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 Commissions 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, 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, through clinical governance underpinned by modernised professional self-regulation and extended lifelong learning.

2. Standards for accreditation of units and individuals

BSUG Definition of a Urogynaecologist

Dedicated Urogynaecology Clinic or equivalent per week including secondary and tertiary referrals, as part of a multidisciplinary service.
Evidence of training in a Unit, which provides the full range of investigations and treatments required for training.
Urodynamics experience e.g. Special Skills Training.
Regular Urodynamic sessions (minimum of one per month) either personally or in a supervisory capacity.
Provide three clinical sessions in Urogynaecology per week.
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.net surgical audit
Three-yearly review (as per membership requirement for BSUG)
CME review; proportion of CME in urogynaecology

Standards of Accreditation

The purpose of accreditation is to define and monitor standards of care, organisation and quality within urogynaecology units. These 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
increase clinical risk management awareness
contribute to the development and implementation of clinical governance

Urogynaecology procedures should be carried out by trained and accredited Uro-Gynaecologists or by trainees under the supervision of a trained and accredited Uro-gynaecologist.
A Urogynaecologist (see definition above) should spend at least 50% of their time in Urogynaecology (3 clinical sessions per week if full-time contract). In the future, they will hold an ATSM or preferably have undergone subspecialty training in Urogynaecology.

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. The urodynamic equipment should undergo regular servicing and re-calibration.

A designated lead Urogynaecologist should manage the services.

Protocols should be available to staff and patients for the diagnosis, investigation and management of all urogynaecological conditions seen in the unit, with evidence that these are regularly audited and reviewed (e.g. for surgery, using the BSUG surgical audit database).

All staff members must be compliant with CPD and the appraisal process.

3. 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*

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, conservative measures and surgical procedures, for women lower urinary tract and gastrointestinal conditions including with incontinence and pelvic organ prolapse. These conditions are not life-threatening and it is important that the 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, and the knowledge and understanding of when to operate, have the required operative skills and when to ask for tertiary advice. 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.

4. 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 (NICE recommend the BSUG.net database for surgery is used)
- 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

5. 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. This information gathering (e.g. surgical outcomes via the BSUG audit database) will be within the remit of the Trust management and Clinical Governance committee and this information should be shared with the Lead Urogynaecologist and the team on a regular basis e.g. by means of the MDT and demonstrated during the assessment. In many Trusts, the 'bottom-up costing' of treatments can provide valuable information about performance of the unit in relation to the national tariff (if applicable). 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.

6. Assessment Visit
(see Appendix B Assessment Sheet)

Assessors will be appointed by BSUG and any BSUG member can apply to be an assessor.

It is expected that assessments will involve 2 assessors, take 1 working day and occur every 5 years. A room will be required by the Assessors, who will also need to visit the Urodynamics suite and meet members of the Urogynaecology team. The visit will be funded by the unit under assessment as far as expenses are concerned for the assessors. 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. 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-visit with assessors chosen from a list provided to the unit by BSUG at that stage only.

All pre-assessment documentation must be with the assessors no later than 6 weeks in advance of the agreed date of the visit. Initially, while assessors re being trained, the documentation will be reviewed by 4 assessors. The assessors will only carry out a visit if the unit is likely to accredit. If the assessors do not believe that the unit currently meets the criteria, they will delay the visit until unit documentation is complete. The aim of the documentation collection will be to overlap to a large extent with those assessments performed for ATSM and subspecialty accreditation and general appraisal/CPD/Revalidation in order to make this process relatively easy to complete. Reports produced by BSUG.net can be used to provide evidence of surgical audit of outcomes.

Documents to be viewed in pre-assessment can be divided into 3 categories:

1. Process

a. Guidelines for the agreed mechanism of referral to secondary care including care pathways/13 weeks pathway
b. History proforma and any quality of life assessment/voiding diaries, evidence of how patients are assessed
c. Patient information leaflets and operation specific consent forms, unit protocols for the management of specific conditions (expect to see haematuria, recurrent UTI, Interstitial cystitis, vault prolapse, third degree tear, stress UI, urge UI). Evidence of when last reviewed.
d. Evidence for regular servicing and calibration log for equipment, less than 5 years old. Full list of equipment including bladder scanners.
e Evidence of MDT working e.g. minutes from MDT attended by nurses, physiotherapists and CAs, colorectal or urology colleagues and terms of reference for MDT
f Referral letters from community team and tertiary referrals from colleagues, or referrals to tertiary colleagues
g Joint clinics for OASIS follow-up and complex urology cases if these occur

2. Personnel

a CVs and Job plans and job descriptions for all staff, evidence of appropriate training for their role, evidence of training and accreditation in Urodynamic investigations if performed
b Evidence of CPD of nurses and clinicians, attendance at local and national meetings
c Evidence regarding the lead Urogynaecologist/any Consultant with special interest:

CV provided showing evidence of training e.g. ATSM, subspecialty training or grandfather status
50% job plan in Urogynaecology/3 sessions

Evidence of referrals by general colleagues, proportion of continence and prolapse surgery done by him and others
Accredited in Urodynamics
1 major pelvic floor procedure per working week
Use of a follow-up database (e.g. BSUG.net) and reports from the database
National or international involvement in Urogynaecology e.g. member of BSUG sub-committee, UKCS, IUGA or ICS)
Other evidence can also be provided of outcomes via Dr Foster, CHKS

3 Procedures

a. Unit throughput data and key performance indicators
12 month data on new outpatient referral numbers
12 month data on follow-up patient numbers
12 month data on primary urodynamic investigations
12 month data on secondary (repeat) urodynamic investigations
12 month data on physiotherapy referrals
12 month data on surgical activity including list of cases (primary and repeat surgery)
New patient/follow-up ratios
Conversion rate to surgery (calculated from patients added to w/L, divided by the total number of outpatients seen)
Length of stay
Returns to theatre
Transfusion rate
Morbidity data and re-operation rate within 12 months for the same condition (all can be identified within BSUG database)

b. Outcome data for both surgical and non-surgical management e.g. patient satisfaction questionnaires, quality of life data, pad test or flow data pre and post-operatively, evidence of examination and post-operative assessment (BSUG.net if used), CHKS or Dr Foster data with a detailed examination of serious misadventures.

c. Evidence of audit and completed cycles with change in practice (list only)

d. Evidence of clinical governance 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.

e. Evidence of NICE compliance

f. Evidence of patient participation in the service provision and feedback which has resulted in a change of practice

If any deficiencies have previously been identified, evidence of work with the Trust or PCT to remedy them

g. Audit of 5 recent consecutive Urodynamics traces for the assessment team to review
Audit of 5 recent consecutive Urogynaecology cases from theatre (proforma at 11.)

Aim is to look at standard of urodynamics and also the decision-making process with regard to surgery.

4 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.

5 . 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. The annual return to BSUG should be completed OR equivalent audit of outcomes carried out. There should be evidence of Clinical Governance support and audit in relation to new procedures.

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. 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. 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.

9. Conclusions

We hope that a system of unit accreditation for Urogynaecology will allow high standards of care to be recognised and preserved. 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 operation specific consent forms and patient information leaflets, care protocols to help with the process. 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.

10. 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*

11. Appendix B Assessment Sheet

The file of data provided should follow the order listed below; the scoring is the maximum number of points available in that section. It is likely that a unit that scores 60/100 is providing a reasonable level of Clinical Governance and will pass. Units scoring less than 50/100 will not be accredited until any issues have been resolved. Units scoring 50-60 points will have to provide further data to substantiate changes in place. The areas marked M are mandatory.

Suggestions for visit. We suggest that having toured the unit and checked some of the data provided with the Lead Clinician and other key staff, that the assessors should probably meet: Lead Physiotherapist, Lead Nurse or CA, other members of MDT. 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 Assessment report should follow the format listed with the scoring against each point.

Unit documentation and Scoring applied

1. Process

1. Copy of the guidelines for the agreed mechanism for referral to secondary care including care pathways (18 weeks) **Score 2.5**

2. History proforma and fluid balance charts, any quality of life questionnaires, any other unit protocols and evidence for when last reviewed. **Score 2.5 M**

3. Copy of all patient-related paperwork: consent forms and Unit protocols for management of specific conditions e.g. haematuria, recurrent UTI, interstitial cystitis. Patient information leaflets including all those for conservative management as well as all surgeries (BSUG website will provide examples) **Score 5 M**

4. Evidence for regular servicing and calibration log for equipment (insert dates below). **Score 2.5 M**

5. Evidence of MDT working e.g. minutes from MDT attended by nurses, physiotherapists and CAs. Terms of reference, membership for the multidisciplinary team meetings.

6. Referral letters from community team and tertiary referrals from colleagues, or referrals to tertiary colleagues.

7. Dates of joint clinics in urology and colorectal surgery, OASIS if these occur. **Score 5**

2. Personnel

8. CVs and Job plans and job descriptions for all staff, evidence of appropriate training for their role, evidence of training and accreditation in Urodynamic investigations if performed
Job description for nominated lead clinician
Job description for Nurse specialist.
Job description for Specialist physiotherapist.
Job description for specialist midwives (perineal clinics) and any admin support, secretarial and patient services staff. Confirm job plan meets Urogynaecologist definition. **Score 5 M**

9. Evidence of CPD/PDR of nurses and clinicians, attendance at local and national meetings, any local or national organisational roles e.g. BSUG committees, UKCS, ACA **Score 2.5**

10. Lead Clinician data

Copy of CV for file
Evidence of Training in Urogynaecology: ATSM, subspecialty training or grandfather status
Copy of Job plan in Urogynaecology (50% or 3 sessions)
Evidence of referrals by general colleagues, proportion of continence and prolapse surgery done by him and others (letters for file)
Evidence of Accreditation in Urodynamics (Training certificate)
At least 20 of each primary procedure per year (list of cases to be reviewed, NB no double-counting e.g. anterior and posterior repair is 1 case)
Use of a follow-up database (e.g. BSUG.net) and reports from the database
Other forms of evidence can also be provided of outcomes via Dr Foster, CHKS **Score 10**

3. Procedures
11. Throughput and KPI:
12month data on new outpatient referral numbers
12 month data on follow-up patient numbers
12 month data on primary urodynamic investigations
12 month data on secondary (repeat) urodynamic investigations
12 month data on physiotherapy referrals
12 month data on surgical activity
KPI hospital data e.g. new-follow-up ratios, Conversion rate to surgery, Length of stay Returns to theatre, Transfusion rate, Morbidity data and re-operation rate for the same condition within 12 months
Score 10 M

12. Outcome data for both surgical and non-surgical management e.g. patient satisfaction questionnaires, quality of life data, pad test or flow data pre and post-operatively, evidence of examination and post-operative assessment (BSUG.net if used) Evidence of regular departmental audits and completed audit cycles with evidence of change in practice
Score 10 M

13. Evidence of clinical governance support for new procedures and audit (correspondence with Clinical Governance committee)
Evidence of NICE compliance (Review working practices with reference to NICE guidance on female incontinence and use of meshes) **Score 5M**

14. If any deficiencies have already been identified, evidence of work with the Trust or PCT to remedy them (Notes by assessors) No score

15. Evidence for patient participation and communication (Focus groups or satisfaction surveys). No score as we regard this as aspirational currently

Audit Data (See Form C for assessment proforma)

Audit of 5 recent consecutive Urodynamics traces for the assessment team to review
Score of 10

Audit of 5 recent consecutive Urogynaecology cases from theatre
Score of 10

Assessment of administrative support Score of 10

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 systems management Score of 10

BSUG.net available in theatre and outpatients

Available person to input data onto audit database

Total score **/100**

Form 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 decision making by Lead clinician or discussion with him/her

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

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

Evidence of decision making by Lead clinician or discussion with him/her