Standards for Service Provision in Urogynaecology Units: Certification of Units

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1. Introduction

The RCOG's role in setting standards and identifying auditable topics has been the basis for improving clinical standards in obstetrics and gynaecology. This has been further developed by the Department of Health (DH) with the introduction of Clinical Governance within Trusts and is applicable to all individuals involved in the provision of patient care. The National Institute of Clinical Excellence further recommends that national standards of clinical care should reflect the commitment to patient-centred care and that standards should address the quality of care that a patient with a given illness or condition is entitled to expect to receive from the NHS. In addition, NICE addresses the roles and responsibilities of the various healthcare professionals who will care for the patient (NICE Recommendation 125).

BSUG is aware of the pressures placed upon all practitioners by clinical governance, continued professional development, appraisal and revalidation. All these developments have brought additional work and challenges to professionals without always additional support or recognition for this extra

work and responsibility. These doctors need to be recognised and supported in order for them to make the improvements necessary to provide the excellent standards of care, which we strive for. If this is carried out in a thorough and professional manner, and is adopted by the Commissioners of Care as the acceptable standard, then registered practitioners can use this to substantiate their role, establish their authority and apply pressure to Trusts to provide the facilities needed to deliver a high quality service. It would also persuade colleagues to follow appropriate care guidelines and pathways of referral.

In the current climate of these regulatory activities and in an era of commissioning, accreditation of Urogynaecology Centres and Units is both inevitable and necessary. With this in mind, the BSUG feels that a form of voluntary registration for certification of units would be beneficial to its members. The objective of certification of units is based on:

- local delivery of high quality health care (credentialised),
- through clinical governance
- underpinned by modernised professional self-regulation
- and extended lifelong learning.

The accreditation process looks at three elements:

1. Personnel: All the staff are well trained, continue satisfactory CPD and have documented good free communication with other pelvic floor colleagues: physio, urology, colorectal, radiology etc.
2. Process: The service and systems within it provide a good level of information to patients and staff members and collects important information to achieve a precise diagnosis and for analysis of outcomes year after year.
3. Procedures: A good volume of investigative and surgical procedures so that skills are maintained. The systems must provide outcome data including procedural failure rates and morbidity eg mesh exposure, dyspareunia, transfusion etc year after year.

2. Background

This document has evolved from a number of previous guidelines and publications relating to services in incontinence and prolapse. In particular:

- Good Practice in Continence Services DoH, 2000.
- NSF for the Older person 2003
- International Colloquium in Incontinence 2005
- NICE guidance Female Incontinence 2006
- 18 week pathways for Incontinence and Prolapse
- NICE guidance on Mesh for Pelvic organ prolapse 2008
- RCOG Standards for Gynaecology/Urogynaecology 2008
  Letter from Sir Bruce Keogh & Prof Keith Willet; Vaginal Tapes & Meshes, 2012
  NICE Guidence Female Incontinence 2013

The rationale for accreditation of urogynaecology units is based on the need to ensure implementation of national guidelines (e.g. NICE 2006) and clinical standards (e.g. RCOG 2008). This emphasises both the multidisciplinary nature of the subspecialty, and the importance of non-surgical as well as surgical management. The changing face of the NHS requires that clinicians work across both the primary – secondary, and the inter-professional, interfaces. To ensure that quality of care is maintained in the face of potentially fragmented services, and to set and maintain high standards of care across the public and private sector, BSUG has proposed that a system of accreditation of urogynaecology units is developed. The provision of urodynamics investigations performed in independent treatment centres (ICATs), away from a urogynaecology unit providing treatment, is an example of this type of fragmentation of services which we wish to avoid.

Urogynaecology incorporates diagnostic investigations, conservative measures, surgical procedures and post-surgical treatment for ongoing symptoms for women with lower urinary tract and gastrointestinal conditions including incontinence and pelvic organ prolapse. These conditions are not life-threatening and it is important that management strategies minimise the need for intervention and any associated morbidity, such as the need for further surgery, the risk of overactive bladder and voiding dysfunction/self-catheterisation. The decision-making process in Urogynaecology requires a good understanding of the pathophysiology of continence and pelvic organ prolapse, the knowledge and understanding of when to operate and when to ask for tertiary advice. This includes arranging appropriate pre-operative investigations, achieving and maintaining relevant surgical skills and having the necessary experience to manage post-operative problems. This is important as there have been a number of documented clinical governance and medico-legal cases related to poor decision-making in relation to surgery. At a clinical level this multidisciplinary subspecialty should be subject to the same, or similar, standards and quality assurance measures as gynaecological oncology. As with many specialties greater experience and knowledge of the subject will result from greater exposure to these issues.

Thus, as in gynaecological oncology, urogynaecology patients are best managed by a dedicated team with operative decisions and procedures confined to this team, thus maintaining a high throughput and with the opportunity to audit and evaluate the service provided to patients. The converse is probably also true, such that cases managed by the general gynaecologist may not receive the relevant pre-surgical work-up (eg defaecating proctogram). Intra-operative expertise or management of any post-operative complications or ongoing or new symptoms of pelvic organ dysfunction.

3. BSUG Definition of a Urogynaecologist

- Dedicated Urogynaecology Clinic or equivalent per week including secondary and tertiary (other consultant colleagues within and outside your hospital) referrals, as part of a multidisciplinary service.
- Evidence of training in a Unit, which provides the full range of investigations (urodynamics, proctograms etc) and treatments required for training eg ATSM
- Regular Urodynamic sessions (minimum of one per month) either personally or in a supervisory capacity.
- Provide three clinical sessions in Urogynaecology per week (approximately 50% of clinical sessions in a standard 9-5, 10PA contract).
- Surgery: One major urogynaecology procedure associated with pelvic floor dysfunction i.e. incontinence and prolapse per working week per year.
- Regular Audit e.g. BSUG database audit

4. The Lead Urogynaecologist

The lead Urogynaecologist is responsible for:

- Liaising with those within the NHS trust who are responsible for providing the facilities to ensure that the service is adequately staffed by appropriately trained individuals (medical and non-medical), such that the service needs can be met in a timely and consumer-sensitive fashion. The equipment e.g. urodynamics used must be appropriate for the task and fully maintained and calibrated.
- Defining the role and job plan of each staff member. Staff must have the appropriate training for their role. Facilitating the CPD requirements of the CAs, nurses and other clinicians within the unit (e.g. BSUG meetings, BSUG membership providing the Urogynaecology Journal, UKCS, ACA)
- Ensuring that locally written guidelines are in place for the service and that these adhere to recommended national guidelines.
- Ensuring that such guidelines are regularly reviewed so that the needs of the users of the service and the commissioners of the service are met. Ensuring that the defined quality assurance standards are being met (e.g. NICE and RCOG Clinical Standards).
- Ensuring that the on-going audit of surgical and conservative management takes place **(The use of the BSUG.net database is now mandatory for BSUG Accreditation). The data from this should be present for all the individual consultants within the urogynae team and for consultants performing urogynae ops not within the team. Greater than 90% of major surgery should be recorded on the database with greater than 50% follow-up data.**
- Ensuring that regular audit of the service takes place to compare practice with local protocols and national targets. For example, conducting regular dialogue with users, providers and purchasers of care to ensure that service and development are both appropriate and meet the needs of the local population.
- Coordinating training for ATSM and subspeciality training via the RCOG
- Convening regular multidisciplinary meetings for case discussion and protocol review.
- Encourage recruitment to national clinical trials via comprehensive local research networks
- It is mandatory for the Lead urogynaecologist(and indeed all within the unit doing urodynamics) to have UKCS Urodynamic certification.

5. Audit

Clinical audit is integral to maintaining quality, recognising shortfalls in the service compared with recommended standards and instituting appropriate remedial measures. As completion of the audit cycle will often depend upon local needs and resources, it must be conducted at a local level in the first instance. Regional and national audit is also important to ensure consistent standards across regions and nationally.

We would recommend 1 Governance audit per year in the urogynaecology unit over and above outcome data eg. Urodynamic record keeping, compliance with local policy on data entry onto BSUG database, etc

As part of the assessment, we have included a case-notes audit of 5 surgical cases and 5 urodynamic traces (proforma at end) in order to provide information on administrative processes and decision-making in the service.

6. Clinical Governance

There should be a robust method of gathering data about the performance of all members of staff in the unit, such as clinic templates, ratios of new patients to follow-ups, conversion rate to surgical management, length of stay, outcomes of non-surgical treatments, outcomes of surgery including morbidity and re-operation rates.

After consent, all surgical procedures should be submitted to the BSUG database. This is especially important when implantable products are used (mesh, urethral bulking agents). All significant morbidity should be recorded on the database and when applicable the MHRA informed via their website.

There should be a robust audit system which produces action on audit issues and there should be a system for the investigation and management of unusual practices.

An open reflective culture is important and therefore this data should be available to the Clinical Director and Trust Governance Committee.

7. Nurse Specialists and Continence Advisors

National guidelines confirm that there should always be a designated nurse with specialist skills to assist in the running of the clinic. This nurse should not be seconded to other duties while a clinic is running. If Urodynamics is performed by nurses and technicians, there should be evidence of training and competence assessment and regular review by Lead UG.

8.Standards for accreditation of units

The standards will be measurable, comparable and identify those units which deliver best practice. They are designed to provide a robust mechanism for ensuring quality control in units practising clinical urogynaecology, which will be of value to service users, commissioners and providers.

The standards provide a framework that will help urogynaecology units to improve patient care, encourage multidisciplinary working, and enhance prospects for individual units to grow and develop.

The standards are designed to:
be measurable
be achievable
be capable of progressive development
engender a spirit of reflective practice
increase clinical risk management awareness
contribute to the development and implementation of clinical governance

The standards can be divided into the following 3 themes

1. **Process**
2. **Personnel**
3. **Procedures**

NB there are some mandatory criteria to accredit

See Accreditation criteria table below:

Accreditation Criteria

		Score / Status	**How Assessed**
1	**Process**	M = Mandatory	
1.1.	Information giving: 1. Guidelines for the agreed mechanism of referral to secondary care including care pathways/13 weeks pathway. 2. Patient information leaflets for all major procedures performed and conservative measures 3. Unit protocols for the management of specific conditions (expect to see haematuria, recurrent UTI, Interstitial cystitis, vault prolapse, stress UI, urge UI). Evidence of when last reviewed.	**Score 10 M**	paper

1.2.	Information gathering: 1. History and examination proforma 2. Voiding diary 3. QoL assessment	**Score 5**	paper
1.3	Evidence of collaborative working: 1. Minutes from MDT attended by nurses, physiotherapists and CAs (Urogynae MDT), colorectal or urology colleagues (Pelvic floor MDT) and terms of reference for MDT 2. Referral letters from community team and tertiary referrals from colleagues, or referrals to tertiary colleagues 3. Joint clinics for OASIS follow-up and complex urology / colorectal cases if these occur	**Score 5**	paper
1.4	Evidence or regular servicing and calibration log for equipment less than 5 yrs old, Full list of equipment including bladder scans.	**Score 5**	paper
1.5	Administrative support Consider: letters going out within 2 weeks, triage of referral letters, MDT notes retrieval, nurses available to give telephone advice, space for urodynamic facilities, space for teaching PFME (appendix B)	**Score 5**	visit
1.6	Assessment of IT / systems management: Access to terminals in theatre, clinic etc to allow contemporaneous data entry, system for post op data entry (appendix B)	**Score 5**	visit
2	**Personnel**		
2.1.	Lead Urogynaecologist: 1. CV including training, CPD certs (& Urodynamic accreditation) 2. Job template demonstrating 3 urogynae sessions / working week 3. Evidence of one major pelvic floor op / working week 4. Evidence of referrals by general colleagues. 5. Proportion of surgery done by him 6. National or international involvement in urogynaecology eg BSUG 7. Up to date appraisals	**Score 10 M**	paper
2.2	Other urogynaecologists / consultants with special interest: 1. CV including training, CPD certs (& Urodynamic	**Score 5**	paper

	accreditation) 2. Job template demonstrating 3 urogynae sessions / working week 3. Evidence of one major pelvic floor op / working week 4. National or international involvement in urogynaecology eg BSUG 5. Up to date appraisals		
2.3	Urogynaecology Nurse, Continence Nurse & Physiotherapists 1. CV including training, CPD certs (& Urodynamic accreditation if applicable) 2. Job template 3. Up to date appraisal or equivalent	**Score 5**	paper
3	**Procedures**		
3.1	Unit Throughput data and key performance indicators 1. 12 month data on new outpatients / review outpatients (& N:R ratio) 2. 12 month data on urodynamic investigation 3. 12 month data on physiotherapy referrals 4. 12 month data on surgical activity for each urogynaecology consultant and for all consultants doing urogynaecological procedures. This data to be generated from the Trust theatre IT software eg eg Theatreman. 5. Evidence that greater than 90% of major procedures (AR, PR, MUT, VH, SSF, SCP etc) are entered onto the BSUG database with evidence that, of these, (ie if 90% becomes your 100%) greater than 60% have follow-up data entered onto the database. (NB use of BSUG database is mandatory for Accreditation)	**Score 10 M**	paper
3.2	Outcome data for surgical and non-surgical management (over a period of 12 months at least) 1. Patient satisfaction questionnaires 2. BSUG follow up data, objective (POPQ) & subjective GII, QoL, EPAQ over 12 months 3. Other objective measures: pad test, flow tests 4. Morbidity data (via BSUG database & other means): extrusion, pain, dyspareunia, change in bowel or bladder function, damage to viscus, return to theatre, transfusion rate etc. 5. Evidence that complications related to Tape or Mesh Prolapse surgery are submitted to the MHRA 6. Audit. Evidence of at least 1 urogynaecology governance audit per year other than outcomes eg	**Score 20 M**	paper

	documentation, compliance with local guidelines. 7. KPI data 8. The systems used to generate the outcome data must be demonstrated, robust & open to scrutiny as determined by the assessors. 9. A printout of the relevant 12 months surgical ops for each consultant from the Trust's theatre IT system 10. Evidence that there is a rolling program producing the above data year after year – a summary of the morbidity as above for the previous 5 years.		
3.3	Evidence of Trust Clinical Governance /Standards Board support for new procedures and audit of the procedures, evidence of risk management strategy for O and G in the Trust and compliance with it. For new procedures, evidence of training, evidence of 12 month audit, information for patients, sufficient case-load > 20 per annum per surgeon.	**Score 5 M**	paper
3.4	Evidence of NICE compliance	**Score 5**	paper
3.5.	Onsite Audit of: 1. 5 recent consecutive urodynamic traces and reports 2. 5 recent consecutive urogynaecology surgical cases 3. We may wish to interrogate your database onsite.	**Score 5**	visit

Urodynamics:
Staff performing urodynamic investigations including Cystometry should be trained according to the training programme of the Royal College of Obstetricians and Gynaecologists/BAUS/BSUG/SFRU/UKCS. See **Website Urodynamic Curriculum and standards for Female A1**

Urogynaecology clinics must be supported by appropriate environmental, equipment, administrative and financial infrastructure according to the level and size of the service. There must be adequate facilities in the clinical environment to allow patient privacy for the discussion of embarrassing issues and a separate area for investigations, with adequate nurse support for the investigations, chaperoning etc.

9. Paper Assessment and Visit
(see Appendix A Assessment Sheet)

Two assessors will be appointed by BSUG and any BSUG member can apply to be an assessor. As much as possible for transparency, assessors may be chosen who are geographically distant from the index unit. It is useful to register an intention to accredit with the Committee Chair who will be able to provide advice on how to go about things and on where other units have struggled.

A maximum of 85% of the marks can picked up from the paper assessment and 15% following the visit. A visit will only take place if greater than **50%** is achieved from the paper assessment.

The file of data provided **must** follow the order listed below as per Assessment sheet with paper dividers as appropriate; the scoring is the maximum number of points available in that section. The areas marked M are mandatory criteria.

Once your unit has compiled the files (x2) contact the Chair of the Governance Committee who will allocate two assessors and provide you with their addresses so that you can send the files out. Please do not ask for an assessment until the files are totally complete and ready to be posted.

The two assessors will independently assess and score the Units file which has been sent to them. There will be an appointed leader of the process to co-ordinate matters. The Lead Assessor will collate the results and correspond with the Lead Urogynaecologist. They would aim to have completed the paper assessment within 8 weeks of receiving the file. If more than **50**% is achieved from the paper assessment a visit will be scheduled at a mutually agreeable time but within 3 months of the paper assessment completion date.

If less than 50% is achieved the Lead Assessor will contact the Unit lead and provide them with the overall score, the breakdown of the score and advise on ways to improve the score. This may require only resubmission of documentary evidence that is suboptimal rather than a completely new file. The resubmission of substandard data has to occur within 12 months of the first report being completed. The unit will then have the status of '**Provisional Accreditation'.** However, if the resubmission data is inadequate, the unit will fail and no further resubmissions will be allowed using that file. A completely new file will then be required at a later date. (it appears that numerous units have submitted substantially incomplete files and hoped for the best, creating a lot of work for the assessors with little prospect of the unit succeeding)

The visit will involve the 2 assessors and take 1 working day. A room will be required by the Assessors, who will also need to tour the unit, visit the Urodynamics suite and meet members of the Urogynaecology team and preferably the wider Pelvic Floor Team. There may be an opportunity to give feedback to the Directorate Manager, Clinical Director, Medical Director or Chief Executive. We also suggest that the Assessors make notes on any

special Good Practice points which can be shared across the BSUG membership.

The visit will be funded by the unit under assessment as far as expenses are concerned for the assessors. The RCOG Travel Policy applies. There will be no fee charged for the Assessors time. A unit may request a more urgent visit if there are concerns e.g. from the HCC, RCOG or the management of the Trust. The pass mark to accredit is 60% as this is likely to represent a reasonable level of clinical governance.

In the case of a unit failing to be accredited, the appeals process will be managed by the BSUG executive committee and the unit would have the opportunity to elect for a re-assessment with assessors chosen from a list provided to the unit by BSUG at that stage only.

During the visit:

Assessment of administrative support
It is the responsibility of hospital management to provide adequate space and facilities whereby Urogynaecology may be practised at a satisfactory level. It is the responsibility of the lead Urogynaecologist and the quality assurance visit assessors to identify where infrastructural support is deficient and to make the relevant administrative staff aware.

Areas to assess: Secretarial support and filing: do letters go out on time, is support adequate. MDT notes retrieval system and minutes/actions to be taken. Referral letters, how triaged and allocated to clinics. Access to information/advice: are the CAs or nurses available to give advice by telephone. Adequate space for urodynamic facilities and physiotherapy rooms for teaching pelvic floor exercises.

Assessment of IT/systems management
The lead Urogynaecologist will endeavour to ensure that the defined standards are met and to maintain data collection that will allow audit to be conducted against these standards. The annual return to BSUG will be the responsibility of the lead Urogynaecologist.

Areas to assess: The BSUG database should be available in out-patients, the urodynamic suite and in theatre (or by paper copy and input by secretary). There should be a robust system for ensuring that surgical follow-ups have their data entered post-operatively. There should be evidence of Clinical Governance support and audit in relation to new procedures.

Notes Audit

- 5 surgical cases
- 5 urodynamic cases

10. Re-accreditation

The process of re-accreditation will need to be broadly the same as for initial accreditation. Units may be under financial strain which could impact on: job plans, eg. resulting in reduction of SPAs reducing units' ability to update their process as necessary, reduce their ability to collaborate with colleagues etc, there may be a reducing in admin staff as examples. This could dramatically affect the quality of care. The assessment will need to be robust enough to ensure that this has not happened to the detriment of quality. However, a unit that has already accredited is likely to have a governance infrastructure in place, so from a pragmatic point of view, a signature from the Lead Urogynaecologist to testify to certain criteria in the Personnel and Process sections will suffice. Any changes to service or personnel will need assessment. A specific proforma for Re-accreditation has therefore been devised (see appendix D). A repeat visit to the unit will be at the discretion of the Chair of Governance Committee, but will probably not be required if the set-up and geography of the clinic and theatres has not altered since the previous visit. Also by negotiation the re-accreditation process could be electronic.

As well as scoring the data provided, we would hope that the recommendations from the first visit would have been addressed prior to the assessment.

The second re-accreditation will require a review of all data as for the 1st accreditation assessment.

11. Conclusions

We hope that a system of unit accreditation for Urogynaecology will allow high standards of care to be recognised and applauded. The assessment process is designed to be relatively straight-forward to undertake, with the data collection mirroring that required for sub-specialty visits, CPD and revalidation. The use of BSUG.net provides an easily available audit report mechanism. The BSUG website will provide patient information leaflets. We envisage this process being helpful to the unit being assessed, for example in achieving support for new equipment, improved staffing levels/training and highlighting necessary improvements. It is also important that Urogynaecology is seen as a sub-specialty covering all aspects of female pelvic floor dysfunction, and not fragmented into stand-alone investigations services.

12. Reference sources

- *Good Practice in Continence Services DoH, 2000.*
- *NSF for the Older person 2003*
- *International Colloquium in Incontinence 2005*
- *NICE guidance 'Female Incontinence' 2006*
- *18 week pathways for Incontinence and Prolapse*
- *NICE guidance on Mesh for pelvic organ prolapse 2008*
- *RCOG Standards for Gynaecology and Urogynaecology 2008*
- *DH (Keogh & Willett) Letter to Medical Directors: Vaginal Tapes and Meshes 21 Nov 2012*

13. Frequently asked questions

Q. How do we go about trying to Accredit??

A. Have a meeting with the whole urogynae team, and if possible the relevant colorectal and urology colleagues. Get the team on board with perceived benefits, eg commissioning etc. Then use the Assessment form (appendix A) to do a Gap Analysis. This is management mumbo jumbo speak for assessing what you can comply with at the moment, where the gaps lie, and then make a plan to address those gaps. I would put your efforts first into what takes the longest to achieve ie. good outcome data via BSUG database. Get mechanisms in place to achieve this. Then whilst you are collecting the data over time, focus on developing written pathways, protocols for common conditions, patient info etc.

Have regular meetings with targets to ensure this happens.

Q. What if one of the Generalists in our unit wants to continue doing urogynae procedures?

A. It is the unit which is accredited. Ideally all urogynaecology procedures ought to be done within the broader urogynaecology team. If the generalist has appropriate training, does the appropriate workup, (eg urodynamics, proctogram), performs the procedures (bearing in mind NICE guidance), enters the appropriate data onto the BSUG database including follow-up data, complications and other outcomes and informs MHRA of relevant morbidity (just as would be expected of the *bone fide* urogynaecologist) then this should not influence accreditation. From a team working and Governance perspective, it may make sense to bring the generalist into the wider Urogynae Team.

14. Appendix A. Assessment sheet

15. Appendix B

Assessment of administrative support Score of 5

Letters sent out within 2 weeks

Method of triage of letters, acceptable clinic templates

Cases proved for MDT and the mechanism

Minutes of MDT

Adequate clean private facilities for urodynamics and physiotherapy

Assessment of IT / systems management Score of 5

BSUG.net available in theatre and outpatients

Available person to input data onto audit database

Total score 10

16. Appendix C

Audit of Surgical Case-notes and Urodynamic Traces (5 of each)
Both case-notes and urodynamic traces should be the last 5 cases completed for ease of access. Copies of theatre lists also attached.

1. Surgical audit

Demographics completed

History sheet completed and signed

Examination documented

Evidence of conservative management prior to surgery

Consent form (including BSUG database consent form) and patient information adequate. Patient expectations recorded.

Surgery as consent form

Post-operative follow-up and adequate management of any post-op complications

Evidence of decision making within MDT

2. Urodynamics Trace Audit 5 cases

Demographics completed

Clear vesical, abdominal and sub-tracted traces, along with filling trace and evidence of good subtraction

Normal range filling rate

Regular coughs documented, change of position

Evidence of provocation testing and the outcome

Printouts to demonstrate bladder capacity, flow rates

Clear diagnosis and description of test results, with a management plan