
M53.5	Partial removal of tension-free vaginal tape
M53.7	Removal of transobturator tape
Injection of urethral bulking agents	
M56.3	Endoscopic injection of inert substance into outlet of the female bladder
Other abdominal/vaginal operations	
M51.1	Abdominoperineal suspension of the urethra
M51.2	Endoscopic suspension of the neck of the bladder
M51.8	Other specified combined abdominal and vaginal operations to support the outlet of the female bladder
M51.9	Unspecified combined abdominal and vaginal operations to support the outlet of the female bladder
M52.1	Suprapubic sling operation
M52.2	Retropubic suspension of the neck of the bladder
M52.3	Colposuspension of the neck of the bladder
M52.8	Other specified abdominal operations to support the outlet of the female bladder
M52.9	Unspecified abdominal operations to support the outlet of the female bladder
M53.1	Vaginal buttressing of the urethra
M53.8	Other specified vaginal operations to support the outlet of the female bladder
M53.9	Unspecified vaginal operations to support the outlet of the female bladder
M55.2	Implantation of artificial urinary sphincter into the outlet of the female bladder
M55.6	Insertion of retropubic device for female SUI – NEC
M55.8	Other specified other open operations on the outlet of the female bladder
M55.9	Unspecified other open operations on the outlet of the female bladder
M58.8	Other specified other operations on the outlet of the female bladder
M58.9	Unspecified other operations on the outlet of the female bladder

NEC, not elsewhere classified.

TABLE 14 Urgency UI/overactive bladder operations

OPCS-4	Description
Enlargement of the bladder	
M36.2	Ileocystoplasty
Botulinum toxin A injection	
M43.4	Endoscopic injection of neurolytic substance into the nerve of the bladder
M49.5	Injection of therapeutic substance into the bladder wall
Neuromodulation	
A70.1	Implantation of neurostimulator into the peripheral nerve
A70.2	Maintenance of neurostimulator in the peripheral nerve
A70.3	Removal of neurostimulator from the peripheral nerve
A70.4	Insertion of neurostimulator electrodes into the peripheral nerve
NEC, not elsewhere classified.	

TABLE 15 The ICD-10 diagnostic codes to supplement procedure codes

ICD-10	Description
N39.3	SUI
N39.4	UUI
R32	Other specified urinary incontinence
N32.8	Unspecified urinary incontinence
	Other specified disorders of the bladder

Appendix 2 Read codes to identify urinary incontinence symptoms/diagnoses (Clinical Practice Research Datalink data)

TABLE 16 Read codes to identify UI symptoms/diagnoses (CPRD data)

Read code category	Read code	CPRD MedCODES	Read code description
1 – history and symptoms	1593.	15918	H/O: stress incontinence
1 – history and symptoms	1A23.00	6161	Incontinence of urine
1 – history and symptoms	1A23000	110001	Functional urinary incontinence
1 – history and symptoms	1A24.00	1929	Stress incontinence
1 – history and symptoms	1A24.11	5844	Stress incontinence – symptom
1 – history and symptoms	1A26.00	3887	Urge incontinence of urine
K – genitourinary system diseases	K198.00	3182	Stress incontinence
K – genitourinary system diseases	K586.00	17620	Stress incontinence – female
K – genitourinary system diseases	Kyu5A00	52763	[X] Other specified urinary incontinence
R – symptoms, signs and ill-defined conditions	R083.00	3283	[D] Incontinence of urine
R – symptoms, signs and ill-defined conditions	R083000	4375	[D] Enuresis – NOS
R – symptoms, signs and ill-defined conditions	R083100	31220	[D] Urethral sphincter incontinence
R – symptoms, signs and ill-defined conditions	R083200	17320	[D] Urge incontinence
R – symptoms, signs and ill-defined conditions	R083z00	15400	[D] Incontinence of urine – NOS

H/O, history of; NOS, not otherwise specified.

Appendix 3 Read codes to identify the history of urinary incontinence procedures/treatments (Clinical Practice Research Datalink data)

TABLE 17 Read codes to identify the history of UI procedures/treatments

Read code chapter	Read code	CPRD MedCODES	Read code description
3 – diagnostic procedures	3940	13421	Bladder: incontinent
3 – diagnostic procedures	3941	13422	Bladder: occasional accident
7 – operations, procedures and sites	7B3..11	2498	Bladder neck operations
7 – operations, procedures and sites	7B30.00	40515	Combined abdominal and vaginal operations to support the outlet of the female bladder
7 – operations, procedures and sites	7B30000	26236	Abdominoperineal suspension of the urethra
7 – operations, procedures and sites	7B30100	34857	Unspecified endoscopic suspension of the bladder neck
7 – operations, procedures and sites	7B30200	36712	Stamey endoscopic bladder neck suspension
7 – operations, procedures and sites	7B30300	67945	Pereyra–Raz endoscopic bladder neck suspension
7 – operations, procedures and sites	7B30400	29989	Gittes' endoscopic bladder neck suspension
7 – operations, procedures and sites	7B30y00	35658	Combined abdominal and vaginal operation to support the outlet of the female bladder – OS
7 – operations, procedures and sites	7B30z00	35662	Combined abdominal and vaginal operation to support the outlet of the female bladder – NOS
7 – operations, procedures and sites	7B31000	15696	Suprapubic sling operation
7 – operations, procedures and sites	7B31011	21250	Aldridge suprapubic sling
7 – operations, procedures and sites	7B31014	64217	Suprapubic urethrovesical suspension
7 – operations, procedures and sites	7B31100	12737	Retropubic suspension of the bladder neck
7 – operations, procedures and sites	7B31112	4313	Marshall–Marchetti suspension
7 – operations, procedures and sites	7B31113	34104	Marshall–Marchetti–Krantz retropubic suspension of the urethra
7 – operations, procedures and sites	7B31200	4202	Colposuspension of the bladder neck
7 – operations, procedures and sites	7B31211	17771	Burch colposuspension
7 – operations, procedures and sites	7B31z00	71003	Abdominal operation to support the outlet of the female bladder – NOS
7 – operations, procedures and sites	7B32000	31461	Vaginal buttressing of the urethra
7 – operations, procedures and sites	7B32011	45544	Kelly urethrovesical plication
7 – operations, procedures and sites	7B32012	98338	Kennedy urethrovesical plication
7 – operations, procedures and sites	7B32200	11197	Introduction of tension-free vaginal tape
7 – operations, procedures and sites	7B32500	57283	Introduction of transobturator tape
7 – operations, procedures and sites	7B32y00	49097	Vaginal operation to support the outlet of the female bladder – OS

continued

TABLE 17 Read codes to identify the history of UI procedures/treatments (*continued*)

Read code chapter	Read code	CPRD MedCODES	Read code description
7 – operations, procedures and sites	7B32z00	48900	Vaginal operation to support the outlet of the female bladder – NOS
7 – operations, procedures and sites	7B33400	46819	Insertion of sphincter around the female bladder neck
7 – operations, procedures and sites	7B33411	42425	Implantation of sphincter around the female bladder neck
7 – operations, procedures and sites	7B33412	52000	Insertion of artificial urinary sphincter in the outlet of the female bladder
7 – operations, procedures and sites	7B33600	49520	Maintenance of the bladder neck sphincter in female
7 – operations, procedures and sites	7B33800	98767	Insertion of retropubic device SUI – NEC
7 – operations, procedures and sites	7B33B00	89908	Reconstruction of the neck of female bladder – NEC
7 – operations, procedures and sites	7B34200	36539	Endoscopic suburethral injection of inert substance in female
7 – operations, procedures and sites	7B34211	18434	Endoscopic suburethral injection of collagen in female
7 – operations, procedures and sites	7B34212	46542	Endoscopic suburethral teflon injection in female
7 – operations, procedures and sites	7B34300	40010	Endoscopic uroplastique injection in the outlet of female bladder
7 – operations, procedures and sites	7B38900	97037	Introduction of transobturator sling
8 – other therapeutic procedures	8C14.00	2739	Incontinence care
8 – other therapeutic procedures	8D7..12	17637	Incontinence control
8 – other therapeutic procedures	8D71.00	48601	Incontinence control
Z – unspecified conditions	Z9EA.00	45495	Provision of incontinence appliance

NEC, not elsewhere classified; NOS, not otherwise specified; OS, other specified.

Appendix 4 Read codes to identify referrals to secondary care (Clinical Practice Research Datalink referrals data)

TABLE 18 Identification of referrals for urinary incontinence using Read codes and CPRD MedCODES

CPRD MedCODES	Read code	Read code description
Physiotherapy[a]		
2407	8E...00	Physiotherapy/remedial therapy
213	8E...11	Physiotherapy
24338	8EZ..00	Other physiotherapy
69779	8E74.11	Pelvic floor exercises
17237	8E77.00	Pelvic floor exercises
9020	8E97.00	Bladder training
33268	8E97000	Bladder drill
8437	9NJ3.00	In-house physiotherapy
6010	9NJ4.00	In-house physiotherapy – domiciliary visit
10089	ZL85.00	Referral to physiotherapist
8164	ZL85.11	Referral to physiotherapist
11894	ZL85100	Referral to community-based physiotherapist
13681	ZL85111	Referral to community-based physiotherapist
32769	ZL85200	Referral to hospital-based physiotherapist
12282	ZL85211	Referral to hospital-based physiotherapist
8543	8HH5.00	Referral to domiciliary physiotherapy
31147	8HHA.00	Referral to community-based physiotherapist
1116	8H77.00	Referral to physiotherapist
13671	8HVb.00	Private referral to physiotherapist
Continence care/assessment (including urodynamics)		
7650	394..00	Bladder – assessment
13424	394..11	Bladder – incontinence assessment
13423	394..12	Bladder – continence assessment
13421	3940	Bladder – incontinent
13422	3941	Bladder – occasional accident
13420	3942	Bladder – fully continent
12424	ZQ3H.00	Bladder assessment
40789	39H..00	Continence assessment
49417	39H0.00	Continence reassessment

continued

TABLE 18 Identification of referrals for urinary incontinence using Read codes and CPRD MedCODES (*continued*)

CPRD MedCODES	Read code	Read code description
5269	317..00	Special urinary procedures
15290	317..11	Urinary – special tests
2916	317..12	Urodynamic studies
20140	3174	Special urinary test abnormal
41472	3174.11	Urodynamic studies abnormal
40731	3174000	Cystometry abnormal
12169	3175	Detrusor reflex testing
10876	3176	Residual urinary volume
103500	3177	Uroflowmetry
103851	3178	Voided urinary volume
103674	3179	Average urinary flow rate
20728	317 A.00	Pad test for incontinence
6716	317B.00	Other urodynamic tests
18036	317C.00	Urinary flow rate
104865	317D.00	Time to maximum urinary flow
105951	317D.11	TQmax –time to maximum urinary flow rate
103615	317E.00	Urinary voiding total flow time
103913	317F.00	Urinary flow time
14962	317Z.00	Special urinary procedure – NOS
64138	7P14300	Urodynamics – NEC
2739	8C14.00	Incontinence care
12138	8C14.11	Continence care
22095	ZLA2400	Seen by continence nurse
18998	8HR6.00	Referral to urodynamic studies
29192	8H7w.00	Referral to continence nurse
25899	8HTX.00	Referral to incontinence clinic
25901	ZL62400	Referral to continence nurse
Gynaecology/urology/GUM referral		
48014	8H4 V.00	Referral to gynaecology special-interest GP
2116	8H58.00	Gynaecological referral
103854	8Hku.00	Referral to community gynaecology service
31873	8HMO.00	Listed for gynaecological admission
13647	8HV7.00	Private referral to gynaecologist
9966	ZL5D.00	Referral to obstetrician and gynaecologist
10663	ZL5D200	Referral to gynaecologist
6589	8H4 A.11	Referred to genitourinary physician

TABLE 18 Identification of referrals for urinary incontinence using Read codes and CPRD MedCODES (*continued*)

CPRD MedCODES	Read code	Read code description
30868	8H4 W.00	Referral to urology special-interest GP
2568	8H5B.00	Referred to urologist
13704	8HTa.00	Referral to genitourinary clinic
13644	8HVA.00	Private referral to urologist
23104	ZL5AJ00	Referral to genitourinary physician
10313	ZL5GP00	Referral to urologist
Further care/general medicine/general surgeon referral[a]		
91	8H...00	Referral for further care
13674	8H4..00	Referral to physician
1861	8H4..11	Medical referral
11219	8H4..12	Refer to physician
7124	8H41.00	General medical referral
20251	8H4Z.00	Referral to physician – NOS
43014	ZL5 A.00	Referral to physician
10449	ZL5AE00	Referral to general physician
22670	8H5..00	Referral to surgeon
3016	8H5..11	Surgical referral
5156	8H51.00	General surgical referral
21020	8H5Z.00	Referral to surgeon – NOS
10214	ZL5G500	Referral to general surgeon
15812	8H7..00	Other referral
6535	8H72.00	Referral to district nurse
3975	8H7a.00	Referral to hospital
2558	8HD..00	Referral to hospital – OPD
32882	8He..00	Referral to intermediate care
39479	8HH..00	Referred – other care
19171	8HT..00	Referral to clinic
30263	ZL6..00	Referral to nurse
25924	ZL62.00	Referral to clinical nurse specialist
11495	ZL63211	Refer to district nurse
56102	ZL65.00	Referral to nurse practitioner
20965	8H61.00	Referral to private doctor
7820	8H61.11	Private referral
17946	8HV..00	Private referral
13634	8HV0.00	Private referral to general surgeon

GUM, genitourinary medicine; NEC, not elsewhere classified; NOS, not otherwise specified; OPD, outpatient department.
a Categories need to be supplemented with a UI diagnosis/symptom code on the day of the referral.

TABLE 19 Identification of referrals for urinary incontinence using referral specialty codes

Specialty code	Description	Data field
Physiotherapy referral – specialty codes[a]		
77	Physiotherapy	NHSSPEC
Gynaecology/urology/GUM referral – specialty codes		
2	Urology	NHSSPEC
32	Genitourinary medicine	NHSSPEC
44	Gynaecology	NHSSPEC
81	Obstetrics and gynaecology	NHSSPEC
6	Gynaecology	FSHASPEC
14	Genitourinary medicine	FSHASPEC
Further care referral – specialty codes[a]		
1	General surgery	NHSSPEC
16	General medicine	NHSSPEC
1	General surgical	FSHASPEC
2	General medical	FSHASPEC

FSHASPEC, referral speciality according to the Family Health Services Authority (FHSA) classification; GUM, genitourinary medicine; NHSSPEC, referral speciality according to the National Health Service (NHS) classification.
a Categories need to be supplemented with a UI diagnosis/symptom code on the day of the referral.

Appendix 5 Read codes to identify patients' ethnicity, smoking status and comorbidities

Ethnicity

Ethnicity information was captured based on Read codes reported in Wright *et al.*[104]

Smoking status

Information on smoking was captured based on Read codes reported in Stocks *et al.*[105] and Joseph *et al.*[106]

Comorbidities

All comorbidities were captured using Read code repositories reported at https://clinicalcodes.rss.mhs.man.ac.uk/medcodes/articles/ (accessed 9 May 2020), with the exception of those listed below.

Comorbidity	Method
POP	Keyword searches of Read code directories, reviewed and finalised by clinical advisory team (table 5a)
Asthma	Keyword searches of Read code directories, reviewed and finalised by clinical advisory team
Cancer	Repository and keyword searches of Read code directories, reviewed and finalised by clinical advisory team

TABLE 20 Read codes to identify POP

Read code chapter	Read code	CPRD MedCODES	Read code description
7 – operations, procedures and sites	7D19.00	17020	Repair of the vault of the vagina
7 – operations, procedures and sites	7D19000	66379	Repair of the vaginal vault combined abdominal and vaginal approach
7 – operations, procedures and sites	7D19100	52417	Repair of the vault of the vagina using an abdominal approach – NEC
7 – operations, procedures and sites	7D19200	57237	Repair of the vault of the vagina using a vaginal approach – NEC
7 – operations, procedures and sites	7D19300	16175	Sacrocolpopexy
7 – operations, procedures and sites	7D19400	1652	Suspension of the vagina – NEC
7 – operations, procedures and sites	7D19500	18931	Sacrospinous fixation of the vaginal vault
7 – operations, procedures and sites	7D19600	96345	Repair of the vault of the vagina with mesh using an abdominal approach
7 – operations, procedures and sites	7D19700	46339	Repair of the vault of the vagina with mesh using a vaginal approach
7 – operations, procedures and sites	7D19y00	27604	Other specified repair of the vault of the vagina

continued

TABLE 20 Read codes to identify POP (*continued*)

Read code chapter	Read code	CPRD MedCODES	Read code description
7 – operations, procedures and sites	7D19z00	48218	Repair of the vault of the vagina – NOS
K – genitourinary system diseases	K195.11	16981	Urethrocele
K – genitourinary system diseases	K51..00	6819	Genital prolapse
K – genitourinary system diseases	K510000	211	Cystocele without uterine prolapse
K – genitourinary system diseases	K510100	25278	Cystourethrocele without uterine prolapse
K – genitourinary system diseases	K510200	2285	Rectocele without uterine prolapse
K – genitourinary system diseases	K510211	37918	Proctocele without uterine prolapse
K – genitourinary system diseases	K510300	4575	Urethrocele without uterine prolapse
K – genitourinary system diseases	K512.00	7870	Uterovaginal prolapse, incomplete
K – genitourinary system diseases	K512000	30419	Cystocele with first-degree uterine prolapse
K – genitourinary system diseases	K512100	12359	Cystocele with second-degree uterine prolapse
K – genitourinary system diseases	K513.00	9356	Uterovaginal prolapse, complete
K – genitourinary system diseases	K513000	25974	Cystocele with third-degree uterine prolapse
K – genitourinary system diseases	K514.00	1057	Uterovaginal prolapse, unspecified
K – genitourinary system diseases	K514000	12845	Cystocele with unspecified uterine prolapse
K – genitourinary system diseases	K515.00	10888	Post-hysterectomy vaginal vault prolapse
K – genitourinary system diseases	K516.00	2846	Vaginal enterocele
K – genitourinary system diseases	K516100	41136	Acquired vaginal enterocele
K – genitourinary system diseases	K516z00	42057	Vaginal enterocele – NOS
K – genitourinary system diseases	K518.00	96896	Female rectocele
K – genitourinary system diseases	K51y.00	23941	Other genital prolapse
K – genitourinary system diseases	K51yz00	41895	Other genital prolapse – NOS
K – genitourinary system diseases	K51z.00	33440	Genital prolapse – NOS
K – genitourinary system diseases	Kyu9100	97649	[X] Other female genital prolapse
L – Pregnancy/childbirth/puerperium	L244.11	20850	Cystocele in pregnancy, childbirth and the puerperium
L – Pregnancy/childbirth/puerperium	L244.13	39492	Rectocele in pregnancy, childbirth and the puerperium
L – Pregnancy/childbirth/puerperium	L244011	20907	Cystocele affecting obstetric care
L – Pregnancy/childbirth/puerperium	L244012	58517	Rectocele affecting obstetric care
L – Pregnancy/childbirth/puerperium	L244111	32286	Cystocele – baby delivered
L – Pregnancy/childbirth/puerperium	L244112	32287	Rectocele – baby delivered
L – Pregnancy/childbirth/puerperium	L244211	66127	Cystocele – delivered with postpartum complication
L – Pregnancy/childbirth/puerperium	L244212	57581	Rectocele – delivered with postpartum complication
L – Pregnancy/childbirth/puerperium	L244311	101354	Cystocele complicating antenatal care – baby not delivered
L – Pregnancy/childbirth/puerperium	L244312	30378	Rectocele complicating antenatal care – baby not delivered

TABLE 20 Read codes to identify POP (*continued*)

Read code chapter	Read code	CPRD MedCODES	Read code description
L – Pregnancy/childbirth/puerperium	L244411	38439	Cystocele complicating postpartum care – baby delivered during previous episode of care
L – Pregnancy/childbirth/puerperium	L244412	51111	Rectocele complicating postpartum care – baby delivered during previous episode of care
L – Pregnancy/childbirth/puerperium	L244z11	39550	Cystocele in pregnancy, childbirth or the puerperium – NOS
L – Pregnancy/childbirth/puerperium	L244z12	64147	Rectocele in pregnancy, childbirth or the puerperium – NOS

[X], mental and behavioural disorders; NEC, not elsewhere classified; NOS, not otherwise specified; OS, other specified.

Appendix 6 Interview topic guide and sample questions

Preamble to interview

My name is Rebecca Lynch and I'm a researcher based at the London School of Hygiene and Tropical Medicine (a university based in London). I'm interviewing women in different parts of the country about their experiences of urinary incontinence and incontinence care for a project that looks to improve the services that women are offered.

I am not directly connected to the clinic where you are a patient. This study is separate to the services offered at the hospital. What we talk about will not affect your treatment and care at the clinic and our conversation won't be disclosed to people working there.

If you're happy for me to do so, I'd like to record our conversation so that it can be written up for analysis. All recordings and access to what we've talked about will be kept confidential, including from those working at the clinic, unless you tell me something that indicates that you or someone else is at risk of harm. I would discuss this with you before telling anyone else. When I write about what patients have told me, this will be anonymised and I will be careful that you cannot be identified in anything I write up or present.

We are planning to write and present our findings in academic journals and at academic conferences, links to papers will be available through our project website. We are also planning to write a summary of our findings that might be easier for people to look through, this will also be available for you to read from our project website.

You have already had a chance to look at the participant information sheet and consent form – do you have any questions about either of these?

Can I talk you through the statements on the consent form to check that these are clear?

Are you happy to participate? If you are happy to be involved, can I remind you again that you are able to leave at any time during the interview if you do not wish to continue, and if you would like to withdraw from the study afterwards, you can ask me to withdraw your data any time up to when we publish, without giving a reason for doing this.

If you are happy to do so, can I then ask you to complete the consent form, including whether you would be happy for me to record the interview?

Interview topic guide and sample questions

1. *Experience of urinary incontinence*

   - When did your urinary incontinence start?
   - How has this changed over time?
   - How has the experience of UI impacted on your everyday life? (Further prompts will be on effects on their personal relationships, social life and employment.)
   - What are the most significant aspects of these experiences for you personally?

2. *Care for urinary incontinence*

   o What medical, or non-medical, forms of care have you drawn on to treat your incontinence?
   o What are the most significant aspects of this for you?
   o What are the symptoms/experiences you'd most like to be addressed?
   o What sorts of options have you been presented with?
   o How did you come to be referred to the hospital clinic?
   o What has your experience been with investigations and assessments of your UI?
   o What have you heard about the surgical options available to you?
   o What do you think about having surgical treatment?
   o What factors are you thinking about in making these decisions?
   o Who, if anyone, have you talked about this with or gained ideas from?

3. *Expectations of surgical/non-surgical care and future outcomes*

   o How do you hope treatment might improve your current circumstances?
   o How do you hope treatment might impact on longer term outcomes?
   o What is your understanding of how your treatment will change your body?

EME
HS&DR
HTA
PGfAR
PHR