

Consultation Guide: Specialised gynaecology surgery and complex urogynaecology conditions service specifications

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Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it, and
- given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

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1 About this guide

NHS England is committed to working with a wide range of patients, patient groups and other stakeholders in the development of its commissioning of specialised services. A public consultation is an opportunity to check whether proposals are right and supported, the public understand their impact, and identify any alternatives before decisions are made.

We have launched this consultation to seek views on proposed changes to specialised gynaecological and urological services for women, which will run from 16 August to 14 November 2018.

The document has information about the proposed changes to the way services may be provided and also explains how you can share your views with NHS England. At the end of the consultation period, all feedback will be considered and amendments made to the service specifications as appropriate.

2 Context

The majority of gynaecological and female urological conditions are treated successfully by clinical teams in local hospitals that are commissioned by their local Clinical Commissioning Groups (CCGs). But for those patients whose conditions require more complex surgical procedures and treatment, care must be delivered by expert clinical teams at specialist centres that are commissioned by NHS England. These specialist centres must meet specific national standards that are set out in service specifications to ensure the best possible outcomes for women.

NHS England currently commissions specialised gynaecological and female urological services for women from a wide range of providers. These services have to deliver to the standards that are set out within the following five service specifications:

- Complex Gynaecology: Severe Endometriosis
- Complex Gynaecology: Urogenital and Anorectal Conditions
- Complex Gynaecology: Recurrent Prolapse and Urinary Incontinence
- Complex Gynaecology: Urinary Fistulae
- Complex Gynaecology: Congenital Gynaecological Anomolies.

These specifications can be found at: NHS commissioning » E09. Specialised Women's Services

3 What we want to achieve

There are currently 47 providers in England carrying out specialised surgical gynaecological and female urological procedures, with some only undertaking a small number of cases a year. We want to improve outcomes for patients by stopping occasional practice, (where clinicians are doing very few of these operations), and make sure procedures are only taking place in centres that meet the requirements set by the service specifications and delivered by surgeons with the right expertise and experience.

The <u>Specialised Women's Services Clinical Reference Group</u> have reviewed the service specifications listed above on behalf of NHS England and have:-

- Reviewed the Urogenital and Anorectal Conditions and Recurrent Prolapse and Urinary Incontinence service specifications and amalgamated them into a single service specification that now covers Specialised Complex Surgery for Urinary Incontinence and Vaginal and Uterine Prolapse;
- Developed a new specification for Women with Complications of Mesh Inserted for Urinary Incontinence and Vaginal Prolapse;
- Updated the Urinary Fistulae service specification.

These revised and new service specifications will ensure those patients who need complex surgery are treated in the right place by clinicians with the right skills and experience, using the right evidence-based techniques.

It is these three service specifications that are the focus for this consultation. Once the consultation on the service specifications has concluded and NHS England has had an opportunity to review and assess the feedback received, further changes may be made to the specifications.

Once agreed by NHS England, the service specifications will be adopted. Following adoption, NHS England will be assessing hospitals against the standards set within the full suite of specifications for these services, (including the revised and new service specification).

The assessment of the hospitals against the full list of service specification standards will be carried out by NHS England's Regional Commissioning staff and NHS England's Quality Surveillance Team during 2019.

The introduction of the new and revised service specifications and the assessment of hospitals against the standards set out in the service specifications will lead to the following benefits:

Improving patient outcomes

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- Reducing the number of women requiring follow-up or revision surgery
- Increasing the confidence levels of women who require this type of surgery
- Supporting the development of experts in complex procedures such as mesh removal

However, this could result in there being fewer hospitals providing complex surgical treatments if hospitals are unable to meet the standards set.

4 Overview of the specifications

4.1 Specialised Complex Surgery for Urinary Incontinence and Vaginal and Uterine Prolapse

This specification covers the management of women with complex urinary and faecal incontinence and uterine and/or vaginal prolapse combined with rectal prolapse where repeat and further surgical treatment is being considered following an unsuccessful surgical procedure. This specification is the result of combining two existing service specifications into one. The benefit of doing this is to ensure that women across the country are offered a more comprehensive service from clinicians who have the right support and experience to deliver the best outcomes.

What does it cover?

Stress Urinary Incontinence (SUI) is the condition where urine leaks with coughing, sneezing or laughing, or with lifting and exercise. A woman's bladder and urethra (water pipe outlet for urine) are supported by pelvic floor muscles and ligaments. If the support is weakened, for example by childbirth, SUI may occur. The problems can be mild, moderate or severe and can lead to a considerable loss in quality of life.

There is a range of non-surgical and surgical treatment options for women with SUI. In England 10,000 stress incontinence operations are carried out each year in hospitals across the country, with a success rate of 85%. Some women may need a further operation and around 1,180 women may require more specialised assessment or surgery. The revised service specification for surgery covers this small group of patients who need repeat or complex specialist treatment.

Pelvic Organ Prolapse (POP) is the condition where the internal pelvic organs bulge (prolapse) from their natural position into the vagina. The organs within a woman's pelvis, (the uterus, bladder and rectum), are normally held in place by ligaments and muscles known as the pelvic floor and these support structures can be weakened by overstretching. Sometimes a prolapse may be large enough to protrude outside the vagina.

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Over 40,000 women each year will undergo surgery for incontinence and/or prolapse with a 90 % success rate. For the 10% whose prolapse recurs, they may require specialised surgeries – this equates to around 4000 cases per year. The revised service specification for complex surgery covers this group of patients.

The revised service specification for complex surgery for urinary incontinence and vaginal and uterine prolapse includes, as part of the treatment options, the use of vaginal mesh for urinary incontinence and vaginal/uterine prolapse.

These sections of the revised service specification have been highlighted as on the 10th July 2018, the Government announced a national 'pause' in the use of vaginal mesh to treat urinary incontinence and vaginal/uterine prolapse.

The 'pause' followed a recommendation from Baroness Cumberlege, Chair of the Independent Medicines and Medical Devices Safety Review. The 'pause' means that all surgical cases (where it is clinically safe to do so) have been postponed. A Clinical Advisory Group has been established to support the 'pause' process, including members from Specialised Commissioning and clinical expertise from the British Society of Urogynaecologists (BSUG) and the British Association of Urological Surgeons (BAUS). If the outcome of the 'pause' process confirms that the decision not to use mesh should be permanent, the highlighted sections of the service specification will be removed.

As part of the 'pause' announcement, NHS England has been asked to complete the consultation on the Specialised Complex Surgery for Urinary Incontinence and Vaginal and Uterine Prolapse and Complications of Mesh Inserted for Urinary Incontinence and Vaginal Prolapse service specifications.

What will change?

Following an initial assessment of existing providers against the standards in the new and revised specification there may be fewer centres delivering the specialist interventions covered by this specification in the future. It is important to note that all centres currently providing gynaecological, urogynaecological and female urological services will continue to be able to provide non-specialised treatments for these conditions.

Within that context, patients requiring specialised treatment may not be able to access services in their 'local' hospital and may need to travel to their closest regional specialist centre. Patients will also be able to choose for themselves which centre they would prefer their treatment from.

4.2 Women with complications of mesh inserted for urinary incontinence and vaginal prolapse

This is a new specification which sets out the standards for a national specialised service for women with complications of mesh that will establish a small number of specialist mesh removal services to deliver an assessment and treatment service for women experiencing severe or complex complications.

What does it cover?

This specification is specifically for women with complications relating to mesh insertion used to treat complex urinary incontinence and prolapse. Complications linked to mesh are vaginal bleeding, pelvic or vaginal pain, the return of incontinence or prolapse, experiencing urinary tract infections, painful sexual intercourse, and exposure and extrusion of mesh into a person's adjacent organs. Vaginal erosions of any size require surgical removal whilst larger symptomatic vaginal exposure and all extrusions would require complex surgery. There are approximately 50-100 complex surgery cases per year.

All women with complications relating to mesh must be discussed by the Mesh service multi-disciplinary team (MDT) which consists of consultant urogynaecologists and urologists, consultant surgeons and consultant radiologists and other health professionals.

What will change?

This is a new service which will support clinical experts with the skills and experience to manage complications of mesh inserted for urinary incontinence and vaginal prolapse. Because of the small number of women that will need this level of care there will be a limited number of centres delivering this service. This does mean that it will not be available in every local area and patients may have to travel to another town or city to receive the treatment. However we believe that patient outcomes are improved when treated by a few surgical teams with a concentration of skills and experiences.

4.3 Genito-Urinary Tract Fistulae (Girls and Women aged 16 and above)

What does it cover?

The service specification is for women who have a genito-urinary tract fistulae which has not healed naturally and requires repair surgery. A genito-urinary fistulae is where urinary fluid leaks or flows out of the vagina via an abnormal passage or connection and can occur following surgery such as a caesarean section or

colorectal, urological or gynaecological surgery such as a hysterectomy or after an intervention for cancer such as radiotherapy. Around 140 procedures of this kind are carried out each year, and it is these procedures that are covered by the updated service specification.

What will change?

The updated specification clarifies the care pathway steps to be followed and the skills and expertise that the surgeons and their multi-disciplinary teams must have. It includes that the method of repair surgery should be as a minimally invasive as possible, appropriate to each individual's woman's clinical presentation and provides more detail on the composition of the multi-disciplinary team membership.

Following an initial assessment of existing providers against the standards in the revised specification there may be fewer centres delivering the specialist interventions covered by this specification in the future. Within that context, patients requiring this specialised treatment may not be able to access services in their 'local' hospital and may need to travel to their closest regional specialist centre. Patients will also be able to choose for themselves which centre they would prefer their treatment from.

5 What questions are we asking

We are interested in what your views are about the description and impact of each of the service specifications. We are also interested in your views about whether you support our approach for assessing hospitals against the service specifications which could mean that fewer hospitals in the future will be offering complex treatments.

6 How to give your views

The consultation period runs from 16 August 2018 and will last for 90 days.

Your views will help NHS England to further shape and refine proposals for the delivery of safe and effective high quality specialised gynaecology and female urology services that are easy for people to access and meets their needs. This is so we can procure the right services from providers who are able to meet the requirements set out in the final service specifications.

- Complete the online survey: https://www.engage.england.nhs.uk/
 Before completing the survey please read the draft services specifications on the consultation home page.
- Email us: england.scengagement@nhs.net
- Write to us: Complex gynaecology and female urology consultation, NHS England, Floor 3B, Skipton House, 80 London Road, London, SE1 6LH.