Engagement Report for Service Specifications

Unique Reference Number	1649
Specification Title	Specialised Complex Surgery for Urinary Incontinence and Vaginal and Uterine Prolapse.
Lead Commissioner	Anthony Prudhoe
Clinical Reference Group	Specialised Women's CRG
Which stakeholders were contacted to be involved in service specification development?	All registered stakeholders with the Specialised Women's CRG. CRG members, including PPV members.
Identify the relevant Royal College or Professional Society to the specification and indicate how they have been involved	Royal College of Obstetricians and Gynaecologists British Association of Uro-Gynaecologists (BSUG) British Association of Urological Surgeons (BAUS) RCOG/BSUG are represented as an affiliate organisation on the CRG and have been involved development of the specification. BAUS have also been represented as part of the specification development.

	Clinicians, patients, commissioners, BSUG, Association of Coloproctology. Stakeholder decision to participate in stakeholder feedback. Limited patient responses, so as part of the public consultation the patient support groups around vaginal mesh will be directly contacted.
Which stakeholders have actually been involved?	CRG clinical and PPV members BAUS CRG Stakeholders
Explain reason if there is any difference from previous question	Stakeholder decision to participate in stakeholder feedback
Identify any particular stakeholder organisations that may be key to the specification development that you have approached that have yet to be engaged. Indicate why?	Limited patient responses, so as part of the public consultation patient support groups will be contacted directly
How have stakeholders been involved? What engagement methods have been used?	CRG, RCOG, BAUS and BSUG all been included in stakeholder testing. Standard stakeholder testing methods have been used plus direct emails to RCOG, BAUS and BSUG
What has happened or changed as a	Changes have been made to the service specification in response to comments received

result of their input?	
How are stakeholders being kept informed of progress with specification development as a result of their input?	Stakeholder updates will be made as part of the formal consultation process
What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement?	90 days

Stakeholder/CRG Feedback

Organisation Responding	Feedback Received		SPWG response	Resulting Action
Fiona Reid Central Manchester Foundation Trust Member of the CRG	Is the **Scope** as outlined in the service specification clear? **If no please outline why**	No Prolapse and incontinence are very common conditions. This document clearly lays out the numbers of women who undergo primary surgery. If one considers the numbers presented in the document under the section titled "Population needs" is apparent that the following conditions and treatments should fall in to specialised commissioning. **Procedures** Secondary surgery for stress incontinence (less than 2500 per year) Recurrent prolapse surgery in the same compartment (less than 4000 per year) All mesh surgery for prolapse (no more than 1000 per year) Excision of mesh Surgery for DO (excluding Botox) **Conditions** Aetiology of POP or SUI due to Congenital Reason	Agree This part of the service specification will be updated to be clearer about surgical procedures. With regard to mesh surgery, there will now be a separate mesh removal service specification and that will be clearer about complex and less complex mesh removal	Service specification reviewed and updated Separate service specification to be developed for mesh removal

		Combined faecal and urogynaecological conditions **No response**		
	Is the Care pathway and clinical dependencies as outlined in the service specification clear? If no please outline why	It would be helpful if the specification outlined minimum staffing standards in units 3 Urogynaecologists 2 Colorectal surgeons 2 Urology consultants 2 Specialist nurse (WTE 1.5) 2 Specialist women's health physiotherapist (WTE 1.5)	Specifying 3 is too restricitive but the main point is that it should not be a single consultant unit	No change
	Please provide any further comments on the proposed service specification and/or outline proposed changes to the document as part of this initial 'sense check'.	My understanding is that in England there are about 180 institutes who provide gynaecological surgery. One would anticipate about 25-35 institutes would provide specialised services. If the specification remains as written the numbers needing	NHS England is to carry out a review of the number of institutes who are carrying out specialist	

		treatment will more likely reflect those of a highly specialised service.	surgery. The intention is, once this service specification has been agreed, to review providers against all of the service specifications and to be clearer about who can deliver specialised surgery. NHS England is developing a commissioning framework to support this work.	
	Please declare any conflict of interests relating to this document or service area.	The concept of regional networks for MDTs which refer in to centres , similar to the model used for gynaecological cancer, is a good idea. However this will require resources to establish these. No response	Good that you agree with the concept of networks for MDTs. We do not envisage that this model will require resources – but it will require a new way of working	
Section of Female, Neurological & Urodynamic	**Is the Scope as outlined in the service specification clear?** **If no please outline why**	No Back in 2013/14 when we first began commenting on these	The intention is to	

Urology British Association of Urological Surgeons Responding on behalf of the British Association of Urological Surgeons		service specifications we pointed out that this process is fundamentally flawed due to the current service provision arrangements for recurrent and complex urinary incontinence. The existing documents are written by gynaecologists for gynaecologists when, by common consent, the range of conditions referred to do not fall solely within the ambit of uro-gynaecologists. Although gynaecologists manage the majority of recurrent and complex prolapse, with very little of this work being undertaken by urologists, the converse is true for recurrent and complex incontinence. In June 2014 in a letter to BAUS Tony Smith, then Chairman of the Complex Gynaecology CRG and James Palmer, Clinical Director of Specialised Services, acknowledged this and wrote regarding the combined specification for recurrent prolapse and recurrent incontinence that "this has proved to be challenging…. We have all agreed that this specification should be divided as soon as possible and a considerable amount of work and progress has been made with this task". Now not only are we presented with a specification which still combines recurrent prolapse and recurrent incontinence; urogenital and anorectal conditions have been added in together with vaginal mesh removal. The documents aims and ambitions remain unmet and it is hard to see how commissioners with limited clinical knowledge could use it to properly structure a specialist	develop a single specification for complex surgery for urinary incontinence and vaginal and uterine prolapse and to offer a service that is managed by clinicians with appropriate expertise who can offer a comprehensive range of treatments and surgical procedures within a multi-disciplinary team structure and to be clear about the MDT membership, pathways and clinical dependencies. Complex vaginal mesh removal will be included in a separate specification Agree	Service specification updated

		service with reference to this document. For example the definition of recurrent incontinence makes no sense - recurrent incontinence is incontinence following one previous failed appropriately performed procedure. BAUS would like to know what was the rationale for combining recurrent prolapse, recurrent incontinence, urogenital and anorectal conditions and vaginal mesh removal in one specification?	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	
	Is the Care pathway and clinical dependencies as outlined in the service specification clear? **If no please outline why**	No The care pathway, labelled 2.1 extends over 3 pages with a number of sub-headings and in general it is hard to follow. For example, under treatment strategy there is only reference to “complex incontinence and prolapse”, surely that should be… “and/or prolapse” recognising that they often do not co-exist and can represent completely distinct entities. There is no mention of the other areas that are	The care pathway section will be reviewed and made clearer and the terminology will be made consistent	Care pathway section reviewed and made clearer

	Please provide any further comments on the proposed service specification and/or outline proposed changes to the document as part of this initial 'sense check'. **Please declare any conflict of interests relating to this document or service area.**	apparently covered by this specification. The Section on data management, audit and governance is particularly poor and it is often unclear whether the bullet points refer to all areas covered by the specification or to a specific area. Some points refer to prolapse surgery and others refer to "these procedures" or "such cases" without being specific as to what procedures or cases are being referred to. The document lacks clarity and balance, is littered with ambiguity and unfortunately would not provide a useable template for commissioning a specialist service. Our readers had difficulty understanding the true tone or intent of the documents without reading between the lines. Perhaps the major reason for this is the lack of separation of the individual components. As mentioned above recurrent and complex incontinence is a separate entity from recurrent and complex prolapse and the document should reflect that. BAUS would advise that a truly multi-disciplinary team be convened to define the core elements of these specialist services and that a final document would benefit from being written by someone with an appropriate expertise in commissioning in a clear house style. We would be willing to provide more detailed tracked comments on the document if that would be helpful. No response	This part of the service specification will be reviewed and updated and will be clearer. NHS England will update the service specification in line with the comments received and will welcome more detailed comments on the final document that will be open to public consultation	This part of the specification has been reviewed and reworked

Theresa Marshall Medtronic Ltd Responding on behalf of Medtronic Ltd	**Is the Scope as outlined in the service specification clear?** **If no please outline why** **Is the Care pathway and clinical dependencies as outlined in the service specification clear?** **If no please outline why** **Please provide any further comments on the proposed service specification and/or outline proposed changes to the document as part of this initial 'sense check'.**	Yes Yes **Section 1.2, page 2, bullet point 1** "Women with urge incontinence who fail to respond to Onabotulinium toxin A injections as a second line treatment or who withdraw from therapy due to side effects and still require further intervention such as ileocystoplasty (or other bowel cystoplasty procedures)". We suggest that ***"further intervention such as.."*** examples include sacral nerve stimulation in line with NICE positioning in the pathway for invasive treatments for overactive bladder in women https://pathways.nice.org.uk/pathways/urinary-incontinence-in-women#path=view%3A/pathways/urinary-incontinence-in-women/invasive-therapy-for-overactive-bladder-in-women.xml&content=view-node%3Anodes-percutaneous-sacral-nerve-stimulation . NICE states "consider percutaneous sacral nerve stimulation after MDT review if a woman's OAB has not responded to conservative management (including drugs) and botulinium toxin A".	Sacral nerve stimulation to be made clearer with reference to the existing NHS published policy	Service specification update

		We suggest and additional bullet point in this section for sacral nerve stimulation for faecal incontinence as NHS England also have a policy for this. **Section 5: Applicable Service Standards** We suggest and additional bullet after bullet 9 for NHS England policy guidance on SNS for faecal incontinence. Medtronic manufacture and supply Sacral Nerve Stimulation devices		As above
	Please declare any conflict of interests relating to this document or service area.			
Dr Rohna Kearney, Clinical Lead, Warrell Unit Central Manchester Foundation trust	**Is the Scope as outlined in the service specification clear?** **If no please outline why**	No We consider women should be referred to specialist services for recurrent stress incontinence after one previous procedure and for recurrent same site prolapse after one previous procedure.	Service specification change to cover this	Change to the specification
Responding on behalf of the Central Manchester Foundation trust	**Is the Care pathway and clinical dependencies as outlined in the service specification clear?** **If no please outline why**	Primary surgery including laparoscopic colposuspension and autologous fascial sling is also specialised. All mesh removal (abdominal and vaginal) except for vaginal trimming and recovering of minor vaginal extrusions should be referred.	Agree Agree and a separate service specification will now address this	Change to the specification

		Combined urinary/prolapse and fecal conditions should be included in the scope e.g urinary and fecal incontinence, pelvic organ prolapse and rectal prolapse.	Agreed	See above Service specification has been updated
		Congenital reasons for incontinence or prolapse should be included.	This specification is related to the small number of women with incontinence and prolapse who will require complex and of invasive specialised surgical treatment	No change
		No		
		MDT should say urogynaecologist rather than a specialist gynaecologist and a urologist with specialised training in female reconstructive urology rather than a specialist urologist	Agreed	Service specification updated
	Is the care pathway and clinical dependencies as outlined in he service specification clear? **If no please outline why**	.		
		Treatment strategy: should say all patients who have had 1 failed continence procedure or same site prolapse	Agreed	See above

		recurrence. All mesh removal (abdominal and vaginal)	Mesh removal will have its own service specification and the service is likely to be delivered by a few centres across the country	
	Please provide any further comments on the proposed service specification and/or outline proposed changes to the document as part of this initial 'sense check'.	Due to the predominance of mid-urethral tapes for treatment of stress incontinence there are fewer trained surgeons available who can offer all surgical options including colposuspension and fascial slings. Therefore we feel repeat continence surgery should be offered in specialised centres. Patient choice of procedure will also play a role in referrals and many women are preferring to avoid a synthetic mid-urethral tape. Women should be offered an alternative for primary surgery to a synthetic tape and this may necessitate women being referred to specialist centres if local providers are unable to offer a choice.	Agreed - See above Repeat continence surgery will be offered only in specialist centres. The service specification needs to reflect a more specialist MDT to non-specialist MDT relationship and description. Good communication between the services is essential to enable the appropriate management of referrals and advice	Change to service specification
	Please declare any conflict of interests relating to this document or service area.	Dr Kearney and Dr Ward are clinical leads on NICE guideline development committee for urinary incontinence update and pelvic organ prolapse. Dr Reid is a member of the CRG for Specialised Women's Services		

			for non-specialist services	
Tamsin Greenwell Consultant Urological Surgeon UCLH and Chairperson BAUS FNUU	**Is the Scope as outlined in the service specification clear?** **If no please outline why** **Is the Care pathway and clinical dependencies as outlined in the service specification clear?** **If no please outline why** **Please provide any further comments on the proposed service specification and/or outline proposed changes to the document as part of this initial 'sense check'.**	No It does not have a standard pattern for the 3 disparate clinical areas included and concentrates significantly on laparoscopic POP No There is no clear care pathway – a flow chart would be of benefit. A lot of the document is cut and pasted from the previous document – with no uniform pathway, style or clarity. Numbers are plucked from the air and changed from one part of the document to the next. It is not a pathway at all but simply concentrates on rare procedures – this is not holistic and it would be far better to revise the 2 previous documents which detailed patient pathways and for a 3rd document for mesh revision surgery (which can be both vaginal mesh and abdominal) which is simply listed as a throw away sentence in this specification. No urologists were involved or consulted during the production of the specification which completely destroys the	Scope to be made clearer more broadly widened to be clear about the treatments that fall under the service The care pathway and the clinical dependencies will be reviewed Agreed the specification needs to be clearer and more consistent Pathway section will be reviewed This will be	Service specification reviewed and made clearer Care pathway section has been reviewed and amended As above As above

	Please declare any conflict of interests relating to this document or service area.	MDT nature of the document	addressed	
Roderick Teo (Lead for Urogynaecology) University Hospitals of Leicester NHS Trust, Urogynaecology Unit Responding on behalf of University Hospitals of Leicester NHS Trust, Urogynaecology Unit	**Is the Scope as outlined in the service specification clear?** **If no please outline why** **Is the Care pathway and clinical dependencies as outlined in the service specification clear?** **If no please outline why** **Please provide any further comments on the proposed service specification and/or outline proposed changes to the document as part of this initial 'sense check'.** **Please declare any conflict of interests relating to this document or service area.**	Yes Yes None None		
Jane Denton Multiple Births Foundation Replying as PPI member of Specialised Women's CRG	**Is the Scope as outlined in the service specification clear?** **If no please outline why**	From the patient perspective it would be preferable to be referred for assessment by the MDT after one failed incontinence or prolapse repair procedure. Although this would increase the number of referrals it should be the more complex cases as presumably this was the reason for the first failed procedure. It could reduce the number of those needing surgery repeated with the associated risks and costs and equally importantly could reduce the time women	Agreed . See above	Service specification changed

		are coping with these often debilitating and stressful conditions. However I appreciate that there may be clinical reasons for the proposed referral protocols which I may have missed.		
	Is the Care pathway and clinical dependencies as outlined in the service specification clear? **If no please outline why**			
	Please provide any further comments on the proposed service specification and/or outline proposed changes to the document as part of this initial 'sense check'.	The proposal for regional networks and MDT is an excellent idea but it will need the commitment and resources to establish them effectively.		As above
	Please declare any conflict of interests relating to this document or service area.	I have no conflicts of interest		