HQIP
Healthcare Quality Improvement Partnership

Interim Database Feasibility Report

Urogynaecological Surgical Mesh

January 2019

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2 Introduction

2.1 Background

After considering an early recommendation from the Independent Medicines and Medical Devices Safety Review (chaired by Baroness Julia Cumberlege) on 10th July 2018 the Department of Health and Social Care (DHSC) have instigated a pause in the use of surgical mesh for the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP). There are an associated 6 recommendations to be met by March 2019 in order for DHSC to lift the pause, three (β) of these relate to the capture and reporting of data for procedures performed utilising surgical mesh:

1. Surgeons should only undertake operations for SUI if they are appropriately trained, and only if they undertake operations regularly;
2. Surgeons report every procedure to a national database (β);
3. A register of operations is maintained to ensure every procedure is notified and the woman identified who has undergone the surgery (β)
4. Reporting of complications via MHRA is linked to the register (β);
5. Identification and accreditation of specialist centres for SUI mesh procedures, for removal procedures and other aspects of care for those adversely affected by surgical mesh;
6. NICE guidelines on the use of mesh for SUI are published.

A full national clinical audit (NCA) or national registry would take an estimated 2 years to procure, set up and to begin data collection, it would then take approximately 1 further year to produce outputs (figure 1). This highlights that an interim measure is needed in order to meet the pause (β) recommendations until a national registry could begin to collect data.

HQIP was commissioned by the DHSC to undertake a short term exploratory feasibility study to investigate urogynaecological surgical mesh data requirements. Specifically, the current sources of mesh, SUI or POP data maintained by three professional societies; The British Association of Urological Surgeons (BAUS), The British Society of Urogynaecology (BSUG) and The Pelvic Floor Society (TPFS), and whether these current data collections could address the (β) recommendations from the Baroness Cumberlege report as an interim measure before a full clinical national registry could be established.

2.2 Report purpose

This report is a summary of the exploratory work that HQIP undertook from September to December 2018 and includes:

1. Exploration of the current BSUG, BAUS & TPFS databases and:
    a. Discussions with clinical and technical representatives of each organisation.
    b. Completion, by each of the three organisations, of the HQIP Understanding Practice in Clinical Audit and Registries tool (UPCARE Tool). A protocol for National Clinical Audits which summarises key information on scope, methodology, engagement and outputs).
    c. Evaluation of available database documents (patient leaflets, privacy notices, consent materials, Section 251 applications[1] and approvals, published reports).
    d. Test site access to BSUG and TPFS maintained databases.

[1] Support under Section 251 of the National Health Service Act 2006 and its current Regulations, the Health Service (Control of Patient Information) Regulations 2002, enable the common law duty of confidentiality to be temporarily lifted. See https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/

2. Requirements of the Medicines and Healthcare products Regulatory Agency (MHRA) and new National Institute for Health and Care Excellence (NICE) guidance[2].
3. Findings from two HQIP workshops:
    - A technical workshop
    - A stakeholder workshop
4. Feasibility of utilising existing databases to develop a fully configured interim mesh database solution to meet the pause (β) recommendations.
5. Option appraisal of the potential models available to the DHSC for the establishment of a new interim database.
6. Options to meet pause(β) recommendation 4 (Reporting of complications via MHRA is linked to the register)
7. Recommendations of modifications required to the existing BSUG, BAUS and TPFS databases to achieve a new interim database

Following this report, it is anticipated that a further piece of detailed implementation work will be carried out to establish the interim database and investigate remaining areas of uncertainty.

2.3 Timelines

Figure 1 below demonstrates estimated timelines for:

- Short term HQIP exploratory work (September to December 2018)
- Medium term implementation work to establish interim database
- Long term work to establish a national clinical audit/registry

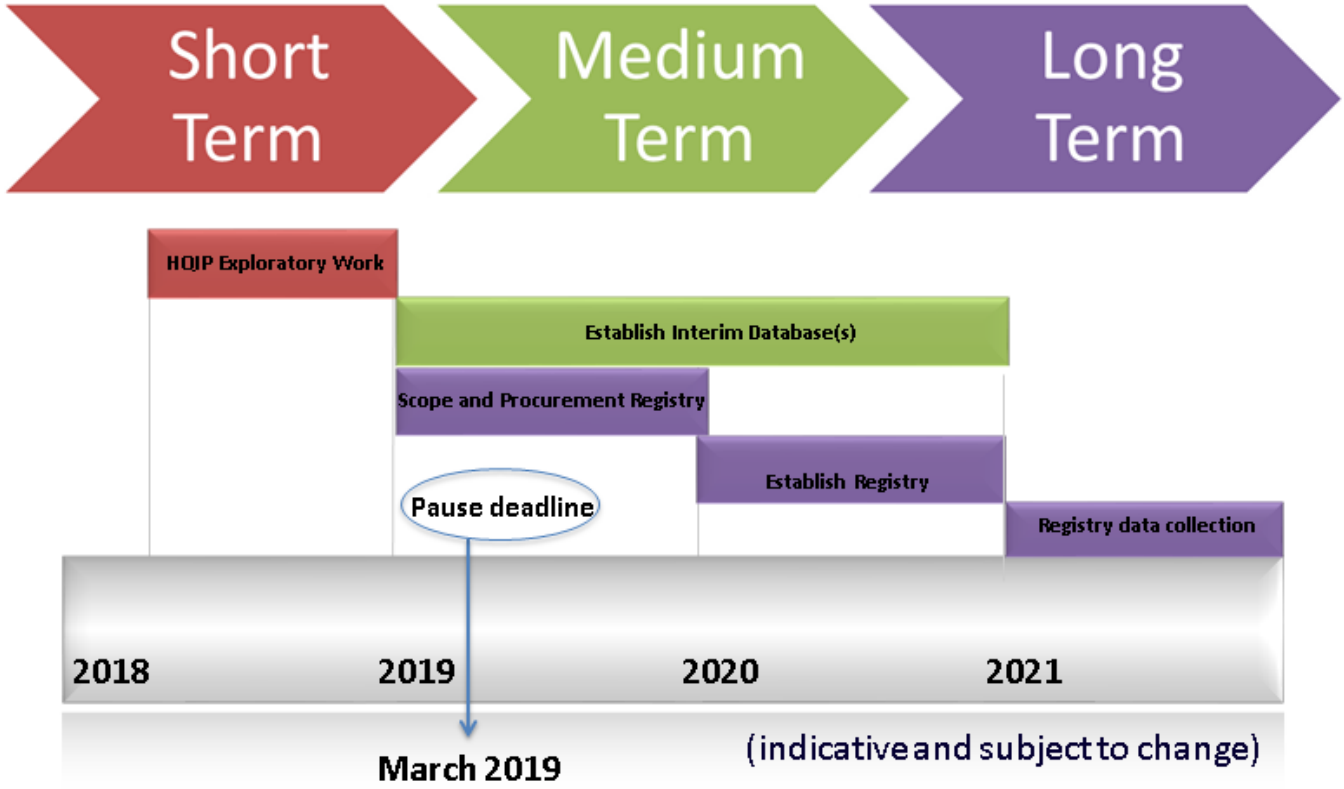


Figure 1: Estimated timescales

[2] Urinary incontinence (update) and pelvic organ prolapse in women: management (GID-NG10035). Expected publication April 2019. Available https://www.nice.org.uk/guidance/indevelopment/gid-ng10035/documents

3 Current BSUG, BAUS and TPFS databases

3.1 Current database aims

BSUG

The BSUG database has been available since 2007, allowing BSUG members to record details of all procedures (including all mesh procedures) performed to treat urinary incontinence and pelvic organ prolapse. There are no defined quality improvements aims or objectives other than to allow individual clinicians the opportunity to record and examine their own practice, for individual appraisal and to produce national level results. The database records complications and has a link to the MHRA to allow direct yellow card reporting of adverse events.

BAUS

The overall aim of the BAUS SUI audit is to drive forward the standards of surgery, help patients make informed decisions about their care, and support surgeon's requirements for professional revalidation. Highlighting median practice of SUI surgery by UK urologists in terms of numbers of procedures undertaken, complications and patient outcomes.

TPFS

The Laparoscopic Ventral Mesh Rectopexy (LVMR) registry is intended to provide a mechanism by which surgeons can record all operative cases of LVMR. The use of the database is a mandatory requirement for accreditation of a pelvic floor unit by the Association of Coloproctology of Great Britain and Ireland or TPFS, although accreditation is voluntary.

Objectives of the LVMR registry are:

- Increase the proportion of patients having LVMR who have their data recorded on the database
- Accurate measurement of:
    - mesh related complication rate for LVMR and determined for the different types of mesh
    - non-mesh related complication rate for LVMR.
- Assess the clinical efficacy of LVMR for the treatment of rectal prolapse and obstructed defaecation syndrome.

3.2 Current database governance arrangements

BSUG

The BSUG Executive Committee have overall accountability for the database, decision making and day-to-day operational responsibility is delegated to the Audit Database Committee and the Chairman of the BSUG Audit Database Committee, assisted by a part-time database administrator and subcontracted IT provider (ICE ICT). The Audit Database Committee oversees the structure of the database and implementation of continuous improvements. There is input from the BSUG Research Committee for clinical research elements. Membership of both committees composed of gynaecologists. There is no specific patient and public involvement.

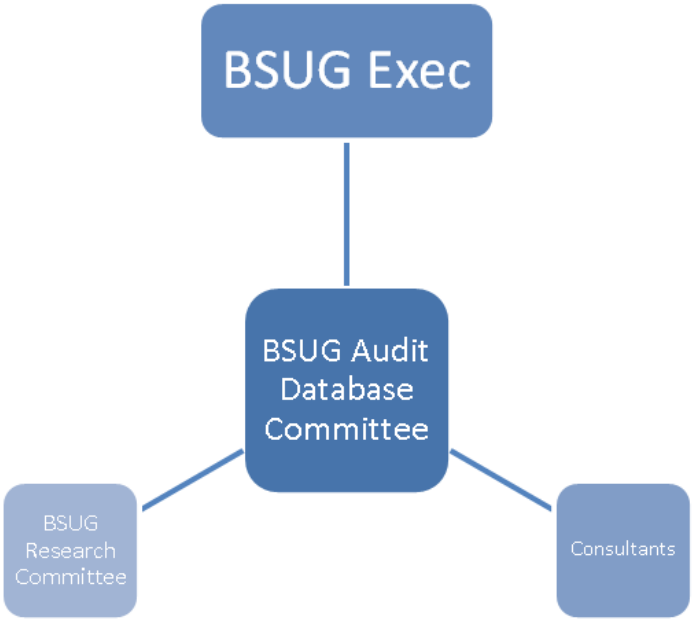


Figure 2: BSUG database governance structure

BAUS

The Executive Committee of the BAUS Section of Female, Neurological and Urodynamic Committee (formerly named Section of Female and Reconstructive Urology) have overall responsibility for the SUI database. Two members of the Section Executive Committee act as clinical leads for the audit, two BAUS staff work part-time on this audit and eight other audits and the IT platform is provided by Dendrite. BAUS Trustees have oversight of all committees and a BAUS Trustee sits on the Section Executive Committee. Membership of the Section Executive Committee is composed of Urological Surgeons (with the exception of the BAUS audit co-ordinator). There is no specific patient and public involvement.

TPFS

The Executive Committee is the decision making body with overall responsibility for the database, with operational day-to-day responsibility delegated to the Treasurer who is supported by a part-time administrator and subcontracted IT provider Formedia. The Executive Committee meet 2-3 times per year and membership is primarily composed of Colorectal Surgeons but includes a non-surgical member representing the Physiotherapy, specialist nursing and AHP sub committee. There is no specific patient and public involvement.

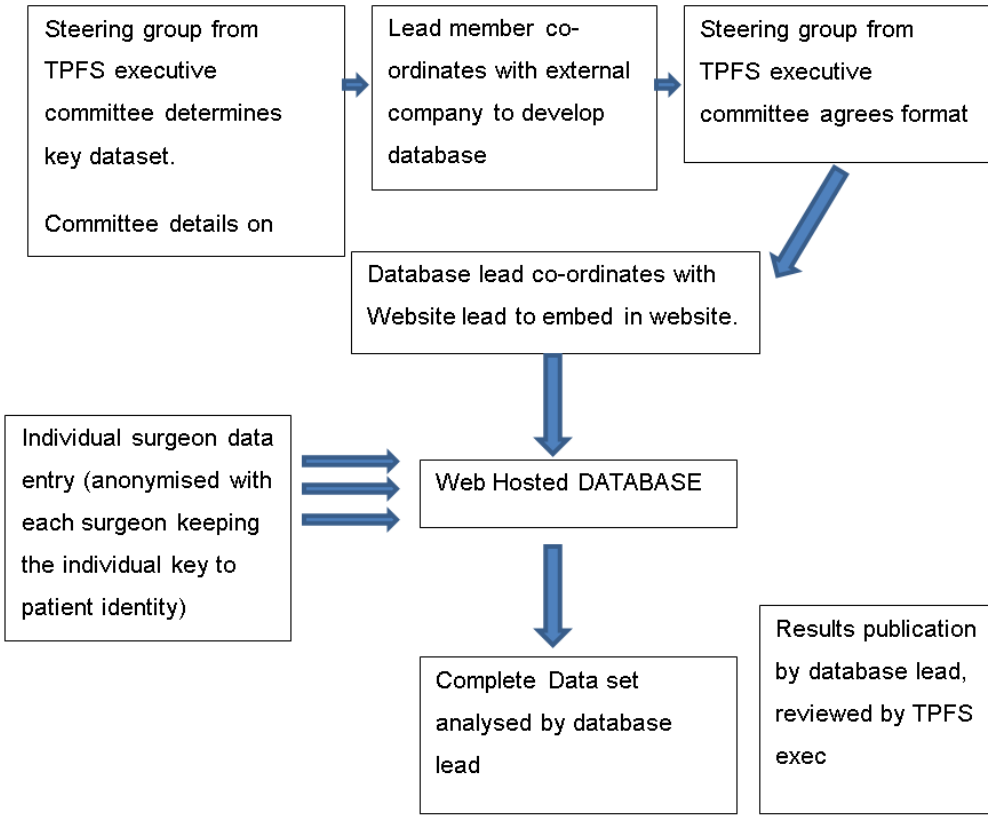


Figure 3: TPFS database governance structure

3.3 Scope of existing databases

3.3.1 Current database clinical conditions

Each of the three databases are distinct in terms of the clinical professions covered but there is some slight overlap in scope between BSUG and BAUS since both cover procedures for Stress Urinary Incontinence. In a general sense the following collect data on procedures performed to treat:

- BSUG - Urinary Incontinence (UI), Pelvic Organ Prolapse (POP) and Rectal Prolapse performed by Urogynaecologists.
- BAUS - female SUI performed by Urologists.
- TPFS - external rectal prolapse and high-grade intussusception with obstructed defaecation syndrome performed by Colorectal Surgeons.

Table 1: summary of clinical conditions covered by databases

Element	BSUG	BAUS	TPFS
Clinical Group	Urogynaecologists	Urological Surgeons	Colorectal Surgeons
Stress Urinary Incontinence	YES	YES	NO
Pelvic Organ Prolapse	YES	NO	NO
Rectal Prolapse	YES	NO	YES

3.3.2 Current database geographical coverage

BSUG, BAUS and TPFS have UK wide coverage including England, Wales, Scotland and Northern Ireland.

BSUG

Any registered member of BSUG can enter data. Geographical coverage includes England, Wales, Scotland and Northern Ireland. It has been reported that barriers are inhibiting the collection of data within Scotland, to date only a small number of units within Scotland have participated. More recently BSUG has gained approval from a Scottish National Caldicott Guardian body but this is subject to establishment of a data sharing agreement, which is still outstanding due to Scottish Government concerns about compliance of the database with the GDPR (General Data Protection Regulation).

BAUS

Any registered member of BAUS can enter data. Geographical coverage includes England, Wales, Scotland and Northern Ireland. However in practice there do not appear to be any participants submitting data from Northern Ireland because of legal obstacles.

TPFS

Any registered member of TPFS can enter data. Geographical coverage includes England, Wales, Scotland and Northern Ireland.

3.3.3 Current database inclusion criteria

All three databases cover the NHS and independent sector (both NHS and privately funded). Rather than patient criteria, inclusion criteria are based upon the clinical professional undertaking the procedure; the procedure performed and the clinical diagnosis.

BSUG

- Female patients only
- Primary and secondary Urinary Incontinence procedures (71 procedures captured, see appendix A for full list)
- Primary and secondary Prolapse procedures (69 procedures captured, see appendix A for full list)
- Primary Mesh Complication Procedures (15 Procedures collected)
- NHS or independent sector (NHS funded and privately funded)

BAUS

- Female patients only
- Primary Stress Urinary Incontinence procedures (32 procedures captured, see appendix A for full list)
- NHS or independent sector (NHS funded and privately funded)

TPFS

- Age >18 years old and able to consent to the operation and the inclusion of data within database.
- Male and Female
- Primary Ventral Mesh Rectopexy
- NHS or independent sector (NHS funded and privately funded)

Table 2: summary of primary procedures captured by databases			
Primary procedure for:	**BSUG Primary Procedures (number of variable procedures)**	**BAUS Primary Procedures (number of variable procedures)**	**TFPS Primary Procedures (number of variable procedures)**
Incontinence	1. Anterior repair (AR) + BNB 2. Artificial urinary sphincter 3. Cystoscopic BNI (5) 4. Cystoscopic Botulinum Injection 5. Coaptite injectable implant 6. Periurethral BNI 7. Non-Cystoscopic BNI (4) 8. Colposuspension (2) 9. MMK 10. Retropubic MUS (16) 11. Transobturator tape TVT (2) 12. Transobturator tape - TOT (11) 13. Single excision tape (8) 14. Laparoscopic urethropexy 15. Sling (8) 16. Urethral Diverticulectomy 17. Closure Fistula (2) 18. Insertion Long Term Suprapubic Catheter 19. Adjustable Continence Therapy (ACT) 20. Discontinued Procedures (3)	1. Retropubic tape trocar passed bottom-to-top (TVT) 2. Transobturator tape - trocar passed outside-to-inside (TOT) 3. Transobturator tape - trocar passed inside-to-outside (TVTO) 4. Mini tape 5. Other tape 6. Colposuspension 7. Peri-urethral bulking agent 8. Autologous sling 9. Artificial urinary sphincter 10. Other operation (12)	Not collected
Pelvic Organ Prolapse	1. Anterior Repair (AR) 2. AR + graft 3. Manchester Repair 4. Vaginal Hysterectomy (2) 5. Laparoscopically assisted vaginal hysterectomy (2) 6. TOAR (7) 7. Needlessness Repair Pinnacle (3) 8. Posterior Repair (PR) (7) 9. Uphold vaginal support system 10. Posterior IVS 11. Infracoccygeal mesh hysteropexy 12. Infracoccygeal vault mesh suspension 13. TVM (4) 14. Paravaginal repair (3) 15. Sacrocolpopexy (4) 16. Sacrospinous fixation (2) 17. Sacrospinous hysteropexy (2)	Not collected	Not collected

	18. Iliococcygeal fixation (2) 19. Sacrocolpohysteropexy (2) 20. Sacrocolpocervicopexy (2) 21. Sacrocervicopexy (2) 22. Laparoscopic suture hysteropexy 23. Laparoscopic uterosacral plication 24. Vaginal uterosacral plication 25. Moscowitz 26. Halban 27. Colpoclesis 28. Total Colpectomy 29. Discontinued (7)		
Rectal Prolapse	1. Ventral Mesh Rectopexy Open 2. Ventral Mesh Rectopexy Laparoscopic 3. Ventral Mesh Rectopexy Robotic	Not collected	1. Ventral mesh rectopexy 2. Ventral mesh rectopexy robotic
Mesh/Graft Complications	1. Suburethral tape - stretched 2. Suburethral tape – divided 3. Excision vaginal part of MUT (not exposed/ eroded) 4. Partial removal retropubic tape (open/ laparoscopic/ robotic) 5. Total removal retropubic tape (open/ laparoscopic/ robotic) 6. Mesh erosion (urethral) – excised 7. Mesh erosion (bladder) – excised 8. Mesh erosion (bowel) – excised 9. Burial of mesh (no mesh removed) 10. Localised excision and closure of mesh exposure 11. Total excision of mesh 12. Total removal of transobturator tape 13. Abdominal removal sacrocolopexy mesh 14. Abdomonal removal sacrohysteropexy mesh 15. Abdomonal removal sacrocervicopexy mesh	Not collected as primary procedure	Not collected as primary procedure

3.3.4 Current database participation requirements

To use the database a clinician must be a:

- **BSUG**
  - Registered member of BSUG, membership has an associated £110 cost for Consultants and £60 for Associates, and it is estimated that approx. 50% of urogynaecologists registered with BSUG are participating within the database.
- **BAUS**
  - Registered member of BAUS. Non-members are able to access the database and one non-member submits data, however in 2018 a monetary fee for non-members was introduced. 95% of urology consultants are members.
- **TPFS**
  - Registered member of TPFS and Association of Coloproctology of Great Britain and Ireland (ACPGBI), there are no membership fees as TPFS is industry funded. There are membership fees associated with ACPGBI.

3.4 Current database dataset

The full BSUG, BAUS and TPFS datasets can be found in Appendices B, C and D however key data items are summarised below.

Table 3: BSUG, BAUS and TPFS summary data items collected

Category	Data Field	BSUG	BAUS	TPFS
Patient details	**NHS Number**	No[3]	Unique identifier – NHS number or CHI (Community health index) preferred but hospital number may also be collected	No
	Hospital Number	*Yes	Yes	No
	Name	*Yes	No	No
	Date of Birth	*Yes	*Yes	No
	Gender	No (see inclusion criteria)	Yes	*Yes
	Post code	No	No	No
	NHS/Private	Yes	Yes	No
	Other	*Consent	*Consent	• Consent • *Pseudonymised identifier composed of hospital reference and patient ID (key stored on local Trust server)
Clinician Details	**GMC number**	No	*Yes	No
	Grade	Yes	No	Yes
Pre-op details	**Height/Weight/BMI**	Yes	Yes	No
	Pelvic Floor	Yes	No	No
	Urodynamics	Yes	Yes	No
	MDT discussion	Yes	Yes	No

[3] Note: since evaluation of the database NHS number has since been added as a collected field

	Prior Surgery	Yes (prior incontinence, prolapse or mesh complication procedure)	Yes (prior procedures for SUI	Yes (prior hysterectomy, TVT in situ, colposuspension)
	Other	Procedure specific information given	• Co-morbidities • Previous radiotherapy	• Menopausal status
Surgery Details	**Clinical Indication**	Primary/repeat: • Incontinence • Prolapse • Incontinence + Prolapse • Mesh/Graft complication	*Kind of surgery: • Primary • Recurrent SUI	Yes: • Obstructive defaecation • Faecal incontinence • External prolapse • Solitary rectal ulcer syndrome • Pain • Middle compartment prolapse
	Procedure	Yes (155 procedures)	*Yes (32 procedures)	Only distinguishes if procedure is robotic
	Procedure date	Yes	Yes	Yes
	Hospital Site	No (automatically attributed to the registered Trust of the clinician entering the record)	*Yes	No (although site code used to derive unique patient identifier)
	Discharge date	No	Yes	No
	Length of stay	Yes	No (but a calculated field)	Yes
	Discharge status	No	Yes	No
Mesh Details	**Unique Device Identifier (UDI)**	No	Yes (Mesh Identification Number)	No
	Manufacturer	No	No	No
	Catalogue Number	No	No	Product Code
	Device nomenclature/classification	No	No	Yes
	Description	No (may be able to distinguish mesh type from procedure chosen)	Yes	Yes
	Material	Yes	No	Yes
	Type of Sutures	No	No	Yes
	Other	No	No	• Batch Code • Sutured to peri-utero ligaments
PROMS/ Outcomes	**ICIQ**	Yes: • ICIQ-UI (SUI) • ICIQ-VS (prolapse) • ICIQ-QAB (overactive bladder)	Yes: • ICIQ-UI	No

		• ICIQ-LUTsQOL (urinary quality of life)		
	POP-Q	Yes	No	No
	PGI-I (Global Impression of Improvement)	Yes	No	No
	E-PAQ for UI-specific QoL	Yes	No	No
	EQ-5D 5L	No	Yes	No

	Other	• Long-term Problems:
		  ○ Prolapse
		  ○ Bladder
		  ○ Bowel
		  ○ Sexual activity
		  ○ Mesh
		  ○ Chronic pain
		• Change in incontinence
		• Requires catheter
			• Patient reported severity of incontinence:
			  ○ 0-1 pad/day
			  ○ 2-3 pad/day
			  ○ 4-5 pad/day
			  ○ >5 pad/day
			• UTI
			• Dependent upon catheter
			• Patient satisfaction
				• Primary Outcome:
				  ○ Success
				  ○ No Change
				  ○ Deterioration
				• Ongoing problems
				• Recurrent prolapse
				• Recurrence stoma

Peri-Operative Complications		Yes: • Ureteric injury • Bladder injury • Bowel injury • Vaginal button hole • Urethral injury • Blood loss>500ml	Yes: • None • Bladder perforation • Urethral perforation • Procedure abandoned • Other	Yes (free text)
Mesh Complications	**Indication**	Yes: • Pain • Dyspareunia • Mesh erosion/extrusion • Voiding difficulty • To relieve urinary urgency • Urinary incontinence • Urinary tract infections • Patient request • Other (free text)	Yes: • Tape Extrusion • Persistent pain after surgery	Yes: • None • Detachment • Vault erosion • Vaginal erosion • Vaginal extrusion • Rectal erosion • RV fistula • Rectal stricture • Rectal extrusion • Bladder erosion • Vaginal pain

	Classification of mesh complication	Intra-operative mesh/graft complication score (ICS-IUGA https://www.ics.org/complication)	Clavien Dindo grade of complications	No
	Intervention required	Yes (15 procedures)	Intervention for extrusion (6 procedures)	Yes (9 procedures)
	Date revision procedure	Yes	No	Yes
Readmission		Yes	No	Yes
Follow up period		12 months	3-6 months	6 weeks to 9months
Footnote: *Mandatory fields				

3.5 Current database data flows and linkage

BSUG, BAUS and TPFS do not link their datasets at a patient level to any other national dataset (such as HES). Data does not flow at a patient level to any other external organisation (although BSUG does have built in functionality to allow yellow card reporting of adverse incidents to the MHRA).

BAUS and BSUG have used aggregate national HES data to determine case ascertainment. It was noted that the introduction of new HES coding for mesh will improve the accuracy of coding and identification of the procedure in the HES denominator. .

3.6 Current database information governance

3.6.1 Data protection and legal basis

There are two elements to legal basis:

1. GDPR/Data Protection Act 2018
2. Common Law Duty of Confidentiality (CLDC).

During this exploratory work it was unclear what the legal basis for processing for each database was under the GDPR/DPA 2018, however all three databases had attempted to establish a legal basis to meet the CLDC.

BSUG

BSUG uses patient consent to meet CLDC, it is unclear if consent is also intended to be the legal basis under GDPR/DPA 2018. An assessment of legal basis to process personal data under the GDPR/DPA 2018 will need to be undertaken as this will have implications for the consent process and patient documentation as well as individual data subject rights. There is a patient information sheet and consent form available on the BSUG website and the database captures whether patient consent has been given to process their data. However it was noted that the test site (access kindly provided to HQIP) allowed the entry and retrieval of patient identifiable data when confirmation had not been given that patient consent was in place. BSUG reports this has now been addressed but it is unclear whether historic data has been checked to ensure personal confidential data has not been captured without consent.

The patient consent form has a general high level description of the purpose of processing name, hospital number, date of birth and clinical and surgical information. It does not include NHS number as an item which is collected and does not describe which data subjects are included, the type of clinical and surgical information collected or the data sources. Permission is requested to process for audit and research purposes with patient identifiable data to only be accessible to treating consultant and database IT provider (ICE IT). There is a standard operating procedure which describes the circumstances under which the BSUG database can be used for research purposes, together with a table to complete for access to data, however it is not clear whether this is restricted to clinicians and hospital trusts who entered data (and only the data they have entered, as is implied within the consent form) or available to third party researchers. The consent form does not provide permission to link BSUG database information with any other data source or permission to onward share personal data with any other organisation or third party. The accompanying fair processing information (patient leaflet) has a more detailed description of the personal data collected and the purpose however as transparency documentation it is currently lacking certain necessary details to meet GDPR standards (such as, lawful basis under GDPR, retention periods, Data Protection Officer details and full range of data subject rights).

BAUS

BAUS uses legitimate interests as the article 6 legal basis to meet GDPR/DPA 2018, however since special category data is collected (health data) an article 9 legal basis is also required. An assessment will be required to establish the most appropriate legal basis under article 9. Under CLDC, BAUS uses a combination of section 251 support and patient consent, the BAUS database captures whether consent has been obtained however there is no centralised patient consent form. BAUS has procedure specific patient information leaflets with some information about the collection of data for the BAUS SUI audit. Where a patient is asked for consent but declines BAUS do not collect their identifiable data but explain that they collect non-identifiable items. Where a patient is not asked for consent, BAUS relies upon s251 support. BAUS has transparency documentation in the form of a privacy notice which covers all of their surgical outcomes audits. This privacy notice is currently lacking certain necessary details to meet GDPR standards (such as, lawful basis under GDPR and full range of data subject rights).

Review of the s251 support provides the legal basis to collect and process forename, surname, date of birth, patient identifier (NHS or hospital number), date of operation, date of discharge/death and cause of death. There is no legal basis under CLDC to link this data with any other national dataset.

The geographical coverage of s251 is England and Wales, it is therefore not clear what is the legal basis under CLDC for processing in Scotland and Northern Ireland, particularly for those patients who are not consented.

TPFS

Currently TPFS does not collect any patient identifiable items. The database does capture if patient consent has been provided, however there is currently no centralised consent form for the database. TPFS has been working to establish an integrated procedure/database consent form and checklist, though these have been difficult to establish and have not yet been rolled out to hospitals. There is no accompanying transparency/patient leaflet or privacy notice which provides more information about database processing of personal data. Before personal data could be collected legal basis under GDPR/DPA 2018, consent documentation and transparency documentation/privacy notice would need to be established.

Table 4: summary of databases legal basis			
Element	**BSUG**	**BAUS**	**TPFS**
Legal basis to collect NHS number	No (NHS number is not included within the consent form or patient information leaflet)	Yes (legal basis in Scotland and N.Ireland unclear)	No
Legal basis to link to other national datasets (such as HES, PEDW, ONS)	No	No	No
Legal basis to share personal data with other organisations	No	No	No
Clear legal basis under GDPR	No	No	No
Legal basis to use for research purposes	Not clear (whilst research is described as a purpose within the consent form there is no legal basis to share personal data with researchers outside of BSUG and the ICE IT system)	No under s251 (non-research support only). Not clear under consent/transparency documentation	No

3.6.2 Information security

BSUG

BSUG subcontracts ICE IT as database IT provider. The system is hosted at an N3 connected datacentre (Daisy Group Limited) and the database is only available via an N3 connection. ICE IT has the following certifications and accreditations:

- Works to ISO 27001 (international information security standard), although it is not clear if there is ISO27001 accreditation and the statement of applicability has not been reviewed (therefore the scope of the Information Security Management System is not known)
- Cyber essentials and cyber essentials plus
- IGSoC (Information Governance Statement of Compliance) to access the NHS National Network (N3)

A data protection impact assessment has not been undertaken (a process to help identify and minimise data protection risks of a project).

BAUS

BAUS subcontracts Dendrite Clinical Systems Ltd as the audit data processor. Dendrite has the following certifications and accreditations:

- ISO 20000 (international IT service management standard)
- ISO 9001 (international standard for a quality management system)
- Security structure works to ISO 27001
- IG Toolkit version 14.1 (2017-18) published satisfactory (81%) grade

It is not known if a data protection impact assessment has been undertaken.

TPFS

TPFS contracts Formedia as the database data processor. Formedia is a small marketing agency, it is unclear what security accreditations are in place. Formedia subcontract website hosting to Heroku, who in turn use the Amazon Web Centre technology which is accredited for ISO 27001.

A data protection impact assessment has not been undertaken.

3.7 Current database data collection and data quality

3.7.1 Data collection

All three databases use an online data platform to collect patient data, with the BSUG database accessible via an N3 connection only.

BSUG

Data is collected continuously at 6 weeks, 3 months, 6 months and 12 months. There is no cut off point for data validation/analysis and comparative data is available instantly and updated on a monthly basis on the BSUG.net site.

BAUS

Data collection is continuous with a collection period of 1st January to 31st December. Data are published annually on a 3 year rolling cycle, with 2015-2017 data included in the 2018 annual report.

TPFS

Data collection is continuous since 2016; there have been no publication of results.

3.7.2 Data quality

BSUG

There are no validation rules or checks built into the web tool to ensure data quality (such as to prevent values that are implausible) and no mandatory data fields (other than the initial patient identifiers) to ensure completeness of a minimum dataset.

An overall data completeness figure is unavailable, although the recent BSUG SUI national report highlights missing data as a limitation of the report. For example for retropubic mid urethral tape there was 10% missing intraoperative complications data and 25% missing post operative complications data.

From 2008 to 2017 there has been participation from 145 centres across the UK, with 116,037 procedures for urinary incontinence and pelvic organ prolapse captured. This gives an estimated case ascertainment of approximately 40% of all continence procedures. This is based upon HES for NHS hospital admissions for SUI procedures in England from all specialities (including urologists), where there were 101,538 procedures for SUI performed from April 2008 to March 2017. Taking into account that only SUI operations using procedure codes for tapes and non-mesh sling operations were identified via HES, and that Wales and the independent sector (privately funded) were excluded, BSUG estimates that case ascertainment is therefore approximately 40% of continence procedures.

BAUS

It is unclear if there are any in built validation checks to the web tool, other than a small number of mandatory fields relating primarily to patient identifiers, consent confirmation and surgical procedure details. Validation is undertaken once data has been extracted from the web based database prior to analysis, this mainly comprises checks for duplicate, missing and invalid/inappropriate entries. Data summaries are also sent to contributing consultants for validation, with opportunity for corrections and submission of additional data prior to extraction.

Overall percentage data completeness is unknown but the 2018 BAUS SUI annual report contains the % null values for main fields, this appeared to be variable ranging from 2% to as high as 77%.

From 2015 to 2017 data has been returned by 106 consultants at 95 centres across the UK. This incorporates 2716 SUI procedures in total (2531 procedures for England only), including 191 private patients from 38 Consultants.

Case ascertainment for 2015 to 2017 is estimated to be 72% of SUI procedures undertaken by Urologists. This is based on HES figures for 2015 to 2017 (inclusive) which indicate that urologists undertook 3,524 stress urinary incontinence (SUI) procedures in England (1472 in 2015; 1059 in 2016; 993 in 2017); the BAUS audit has, therefore, captured data on 72% of these. Comparatively gynaecologists performed 17,409 SUI procedures in England during the same period (7437 in 2015; 5265 in 2016; 4707 in 2017). It should be noted that HES shows a marked reduction in these procedures year on year from 2015 and, as a result, a number of centres no longer perform them.

TPFS

It is reported that at present there are no in built validation checks (other than a small number of mandatory fields and rule to ensure numerical patient number) and overall % data completeness is unknown.

Since August 2016 70 Consultants have entered data on 678 cases, of which 252 have been entered in 2018 and 113 in August 2018 alone, representing a significant increase in participation. It is estimated (based on HES activity) that that approximately 750 ventral mesh rectopexies are undertaken per year and therefore annual case ascertainment could be estimated to be approximately 40%.

Table 5: data quality summary of databases

Item	BSUG	BAUS	TPFS
Data validation	Minimal validation rules (compulsory patient identifiers)	Minimal inbuilt validation rules (small number of mandatory fields) Consultants required to validate data pre-extraction Validation post extraction	Minimal validation rules (small number of mandatory fields and rule to ensure numerical patient number)
Data completeness	Overall % completeness unavailable	Overall % completeness unavailable	Overall % completeness unavailable
Case ascertainment	40% of incontinence procedures (undertaken by any speciality) 2008 - 2017	Estimated 72% of SUI procedures undertaken by Urologists 2015-2017	Estimated 40% (2016 – 2018)

3.8 Current database outputs

BSUG

Clinicians are able to extract their own raw data and generate activity reports of their own data benchmarked against national (UK wide) results from the BSUG database. The main elements included in these outputs are:

- Surgical procedure activity (can be benchmarked against centre and national results)
- % Complications for certain pre and post op conditions (can be benchmarked against centre and national results)
- PROMS results:
    - Global impression of improvement (absolute numbers and % which can be benchmarked against centre and national results)
    - ICIQ changes in quality of life scores
    - POPQ changes in quality of life scores
    - Graft complications

It should be noted that all activity undertaken by a clinician will be attributed to the centre the clinician is registered to within the database, even where a clinician works across multiple sites/centres.

BSUG has published their first annual report contains national level aggregate results for five main incontinence procedures:

- Retropubic mid urethral tape (RP MUT)
- Transobturator mid-urethral tape (TO MUT)
- Bladder neck injection (BNI)
- Colposuspension (open and laparoscopic)
- Autologous rectus fascial sling

BAUS

BAUS publish consultant level results online and as part of the Clinical Outcomes Publication (COP) Programme on NHS Choices. BAUS SUI results are published annually (in May) on a three year rolling cycle (2018 report contains 2015-2017 outcome data). Clinicians can export their own data into an Excel spreadsheet via Dendrite and access more detailed reports on their data in comparison to the national data in the format of dashboards and funnel plots.

Publically available online individual clinician results contain:

- Type and volume of surgery
- Patient reported outcome measures (benchmarked against national results)
- Complications data (benchmarked against national results.

BAUS publish an annual report which contains national (UK) results.

BAUS have recently published a peer reviewed paper for the last 3 years of data (Cashman S, Biers S, Greenwell T, Harding C, Morley R, Fowler S, Thiruchelvam N; BAUS Section of Female Neurological and Urodynamic Urology. Results of the British Association of Urological Surgeons Female stress urinary incontinence procedures outcomes audit 2014-2017. BJU Int. 2018 Sep 17. doi:10.1111/bju.14541. [Epub ahead of print]).

TPFS

Each individual clinician can review their data online via TPFS website. It is anticipated that an annual report will be published which will include:

- Types of mesh used
- Overall complication rate
- Mesh complication rate
- Recurrence rate for external rectal prolapse
- Improvement in obstructed defaecation

3.9 Current database funding

BSUG and BAUS databases are funded via society membership fees whilst TPFS is industry funded.

3.10 Early Society suggestions

Following initial discussions with BSUG, BAUS and TPFS some key suggestions required of a registry or interim data solution include:

- Collection of unique patient identifier (NHS number) to enable data linkage and follow up
- Standardise data input and outcomes collected across databases
- Common minimum dataset across databases
- Considerably increased patient follow up data capture (PROMS data capture should be extended to enable outcomes assessment)
- Collect outcome measures important to patients and PROMS to be collected directly from patients, giving them the opportunity input independently and to access their results
- Linking to national datasets such as HES in England, PEDW in Wales and to corresponding national datasets in other devolved countries (requires review of information governance to ensure compliance with data protection legislation)
- Capture of non-surgical treatments/management (i.e. bulking agents)
- Include mesh removal and outcomes on any planned database

BSUG have proposed minimum dataset for an interim database (see appendix E).

4 MHRA data requirements

The MHRA has provided a summary of their key data requirements of a mesh registry.

General

For any device registry to be successful, the following criteria need to be fulfilled:

- Registry aims and objectives should be clearly defined and accepted by key stakeholders. Questions that the registry needs to answer (and hence the data that needs to be collected) can only be identified based on this
- Registry should have a sustainable long term funding mechanism. Implant registries can only yield useful information on device performance and patient safety if they can be maintained in the long term and funding includes adequate provision for data collection, data analysis and reporting

Registry should have appropriate governance structure and mechanisms in place, e.g. oversight by a steering committee or similar (involving key stakeholders) , appropriate data confidentiality arrangements, appropriate transparency (reporting / feedback to key stakeholders)

MHRA Specific

As a medical device regulator, the primary focus of MHRA is on the safety and performance of devices.

- Aims and objectives from an MHRA perspective:
  - To monitor the performance of the devices to improve patient safety and take action where necessary
  - To identify possible trends and complications relating to specific devices (outlier detection)
  - To identify patients implanted with specific devices in the event a subsequent device recall or the need for enhanced patient follow-up (track and trace)
- Scope of a registry could include:
  - All urogynaecological and rectopexy operations where mesh is used and the equivalent non-mesh operations (to include orthotopic native tissue repair and variations of mesh such as biological
  - All non-operative/conservative treatments for the diseases covered
- Key data requirements for device information:
  - Unique device identifier (UDI)
  - Catalogue number
  - Manufacturer
  - Description
- Provision of relevant information about device performance
- Ideally, manufacturers should have access to appropriately anonymised raw data about their products
- Relevant variables:
  - The overall % of patient exposure to the device that are captured in the registry and representativeness of the registry population to the treated population
  - The extent to which exposed patients within the scope of the registry are actually consecutively captured (i.e. minimization of selection bias)
  - Extent of follow-up available at important durations of times following the index procedure; if inadequate, ability to link to additional datasets may potentially be a good surrogate

5 Evidence-based standards

Relevant NICE guidance includes the following:

Table 6: NICE guidance

No	Reference	Weblink	Comment
1	Urinary incontinence (update) and pelvic organ prolapse in women: management	Urinary incontinence (update) and pelvic organ prolapse in women: Management (NG10035) In consultation and expected publication April 2019	In development [GID-NG10035] Expected publication date: 02 April 2019
2	Urinary incontinence in women	Urinary incontinence in women Quality standard (QS 77) Published January 2015	Quality standard [QS77] Published date: January 2015
3	Transvaginal mesh repair of anterior or posterior vaginal	Transvaginal mesh repair of anterior or posterior vaginal wall prolapse (IPG 599)	Interventional procedures guidance [IPG599] Published

	wall prolapse	Published December 2017	date: December 2017

Draft NICE (NG10035) Urinary Incontinence and pelvic organ prolapse in women guidelines (see above no. 1) includes recommendations regarding the collection of data on mesh surgery and mesh related complications. These should be incorporated within a final interim database or long term registry:

Table 7: NICE draft recommendations, Urinary incontinence and pelvic organ prolapse in women

No	Recommendation
1	In women having mesh surgery for stress urinary incontinence or pelvic organ prolapse, or who have mesh-related complications, seek consent to enter the data in a national registry and give them a copy of those data.
2	Ensure that the following data are collected in a national registry of surgery involving mesh insertion to treat all surgical procedures for urinary incontinence or pelvic organ prolapse that involve the insertion of synthetic polypropylene mesh, including: ○ date and details of the procedure ○ mesh material and type of sutures ○ the woman's NHS number ○ hospital and consultant identifiers ○ follow-up information on key short- and long-term (at least 5 years) outcomes, including: ▪ symptom improvement or deterioration ▪ objective measures of UI or POP ▪ adverse events ▪ suspected and confirmed mesh-related complications ○ date and details of any investigation for mesh-related complications ○ date and details of any surgical or non-surgical intervention for mesh-related complications.
3	The national registry of surgery involving mesh insertion to treat urinary incontinence or pelvic organ prolapse in women should report annually and be quality assured.

6 Exploratory workshops

Two exploratory workshops were held:

1. A technical workshop
2. A stakeholder workshop.

6.1 Technical workshop

HQIP held a technical workshop on the 13th November to examine the current data sources maintained by three professional societies, BSUG, BAUS and TPFS. The aim was to understand how the current data sources might be able to address the pause recommendations as an interim measure before a full clinical registry could be established. The workshop was chaired by Professor Keith Willett, NHS England Director for Acute Care and Emergency Preparedness, and had 31 attendees representing:

- NHS England
- Department of Health and Social Care
- Northern Ireland Department of Health
- Welsh Government
- Scottish Government
- National Institute for Health and Care Excellence (NICE)

- Medicines and Healthcare Products Regulatory Agency (MHRA)
- British Association of Urological Surgeons (BAUS)
- British Society of Urogynaecology (BSUG)
- The Pelvic Floor Society (TPFS)
- NHS Improvement
- Independent Medicine and Medical Devices Safety Review (IMMDS)
- NHS Digital
- Private Healthcare Information Network (PHIN)
- Mesh Clinical Advisory Group
- HQIP

The workshop aims were to:

1. Explore the current sources of available data for SUI and POP procedures involving surgical mesh
2. Discuss the recommendations of the Independent Medicine and Medical Devices Safety (IMMDS) Review and agree the requirements of an interim database(s) to meet those recommendations
3. Discuss the data and reporting requirements of an interim database(s)
4. Agree the scope of the interim database(s) and explore a minimum mesh dataset for collection
5. Outline the practicalities and explore the steps necessary to develop a feasible outcome data collection solution
6. Consider the longer term requirements of a SUI and POP registry
7. Facilitate the development of a feasible interim data solution to meet the recommendations of the IMMDS Review

6.2 Technical workshop summary

See appendix F for the notes from the technical workshop however below is a summary of key points raised, the implications for an interim database and areas for further investigation (related comments from the stakeholder workshop have been included to reduce duplication).

For ease of summarising information the key points from the workshop have been categorised using an evidence-based healthcare 'PICO' framework as follows:

- **P**opulation
- **I**ntervention
- **C**omparison
- **O**utcome

Table 8: Summary of key points from technical workshop (and related comments from stakeholder workshop)

Key points	Implications for an interim database	Uncertainties and further feasibility to be established
Population		
1. Population: Reporting should, as a minimum, be at individual surgeon level, hospital provider level and national level reporting for England, Wales, Scotland and Northern Ireland to present variations in the quality and	1. Dataset to include: • Hospital site identifier • Country of residence • Postcode • GMC number 2. Reporting consultant level data	

safety of care.	on NHS Choices.	
2. Population: Include information on procedures undertaken within the private sector.	3. Dataset to include: • Hospital provider (site code) • NHS or privately funded 4. Independent sector to participate	1. Further work to be undertaken with PHIN to drive participation from independent sector organisations
3. **Population:** Universal identifier should be collected (NHS number in England/Wales and CHI in Scotland) to allow for linkage with other national datasets and tracking of patients between providers (both NHS and independent). It was noted that patients may have mesh procedures undertaken within the NHS but mesh removal undertaken within the independent sector and so tracking of these patients across sectors is essential.	5. Collection of patient identifiers to allow for tracking of patients across providers (including NHS and independent sector). 6. Dataset to include: • capture of NHS number • or other National Patient Identifier (e.g. CHI in Scotland) • patient name • Patient Date of Birth • Patient postcode 7. NHS digital able to complete missing NHS number (if name, DOB and postcode provided) 8. Similarly CHI seeding may be possible in Scotland if other patient identifiers are available. 9.	2. Can identifiable data flow from Northern Ireland under patient consent? 3. How can patient contact details (i.e. address) be traced if not a resident in England? (i.e. for devolved nations?) 4. Do devolved nations want to capture independent healthcare activity?
Interventions and Comparisons		
4. Interventions and comparisons: and analyses should be risk adjusted where appropriate and therefore sufficient patient information must be collected to allow for risk adjustment.	10. Development of a risk adjustment model may not be feasible for the interim. 11. Dataset to include collection of sufficient patient information to enable risk adjustment. Likely to include age, co-morbidities, body mass index/height/weight, previous mesh surgery.	5. Feasibility of risk adjustment to be established.
5. **Interventions and comparisons:** BSUG proposed minimum dataset was discussed with general agreement from BAUS. Will need to be tailored to ensure patient outcomes collected (validated PROMS and bespoke outcomes and complications) are important to patients. It was acknowledged that the proposed minimum dataset may require some variation to meet the requirements of TPFS.	12. Present minimum dataset suitable for BSUG and BAUS. 13. Interim dataset to include patient outcomes which are important to patients.	6. Further work needed with TPFS to develop a minimum dataset appropriate to their database
6. **Interventions:** BSUG proposed overarching mesh procedures	14. Development of concise list of procedures to be collected for	7. Further work needed with BSUG and BAUS to develop concise list

were discussed: • TVT (or Retropubic Mid-Urethral Tape) • TOT (or Transobturator Mid-Urethral tape) • Vaginal Mesh for Prolapse • Sacrocolpopexy • Sacrohysteropexy (including Sacrocervicopexy) • Rectopexy These should include mesh comparator procedures and mesh complication and procedures	BSUG and BAUS which includes: • Mesh procedures • Non-mesh (comparator) procedures • Mesh complication and removal procedures	of procedures for collection and comparison 8. Further work needed with TPFS to develop concise list of mesh and comparator procedures for collection and comparison
7. **Intervention:** Sufficient information on the mesh device inserted to allow tracking of patients and comparison of outcomes between types of mesh.	15. Aims of audit to include: • tracing patients in the event of a product recall or other safety concern relating to a specific type of implant • identification of possible trends and complications relating to specific implants 16. Dataset to include: • Mesh details: ○ Unique device identifier ○ Material ○ Type of sutures ○ Manufacturer ○ Device Catalogue Reference Number (if no UDI) ○ Device Lot number (if no UDI) ○ Device serial number • Patient details: ○ capture of NHS number ○ or other National Patient Identifier ○ patient name ○ Patient Date of Birth ○ Patient postcode • Hospital details: ○ Site identifier	9. How can a track and trace process be developed for the interim database in England? 10. How can a track and trace process be applied to devolved nations?
8. **Comparison:** An interim database should collect data on common non- mesh (comparator) procedures in addition to mesh procedures to enable comparisons of outcomes and safety between mesh and non-mesh procedures. This may be complex for rectopexy	17. Procedures captured should include mesh, non-mesh (comparator procedures) and mesh complication procedures. 18. Outputs should include comparisons in outcomes and safety between mesh and non-mesh procedures.	11. Agreement needed on which non-mesh comparator procedures should be collected for SUI and POP. 12. Is it feasible to include within the interim database comparator procedures for rectopexy? 13. Agreement on which mesh complication procedures to be

procedures since the scope of TPFS database only currently covers mesh procedures.		collected for SUI and POP. 14. NICE recommends the date and details of any investigation for mesh-related complications be captured. Further work required to determine whether this should be incorporated within the interim database or long term registry.
Outcome		
9. Outcome: Ensure outputs and data collected are proportionate and aligned to clear aims and objectives of the database	19. Development of overarching aims and objectives	
10. **Outcomes:** Outputs to include longitudinal analyses allowing the identification of trends over time to support governmental decision making	20. Analysis plan required with statistical input. A partner organisation, independent of BSUG, BAUS and TPFS to undertake this function.	15. To agree with NHS Digital if they could act as Interim database repository, perform analytical function and produce robust outputs.
11. **Outcomes:** MHRA requires that outputs to present information on device type, material and manufacturer	21. Dataset to include: • Unique device identifier • Material • Type of sutures • Manufacturer • Device Catalogue Reference Number (if no UDI) • Device Lot number (if no UDI) • Device serial number 22. Outputs to allow identification of possible trends and complications relating to specific implants	12. What data would mesh manufacturers require to support them in their role to improve quality and safety?
13. Outcome: Data flows to and from the MHRA were discussed in relation to pause recommendation 4 'reporting of complications via MHRA is linked to the register'. An interim database can have functionality built in which links to the MHRA yellow card reporting system to allow a clinician to report an incident, this is currently built into the BSUG database, however the feasibility of flowing data from the MHRA yellow card reporting system to an interim database due to legal restrictions. As explained by the MHRA there is a duty of	23. Build in functionality which will link all three society databases to the MHRA yellow card system to allow clinician reporting (replicate what has already been done for BSUG to BAUS and TPFS) 24. Present options for flowing data from the MHRA yellow card system or manufacturer database for a long term registry	

confidence owed to manufacturers as well as patients.		
14. **Outcomes:** Manufacturer access to data is desirable but there was a recognition that this could be delayed until a long term registry is established	25. Manufacturer access to data to be incorporated into long term registry	
15. **Outcome:** New NICE guidance will recommend that patients are informed of which device they have inserted. It was agreed that a desired output of the database is to provide patients with summary information of their procedure and device. Patient groups echoed this request and suggested that providing information by email would be preferable since this is likely to be retained long term.	26. Development of a clear subject access process providing patients with access to their own data (subject access) 27. An output of the interim database to include the ability to produce an extract for patients which details their procedure and the device inserted.	16. The feasibility of providing a secure summary to patients, via email if possible, would need to be further explored.
16. Outcomes: Outputs to include case ascertainment figures to ensure data for all eligible procedures is captured, this can be obtained from other national datasets such as HES and PEDW, with PHIN responsible for collecting denominator data within the independent sector	28. Interim database to access HES, PEDW, PHIN or other national data sources (including those from devolved nations) to ascertain denominator data. 29. Publication of data quality assessments at national and provider level which includes, % participation, ascertainment, data completeness. 30. Analytical/statistical expertise to be provided to enable the production of robust and reliable results.	17. To work with NHS Digital to establish appropriate HES codes for case ascertainment 18. To work with PHIN to establish denominator data for the independent sector 19. Work with NWIS (for PEDW), ISD Scotland and equivalent for Northern Ireland to establish denominator data.
17. Outcomes: Include information on readmissions and attendance at other services (e.g. Pain clinic).	31. Link interim database results to other national datasets to establish readmissions, attendance at other services (e.g. Pain clinic 32. Revise consent forms and transparency documentation to ensure legal basis to link to other data sources	20. Work with NHS Digital to establish relevant HES classification to undertake data linkage (readmissions and attendance at other services). 21. Work with NWIS, ISD Scotland and N.Ireland to investigate feasibility of undertaking data linkage (readmissions and attendance at other services) in devolved nations.
18. **Outcome:** Current follow up of patients is insufficient and should be extended to 5 years (as per NICE recommendations) as a minimum. The feasibility of long term follow up was questioned	33. Long term registry to take forward development of appropriate methodology to follow up patients for minimum 5 years. 34. For the interim database follow	22. Further work required to establish for a long term registry a feasible follow up methodology for all patients (mesh and comparator procedures) to capture good and bad outcomes

since 94% of patients are not readmitted back to hospital as an inpatient; certain complications may not be reported back to performing clinician but are managed in alternative settings such as pain clinic. There was a discussion over whether patients should have an annual review in the clinical setting but this was not considered practical (due to current services infrastructure) for up to 5 years post procedure. Suggested possible solutions: • To align data submission with other women's health initiatives such as mammogram or cervical smear screening whereby patients would receive a reminder to return PROMS. • To collect patient telephone number and send text message reminders to complete outcomes questionnaires • The stakeholder workshop highlighted concern that patients might return information indicating a complication or poor outcome and an expectation that this is followed up.	up should: • Collection of primary, revision/repeat, removal or complication procedures (patients can be linked • Linkage to other national datasets (including devolved nations) to augment with readmissions data, attendance at other services/clinic	23. Further work required to establish appropriate follow up period and methodology for interim database.
19. **Outcome:** Long term follow up of patients would significantly increase patient cohort size and it was questioned whether detailed data needed to be captured only for patients who experienced complications. Possible solutions: • patients to complete a simple screening question to identify whether they are experiencing complications or poor outcomes which would then lead to a more detailed data capture for those patients with issues only. • long term follow up could be conducted on a representative sample, rather than the whole cohort. But there was concern that this would provide insufficient information by surgeon and providers. Patients	35. Long term registry to take forward development of appropriate methodology to follow up patients for minimum 5 years.	24. Further work required to establish for a long term registry a feasible follow up methodology for all patients (mesh and comparator procedures) to capture good and bad outcomes

also suggested that the use of patient sampling would be less agreeable if NICE recommended the use of mesh as a first line or second line treatment (i.e. if NICE recommend that mesh may be used as a first or second line treatment, patients indicated they would like to see long term follow up on all patients)		

Barriers identified at the workshop and that would need to be overcome to establish an interim database were discussed, the table below presents the key points raised, the implications for an interim database and areas for further investigation.

For ease of summarising barrier information the key points from the workshop have been categorised as follows:

- Information governance
- Host organisation
- Public confidence
- Patient confidence

Table 9: Summary findings barriers to be overcome

Key point	Implications for an interim database	Further Feasibility to be established
20. **Information governance:** The complexity of information governance and new data protection requirements (introduced with the General Data Protection Regulation in 2018) were highlighted as an important barrier to overcome. TPFS database does not collect identifiable data and would need to meet GDPR compliance before patient identifiers could be collected.	36. Expert information support to be provided to implement key changes to ensure data protection/IG compliance and a robust legal basis 37. Unlikely that TPFS database, in current form, will be able to collect identifiable confidential patient information. Propose options for either inclusion in interim or exclusion from interim and inclusion within long term registry	25. Expert IG provision to be identified
21. **Information governance:** Patient consent was identified as the most appropriate legal basis to meet the common law of confidentiality. This is essential in devolved nations since s251 is not available. Patient consent would also serve to increase public confidence.	38. Establish patient consent as the legal basis for an interim database to meet the common law duty of confidentiality	
22. **Host organisation:** An independent organisation, such as NHS Digital, should act as a repository for the interim database but consideration must	39. Potential model for DHSC to direct NHS digital to collect this data. 40. Devolved nations may be able to issue a discretionary request to	26. For the interim database could DHSC direct NHS Digital to collect and analyse the necessary data either from the existing society databases or directly from

be given to how this could function for devolved nations.	NHS digital	hospitals?: a. Further work to establish under which section of Health and social care act 2012. b. What would the implications be to procurement processes (for the interim and long term) of issuing a direction to NHS Digital? c. Can a direction be applied to the collection of data/information relating to non NHS funded services within the independent sector or is it limited to NHS funded/commissioned services? d. What contractual arrangements need to be set up to allow monitoring of performance of a directed service? e. Does use of a direction impact upon the ability of a 3rd party to undertake a commissioner or contract management role on DHSC behalf? f. Who will be the data controller under a direction? g. How are the costs established and what is the process for setting up a direction? h. Could a discretionary request be established for devolved nations and would devolved nations be prepared to issue a request?
23. **Public confidence:** Low case ascertainment of eligible cases currently captured by existing BSUG, BAUS and TPFS databases. This was reported to impact upon public confidence in reported outcomes and findings.	41. Mandating data collection to be recommended	27. Method of mandating collection to be further explored.

Mandating this collection of data was seen as the preferable solution to increase reporting.		
24. **Patient confidence:** Patient outcomes are currently clinician collected and patient trust and confidence would be increased by enabling patients to enter their own outcomes and access their own data.	42. Development of a clear subject access process for an interim database, providing patients with access to their own data (subject access)	28. Further exploration of feasibility to enable patient entry of PROMS and enable patient access to data.
25. **Patient confidence:** Patients have an acknowledged lack confidence and trust in the databases. This suggests that independent governance and oversight must be established for the interim database and supports the view that the database is hosted by an independent organisation such as NHS Digital. Independence governance group should include patient and charity representation.	43. Establish independent 4-countrygovernance/oversight group for interim database 44. Impression that visibility of reports would serve to improve public perception and transparency, recommend the publication of annual reports including public/lay reports (including reporting on NHS choices).	

6.3 Stakeholder workshop

HQIP held a wider stakeholder workshop on the 28th November which was independently chaired by Annie Laverty, Chief Experience Officer at Northumbria NHS Trust, and had 28 attendees representing:

- NHS England
- Welsh Government
- Scottish Government
- Scottish Transvaginal Mesh Oversight Group (TVMO) Department of Health and Social Care
- Sling the Mesh
- Pelvic Pain Network
- Fibroid Network
- Royal College of Obstetrics and Gynaecology (RCOG)
- Independent Clinical Representatives (covering Urology, Urogynaecology and Physiotherapy)

The workshop aims were to:

1. Understand the purpose and exploratory work undertaken by HQIP to date
2. Listen to views about patient outcomes and agree what is important for women
3. Explore practicalities and possible solutions

6.4 Stakeholder workshop summary

See appendix G for the notes from the stakeholder workshop. The stakeholder workshop included representatives from patient groups and the below summarises the symptoms and complications that were highlighted to be of importance and for consideration when deciding outcomes to be collected by the interim database.

For ease of summarising information the key points from the workshop have been categorised as follows:

- Patient symptoms & complications
- Patient reported outcome measures (PROMs) – validated
- Patient outcomes

Table 10: Patient symptoms and complications

Key points	Descriptor
Pain	Onset: • Instant • Delayed and may not necessarily be associated with the procedure due to the time lag in experiencing these symptoms.
	Location of pain and radiation: • Leg pain, how much the leg was affected • Calf pain • Buttock pain • Hip pain • Lower back pain • Vaginal/bladder pain • Nerve damage pain
	Type and characteristics : • Heavy • Grinding • Slicing • Burning and/ or stabbing sensation • Chronic pain
Sex life	• Loss of sexual life • painful intercourse
Infections	• Urinary tract infections • Low grade infections • Abscess • Antibiotic resistance, reportedly affects 8% of women
Bladder	• Over active bladder
Trauma	• Erosion of mesh • Obstructive and whether the mesh entered the bladder • Foreign bodies • Small bowel injuries

Table 11 (below) summarises the validated PROMS suggested by BSUG, BAUS and TPFS as potentially feasible to capture through an interim database (before and after procedure). These were discussed at the stakeholder workshop, the below captures the benefits and limitations of each as suggested by the surgical societies and relevant stakeholder workshop comments.

Table 11: Summary validated PROMS				
Measure	**Description**	**Benefits**	**Limitations**	**Stakeholder workshop comments**
EQ-5D_5L	Measure of health related quality of life covering mobility, self care, usual activities, pain/discomfort, anxiety/depression).		Charges may be incurred (cost of licence)	Noted that this has been based upon health economics.
ICIQ-UI	Assesses impact of symptoms of incontinence on quality of life and outcome of treatment, covers frequency / amount/ impact / perceived cause.	Short, easy and covers generic quality of life and incontinence. Could be designed for patient self completion.	Does not cover Sexual function or urinary tract infections (UTIs).	ICIQ tool has been suggested by NICE for assessment of incontinence, however it was felt to be insufficient on its own to cover all issues.
(PGI-I) Global Impression of improvement	1 item questionnaire designed to assess the patient's impression of changes. PGI-I for Prolapse PGI-I for Incontinence	Quick and easy and identifies if patients are better, the same or worse after surgery.	Does not assess the different types of incontinence. Weak correlation with sexual function and studies have shown poor performance in this domain.	PGI tools are noted to be good from a patient perspective however are vague and fail to capture organ damage.
EPAQ-PF (pelvic floor)	Covers all domains of pelvic floor function including urinary, vaginal, bowel and sexual. It has been validated in women with pelvic floor problems.	Can be set up for patient self completion. Includes sexual function. Suitable for all domains of pelvic floor function, including bowel.	Onerous and time consuming, completion in clinical practice is therefore poor (20-25%). Requires internet access and a licence must be purchased.	
UTI symptoms assessment Questionnaire	14 item questionnaire assessing most frequently reported signs and symptoms of uncomplicated urinary tract infection (UTI).	This is a single sided questionnaire and is relatively quick and easy to complete.	May need to be supplemented with a single question on patient estimated frequency of UTI in the preceding 6 months.	May not capture the impact of having recurrent UTIs for a number of days.
Arizona Sexual Experiences Scale	Questionnaire commonly used in	Short 5 question scoring system.	Does not ask about dyspareunia	An alternative, PIS-Q tool, was suggested

	clinical trials to assess sexual functioning.		(painful/difficult intercourse), which is a key area of interest following continence surgery. Unsure if validated for use in women with pelvic floor disorders.	which is validated for sexual function and does not appear too onerous for patients to complete. Patients felt it was important to capture loss of sexual function.

Other key points raised during the stakeholder workshop relevant to the collection of patient outcomes:

Table 12: Patient outcomes	
Key points	**Descriptor**
Clinical jargon	The importance of avoiding clinical jargon (such as dyspareunia) and using lay terms easily understood by patients.
PROMs	Importance of capturing the ability to perform physical activities and including a validated tool to capture and assess pain.
	It was questioned whether the tools used needed to be validated for urinary incontinence and pelvic organ prolapse, for instance the tool chosen for sexual function does not need to capture whether symptoms of incontinence are improved.
	It was suggested that existing proms validated for other conditions may be of use, such as the ehp-30 which has been validated for endometriosis but captures pain, control and powerlessness, emotion, social support and self image, with additional modules on work, relationships with children, sexual intercourse, interactions with the medical profession and treatment. There is the standard 30 questionnaire tool and a shorter 5 question tool.
	Whilst it may be more effective to use a validated tool which is comprehensive, this should be balanced against the importance of considering the burden to the patient to complete which may impact upon data capture.
	Tools should be sensitive to the nature of the complications patients report, such as capturing the severity and impact of pain.
	It was suggested that a bespoke tool may be more appropriate due the nature of what needs to be captured, whilst this was acknowledged as being worthwhile, it was acknowledged that this would take a minimum of four years work prior to a new tool being validated.
	For the interim database, something needs to be in place to provide assurance and it was suggested that using appropriate validated tools with the ability to record patient experience may be suitable. While more sophisticated tools might be able to be developed and incorporated into the full registry in time.
	The interim database would be used to get an understanding of whether it is capturing meaningful data before going on to develop bespoke validation tools.
Clinician report outcome	It was felt some complications must be clinician reported, such as mesh erosion.

The following table summarises the key points raised, the implications for an interim database and areas for further investigation.

Table 13: Patient outcomes summary		
Key point	**Implications for an interim database**	**Further feasibility to be established**
26. Interim database to capture the following key elements: • Pain • Loss of sexual life • Urinary tract infections • Impact upon quality of life • Impact upon Mobility • Presence or recurrence of incontinence	45. Dataset to capture validated: • Pain questionnaire, such as Brief Pain Inventory (short form) or Visual Analogue Scale for Pain Assessment • UTI questionnaire to be included, such as UTI Symptoms Assessment Questionnaire • Sexual health questionnaire, such as ePAQ-PF or PIS-Q or Female Sexual Function Index • Quality of Life questionnaire such as the EQ-5D_5L (also includes mobility and pain) • Patient satisfaction questionnaire such as the PGI-I (for prolapse and incontinence) • Incontinence questionnaire such as ICIQ-UI 46. May want to use the ePAQ questionnaire which is more encompassing and would include bowel/sexual function but feasibility and cost would need to be further explored.	29. Agreement needed from BSUG/BAUS on the validated PROMS to collect. 30. Further engagement to be done with patients during the establishment of an interim database to ensure those outcomes and complications collected are appropriate. 31. Further work to be done with patients to develop PROMS and bespoke outcomes for collection within a long term registry.
27. Patients would like the ability to report patient experience	47. Patient experience to be recommended for long term registry 48. Options for interim database to include the establishment of patient experience survey.	32. Further work required to establish feasibility of conducting a patient experience survey for the interim database.
28. Development of a bespoke PROM tool. Acknowledgement that this is not feasible for the interim	49. Recommendation that an evaluation is undertaken of interim database to establish outcomes collected are meaningful and whether long term registry should undertake development work with patients to develop a bespoke PROM that captures the areas important to patients.	
29. Capture of complications to be included	50. Dataset to include: • mesh complications, such as: ○ Erosion of mesh ○ Removal of mesh (and whether partial or full) ○ Erosion of mesh into other	

	organs ○ Abscess • Peri and post operative complications	

7 Option appraisal: Models for establishment of an interim SUI/POP database

It appears feasible that existing mesh databases maintained by BSUG and BAUS could be used to establish an interim mesh database which would function until a long term registry or national clinical audit can be established. These are mature databases with reasonable engagement and participation from the clinical community and appear to have sufficient information security set up. However the rectopexy database maintained by TPFS is less mature in its development and set up and it is unlikely that it currently has sufficient information security arrangements to be capable of processing identifiable confidential patient information without investment of time and resource. The establishment of an interim database from the existing society run databases would require the incorporation of a partner organisation to act as a data repository, to undertake data linkage and analysis and to produce outputs.

Alternatively a new interim database could be built with a new bespoke data collection platform, this would replace all existing society run databases.

The report will now expand upon these high level options for development of an interim SUI/POP database, following this the report will present options to meet pause recommendation 4, and finally will summarise the recommended changes to existing databases (or newly built database, depending upon the model chosen) to establish an interim urogynaecological mesh database.

7.1 Model 1

Existing society run databases collect patient level data from hospital sites and flow this data periodically to a partner organisation that acts as an interim database/repository undertaking analytical functions, linkage with other datasets and production of output reports.

Table 13: Model 1 options

Options	Implications	Advantages	Risks
A) 1) All three databases are incorporated	• Alignment would be required between BSUG, BAUS and TPFS: ○ Mesh procedures ○ Non-mesh comparators ○ Minimum dataset ○ Proms and outcomes • TPFS may need to transition to a different provider capable and accredited to process confidential patient information and would require significant IG/data protection modification • Funding must be provided to align, improve and maintain all three databases • Expert IG provision must be	• A comprehensive database can be established covering all elements of SUI and POP • Implant track and trace possible for all SUI/POP mesh implants • Existing databases have already reasonable engagement from clinical community • Maintains clinical leadership from BSUG, BAUS and TPFS	• Difficulties aligning all three databases within short timescale • TPFS may need to transition to an alternative data processor which may have contractual implications • Only BSUG and BAUS fall within the remit of the mesh pause and this may delay implementation of interim database • May have additional resource and financial implications • Partner organisation experiences difficulties

	sourced • Establishment of overarching independent governance oversight group		extracting and linking data from multiple sources • The costs of this model are unknown and may be more expensive than establishing new data collection platform within NHS Digital • May be difficult to establish BSUG/BAUS/TPFS within devolved nations
A) 2) Only BAUS and BSUG are incorporated within the interim database. Rectal prolapse is incorporated within the scope of a long term registry.	• Alignment would be required between BSUG, BAUS: o Mesh procedures o Non-mesh comparators o Minimum dataset o Proms and outcomes • Funding must be provided to align, improvement and maintain both databases • Expert IG provision must be sourced • Establishment of overarching independent governance oversight group	• Only BSUG and BAUS fall within the remit of the mesh pause • BSUG and BAUS dataset and procedures more comparable and therefore simpler to achieve alignment • BSUG and BAUS databases have sufficient security set up and can process confidential patient information • More likely to be able to achieve rapid interim position • Existing databases have already reasonable engagement from clinical community	• Lack of a comprehensive mesh database until a full registry can be established • Partner organisation experiences difficulties extracting and linking data from multiple sources • The costs of this model are unknown and may be more expensive than establishing new data collection platform within NHS Digital • May be difficult to establish BSUG/BAUS within devolved nations
A) 3) BAUS and BSUG continue to deliver existing database and rectal prolapse data collection platform is developed and delivered by	• Alignment would be required between BSUG, BAUS and TPFS: o Mesh procedures o Non-mesh comparators o Minimum dataset o Proms and outcomes • Funding must be provided to align, improvement and	• A comprehensive database can be established covering all elements of SUI and POP • Implant track and trace possible for all SUI/POP mesh implants	• Dependent upon which partner organisation sourced to host interim database, may not be willing or capable • Difficulties aligning all three databases within short timescale • Only BSUG and BAUS fall within the remit of the

partner organisation	maintain databases • Expert IG provision must be sourced • Development of separate data collection platform for rectal prolapse procedures • Establishment of overarching independent governance oversight group	• Existing databases have already reasonable engagement from clinical community	mesh pause and this may delay implementation of interim database • May have additional resource and financial implications • Partner organisation experiences difficulties extracting and linking data from multiple sources • The costs of this model are unknown and may be more expensive than establishing new data collection platform within NHS Digital • May be difficult to establish BSUG/BAUS/TPFS within devolved nations
B) 1) NHS Digital act as partner organisation under direction from DHSC	• Direction to be set up • Alternative 'discretionary request' for devolved nations to be established • As per options (A) alignment and governance establishment still required between existing databases	• NHS Digital is a trusted partner and experienced in providing a linkage service • NHS Digital has capability to input missing NHS numbers for independent organisations • NHS Digital has capability to trace patients current registered addresses necessary for track and trace • NHS digital has secure infrastructure to act as data repository and has ability to provide data access request function to third party applicants (such as researchers) • NHS Digital has expert IG provision	• NHS Digital may not have the resource available to undertake this function • Discretionary request may not be possible for devolved nations • Direction may be time consuming to establish • Direction may impact upon ability to procure for long term registry • The costs of this model are unknown and may be more expensive than establishing new data collection platform within NHS Digital • May be difficult to establish access/linkage to devolved nations datasets

		• NHS has access to HES/ONS	
B) 2) An alternative partner organisation is sourced	• May require a procurement process due to financial value • Will require additional scoping and engagement to source appropriate partner organisation • As per options (A) alignment and governance establishment still required between existing databases	• Identification of good provider and innovative solution is possible	• Partner organisation may not have sufficient experience and set up of the interim database may be delayed • Identification of a suitable partner organisation may cause delays • Partner organisation may not have sufficient experience to undertake complex linkage

7.2 Model 2

Replace existing databases and set up a new data collection platform within new organisation for SUI and POP (including rectal prolapse)

Table 14: Model 2 options

Options	Implications	Advantages	Risks

C) 1) Set up new platform within NHS Digital	• Datasets must be established for SUI and POP (including rectal prolapse):
	  ○ Mesh procedures
	  ○ Non-mesh comparators
	  ○ Minimum dataset
	  ○ Proms and outcomes
	• Engagement with clinical professions required
	• Establishment of a governance structure and steering groups
	• Set up of direction between NHS Digital and DHSC
	• Establishment of 'discretionary request' between devolved nations and NHS digital
		• NHS Digital have existing clinical audit platform that could be adapted for SUI/POP
		• Reduce the need for complex data linkage
			• May not be rapid enough to meet pause deadline
			• Clinical professions may not engage with NHS Digital
			• Discretionary request may not be possible for devolved nations
			• Professional societies may be reluctant to close down existing databases
			• May need to incorporate extra requirements of society databases
			• Costs of setting up new database unknown
			• Case ascertainment and participation may be poor while database drives engagement

C) 2) Set up new platform within alternative organisation	• Procurement process to identify suitable provider • Datasets must be established for SUI and	• Identification of good provider and innovative solution is possible	• May not be rapid enough to meet pause deadline • Clinical professions

	POP (including rectal prolapse): ○ Mesh procedures ○ Non-mesh comparators ○ Minimum dataset ○ Proms and outcomes • Engagement with clinical professions required • Establishment of a governance structure and steering groups		may not engage with new organisation • It may not be possible to establish data collection within devolved nations • Professional societies may be reluctant to close down existing databases • May need to incorporate extra requirements of society databases • Costs of setting up new database unknown • Case ascertainment and participation may be poor while database drives engagement • Development of interim database may be delayed through set up and identification of provider

8 Options to meet requirement that 'Reporting of complications via MHRA is linked to the register'

Pause recommendation 4 states that 'Reporting of complications via MHRA is linked to the register'. As identified during the workshops and exploratory work there is some ambiguity as to how this recommendation could be interpreted; either that an interim database (or registry) will permit reporting of complications to the MHRA, or that MHRA databases will flow information to an interim database (or registry). The workshops highlighted that there are legal obstacles to flowing data from the MHRA to an interim database or registry. This section will therefore consider in further detail the two main databases MHRA maintain which collect safety incident information and present an options appraisal for the interpretation of pause recommendation 4. A decision on which option to proceed with will be required.

The MHRA currently has two databases used to report safety incidents; the yellow card system used by clinicians and the public, and manufacturer vigilance reports submitted by manufacturers.

Yellow card reporting:

- Yellow card reporting is for reports from health care professionals, patients, public etc. Everyone except manufacturers. Mostly this is healthcare professionals, but in the case of mesh, there are a reasonable proportion of patient reports.
- The form asks for the reporter's details, patient details, manufacturer and device details and a description of the adverse event.

- Where MHRA can identify a manufacturer, the report is forwarded to that manufacturer who is obliged to investigate and report back to MHRA.
- In this case MHRA send an anonymised version of the report to the manufacturer, but there is usually little practical they can do with the report
- Of reports received, most include some sort of undesired event happening to the patient. However, there is a wide range of causes of these events, many of which are not the device, and most events have multiple causes, so the idea of a single root cause is problematic.
- All reporting is voluntary. Like most incident reporting systems the likely ascertainment rate is probably in the range 2—10%. There is no evidence that mandatory reporting for healthcare professionals significantly increases the quantity or quality of this data in incident reporting systems generally.
- The bulk of the form is a free text description of the event. The quality and quantity of this data is hugely variable.
- The manufacturer and device details are missing or incomplete most of the time.
- Consent is sought for the patient identifiers to be passed to the manufacturer to help them undertake their investigation, but is frequently refused

Manufacturer vigilance reporting:

- Only for reports from manufacturers
- Reports that meet the reporting criteria that occur in the UK must be reported to MHRA. One of the main criteria is that the event led or might have led to death or serious injury. The majority of reports in any reporting system are of low or no severity, so most incidents are not reported by the manufacturer under these rules (but these types of reports may be received directly from the user/patient)
- The report may be about events that have no identifiable patient (e.g. a batch of devices not sterilised properly but was detected before being used) or about a group of patients (a single event affected several patients)
- The form used (see appendix H) includes the manufacturer and device details, but does not usually contain patient identifiers
- The patient identifier fields are optional, and frequently the manufacturer does not have this data because patients and healthcare professionals do not wish to provide them
- The form contains the free text description of the event, which is very variable in quality and quantity
- Some manufacturers are already using UDI; some are using a device identifier that is unique to the manufacturer, but not globally unique
- The fields of this form are defined at European level, cannot be unilaterally changed by MHRA.
- The requirements of this system are changing with the new regulations:
- UDI will become universal and mandatory - for all implants the deadline is May 2021
- The fields will change, notably to include a classification of the type of event
- The form will be recorded in a central European databank (EUDAMED)
- That databank may include public access to individual vigilance reports, yet to be agreed at European level

Table 15 presents an option appraisal for four options to meet pause recommendation 4, considering the advantages and risks of each option.

Table 15: Options to meet pause recommendation 4			
Options	**Implications**	**Advantages**	**Risks**
1. Database has functionality which links to the MHRA yellow card reporting system, this allows the clinician to make a yellow card report	• This functionality is currently built into the BSUG database (although it is currently limited as it does not autofill any information to the report). It is extended across the BAUS and TPFS databases for the interim with consideration given to development of an improved form for mesh complications (such as for cochlear implants or joint replacements).	• This will likely increase the rate and accuracy of reporting to the MHRA at the time complications are recorded via the databases.	• Independent Medicine and Medical Devices Safety Review may consider this insufficient to meet the recommendation
2. Yellow card reporting as per option 1 and in addition interim database flows de-identifiable patient level data to the MHRA, reporting rates of complications	• This ability to link to the MHRA yellow card reporting is currently built into the BSUG database (although limited in functionality, as explained above). It is extended across the BAUS and TPFS databases for the interim with consideration given to development of an improved form for mesh complications (such as for cochlear implants or joint replacements). • The MHRA currently receives de-identified data from other registries, such as the NJR. It would be desirable to establish a de-identified flow of data from the registry to the MHRA • The exact data items required by the MHRA would need to be established and, although data will be	• This will likely increase the rate and accuracy of reporting to the MHRA at the time complications are recorded via the databases. • May be of benefit to the MHRA	• Independent Medicine and Medical Devices Safety Review may consider this insufficient to meet the recommendation • It may not be feasible or productive to establish a de-identified flow to the MHRA within the short time period of the interim database

	de-identified, if the mesh device details permit re-identification of the patient a legal basis under which this data will flow must be established		
3. MHRA flows yellow card incident reports to the database It is recommended that the database/registry does not explore feasibility of flowing yellow card information from the MHRA.	• Establishment of consent permissions from patients, manufacturer and any other identifiable element within the report to onward share to a database • Establishment of the information to be gained from linking the interim database to this information source		• The feasibility of linking to this data source is unlikely. It would be difficult to achieve since consent must be obtained from the patient and the manufacturer. In addition identifiability is frequently not possible, therefore linkage would be impossible. • Case ascertainment is very low and the information submitted is variable therefore the quality of the data is poor. Benefit/gain is therefore unknown but unlikely. • May take considerable time and resource to attempt to establish with little information gain
4. MHRA flows manufacturer vigilance reports to the database It is recommended that flowing of manufacturer vigilance data from the MHRA to a database/registry is not currently feasible and unlikely to derive benefit, where this may be technically feasible post 2021 the benefit of linking that data at a patient level must be established first.	• Establishment of consent permissions from manufacturer and any other identifiable element within the report to onward share to a database • Establishment of the information to be gained from linking the interim database to this information source		• Currently it is unlikely to be feasible to link this information source to a Mesh database/registry without UDI (unique device identifiers) or patient identifiers. • From 2021 it will be compulsory for manufacturers to use the UDI, this would make linkage technically feasible, however consent from the patient may be necessary as this would essentially re-

			identify the patient. • Currently the standard vigilance form is not compulsory and the information is variable in content and quality. • In the future there may be a mechanism to make public access to individual vigilance reports, via the European databank EUDAMED therefore making this data publically available

9 Recommendations and way forward

The report will now summarise the recommended changes to be made to existing databases, or a newly built database (depending upon which model from section 7 is selected) to establish an interim urogynaecological mesh database. The recommendations presented below are a summary of the findings (in sections 6) of the exploratory scoping work, discussions and the technical and stakeholder workshops.

Evidence-to-recommendation rationale for recommendation 1: It was highlighted within the technical workshop that clear aims and objectives should be developed for the interim database to ensure appropriate outputs are produced and the data collected is proportionate and adequate to meet those aims and outputs. Based upon the pause recommendations and feedback within the workshops, that the database should collect meaningful data to provide assurance of the quality and safety of care, the following aims are proposed which should be refined and agreed by DHSC and devolved nations.

Recommendation 1: Interim database aims

Ensure the new interim database aims include the following:

- To provide benchmarked information which supports:
  - Patients in making informed decisions about their care and to improve public confidence
  - Improvements in the quality of care delivered for procedures to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP) by the NHS and independent organisations
  - Clinicians in making informed decisions for SUI and POP treatments
  - The MHRA and other regulators to monitor the performance of mesh implant manufacturers and provide a track and trace mechanism.
- To provide assurance of the quality and safety of care with reporting through to the CQC to inform their inspections programme.

Evidence-to-recommendation rationale for recommendation 2: Good national clinical audits have an independent governance structure to provide leadership, assurance and direction. Often this includes a project board and clinical steering group with representation from the range of stakeholders, professionals and patients involved with and dependent upon the audit. Existing databases do have oversight from society governance groups, however the composition of these groups is not representative of all stakeholders and excludes patients or patient groups. This,

together with workshop findings that patients have a lack of confidence and trust in existing databases, supports the recommendation that an independent overarching group be established for the interim database to provide oversight, assurance and direction.

Recommendation 2: Governance arrangements

Recommendation 2.1: Ensure an oversight governance group is established, meets quarterly as a minimum and consider representation from the following groups:

- DHSC and devolved nations (Welsh Government, Scottish Government, Northern Ireland)
- NHS England (specialised commissioning)
- NHS Digital
- National informatics providers from devolved nations (such as, ISD NHS National Services Scotland and National Wales Informatics Service)
- BSUG database (British Society of Urogynaecology)
- BAUS database (British Association of Urological Surgeons)
- TPFS database (The Pelvic Floor Society)
- MHRA (Medicines and Healthcare Products Regulatory Agency)
- PHIN (Private Healthcare Information Network)
- Independent Healthcare Providers Network (IHPN)
- Patient representatives (including from patient groups such as Sling the Mesh and the Scottish Mesh Survivors)
- Transvaginal Mesh Oversight Group (Scotland)
- Manufacturing industry representatives
- NHS Improvement
- Scan 4 safety
- Clinical specialists:
    - Urogynaecologists
    - Urology surgeons
    - Colorectal surgeons
    - Specialist nurses
    - Specialist physiotherapists
- Pain specialists

Recommendation 2.2: Ensure the Oversight Group Terms of Reference include and clearly set out:

- Representation
- Declarations and conflicts of interest
- Quoracy
- Scope
- Roles and responsibilities
- Frequency of meetings

Evidence-to-recommendation rationale for recommendation 3: The geographical scope of existing databases already extends across England, Wales, Scotland and Northern Ireland however participation from devolved nations has not been comprehensive. Implementation work should investigate in further detail barriers to involvement within Scotland and other devolved nations.

Scope already allows the recording of NHS and privately funded procedures within both NHS and independent organisations. To ensure the comprehensive capture of all relevant procedures and cross sector pathways this should continue. Whilst all three databases collect data across NHS and independent sector, although only BAUS and BSUG can distinguish NHS from private patients. However only BAUS collects which hospital site the patient is treated in and therefore is able to attribute private or NHS activity to specific independent hospitals. Therefore all

three databases must collect hospital site and whether patients are NHS/privately funded.

Devolved nations must advise if they would like to capture independent and privately funded healthcare activity, if so then a method of inserting missing patient identifier and tracing contact details must be explored.

Further work with PHIN and IHPN is required to drive participation within independent sector. A decision must be taken on whether to include rectal prolapse and rectopexy procedures (TPFS) within the interim database.

Recommendation 3: Scope

Ensure that the new interim database considers:

- Inclusion of all devolved nations
- NHS and privately funded independent sector procedures.

Evidence-to-recommendation rationale for recommendation 4: It was identified through the technical workshops that an interim database must include information on mesh and non-mesh comparator procedures, in order to compare outcomes and safety. An examination of current databases found that rationalisation of the procedures mesh surgical procedures captured by BSUG, BAUS and TPFS must be undertaken, to ensure consistency of data collection, analysis and reporting. All three Societies were invited to submit a rationalised list of procedures and BSUG submitted a proposed list which was discussed briefly within the technical workshop with conclusion that this list should include non-mesh comparators and mesh complication procedures. It was noted that whilst BSUG and BAUS databases have comparable procedures, it would be more difficult to align with and identify non-mesh comparators for TPFS rectopexy database.

Recommendation 4: Inclusion criteria

Recommendation 4.1: Ensure that both mesh (interventions) and non-mesh (comparator) procedure inclusion criteria for the treatment of SUI and POP are collected.

Recommendation 4.2: Consider a rationalised minimum core mesh procedures dataset including:

- TVT (or Retropubic Mid-Urethral Tape)
- TOT (or Transobturator Mid-Urethral tape)
- Vaginal Mesh for Prolapse
- Sacrocolpopexy
- Sacrohysteropexy (including Sacrocervicopexy)
- Rectopexy.

Recommendation 4.3: Reach consensus agreement for including some non-mesh (comparator) procedures. The following list of procedures used by NHS Digital in their retrospective HES analysis can be used as an initial guide and should be refined:

a. Non-mesh procedures for urogynaecological prolapse:
    - P22.1 Anterior and posterior colporrhaphy and amputation of cervix uteri
    - P22.2 Anterior colporrhaphy and amputation of cervix uteri NEC
    - P22.3 Posterior colporrhaphy and amputation of cervix uteri NEC
    - P22.8 Other specified repair of prolapse of vagina and amputation of cervix uteri
    - P22.9 Unspecified repair of prolapse of vagina and amputation of cervix uteri
    - P23.1 Anterior and posterior colporrhaphy NEC
    - P23.4 Repair of enterocele NEC
    - P23.5 Paravaginal repair
    - P23.8 Other specified other repair of prolapse of vagina
    - P23.9 Unspecified other repair of prolapse of vagina.
b. Non-tape procedures for stress urinary incontinence (SUI)

- M52.1 Suprapubic sling operation.

Recommendation 4.4: Reach consensus agreement for including mesh complication and removal procedures. For example the following procedures but this list should be refined:

- Suburethral tape stretched (stretched/divided)
- Excision vaginal part of MUT (not exposed/ eroded)
- Partial removal retropubic tape (open/ laparoscopic/ robotic)
- Total removal retropubic tape (open/ laparoscopic/ robotic)
- Mesh erosion (urethral/bladder/bowel) – excised
- Burial of mesh (no mesh removed)
- Localised excision and closure of mesh exposure
- Total excision of mesh
- Total removal of transobturator tape
- Abdomonal removal sacrocolopexy mesh
- Abdomonal removal sacrohysteropexy mesh
- Abdomonal removal sacrocervicopexy mesh.

Recommendation 4.5: Consider whether rectopexy (TPFS) should be included with the interim database and reach consensus agreement on mesh comparator procedures relevant to rectal prolapse.

Evidence-to-recommendation rationale for recommendation 5: It is proposed that membership restrictions should be lifted to allow for 100% participation and case ascertainment. It is also proposed that data collection should be mandated to increase the level of reporting and to transfer responsibility from the individual clinician to the hospital provider; this may also serve to improve the support provided to clinicians to facilitate data collection.
DHSC and devolved nations to determine the most appropriate method to mandate participation within the interim database.

Recommendation 5: Participation requirements

Consider the following aspects to increase participation and case ascertainment:

- Lift Society membership restrictions to entering data
- DHSC and devolved nations work towards mandating data collection.

Evidence-to-recommendation rationale for recommendation 6: Exploratory work identified that each existing database collects different data items. In order to permit linkage and analysis across these databases a common minimum dataset must be agreed. A minimum dataset was proposed by BSUG (see appendix E) and discussed at the technical workshop with suggestions to incorporate NICE, MHRA and other stakeholder requirements (as identified through exploratory work and workshops). See table 8 for all dataset suggestions aligned to discussion points from workshops.

PROMS have been suggested within the below dataset but agreement is required from BSUG/BAUS on which specific validated proms should be consider for inclusion within interim database.

Further patient engagement is required during the establishment of an interim database to ensure those outcomes and complications collected are appropriate and take important patient outcomes into consideration (this should include wide representation from patient groups, including from devolved nations).

Further work is required to establish the feasibility of including a patient experience survey as part of the interim database.

NICE recommends the date and details of any investigation for mesh-related complications be captured. Further work is required to determine whether this should be incorporated within the interim database or long term registry.

If rectopexy (TPFS) is to be included within the interim database, agreement must be reached on a minimum dataset and PROMS for rectal prolapse.

An evaluation of the interim database, to establish whether the outcomes collected have been meaningful and useful, should aid decision making on whether a long term registry should continue to collect these outcomes or undertake work with patients to develop a bespoke PROM that captures the areas important to patients.

Recommendation 6: Minimum dataset

Consider the following minimum dataset and parameters for mandatory and optional collection:

- M = mandatory items for collection
- O = optional items for collection

Proposed minimum dataset

Item	Primary Procedure	Subsequent Procedure(s)	Mesh Complication Procedure
Consent Obtained	M	M	M
NHS number or CHP number	M	M	M
Date of Birth	M	M	M
Name	M	M	M
Gender	M	M	M
Postcode	M	M	M
Country of Residence	M	M	M
Site code and name	M	M	M
Responsible Consultant GMC number	M	M	M
Operating Surgeon GMC number	M	M	M
Date of Procedure	M	M	M
NHS or privately funded	M	M	M
Procedure Performed	M Options: • Retropubic Midurethral Tape (for incontinence) • Transobturator Mideurethral Tape (for incontinence) • Vaginal Mesh (for prolapse) • Sacrocolpopexy • Sacrohysteropexpy / sacrocervicopexy	M Options: • Retropubic Midurethral Tape (for incontinence) • Transobturator Mideurethral Tape (for incontinence) • Vaginal Mesh (for prolapse) • Sacrocolpopexy • Sacrohysteropexpy / sacrocervicopexy	M Options: 16. Suburethral tape stretched (stretched/divided) 17. Excision vaginal part of MUT (not exposed/ eroded) 18. Partial removal retropubic tape (open/ laparoscopic/ robotic) 19. Total removal retropubic tape (open/ laparoscopic/ robotic) 20. Mesh erosion (urethral/bladder/bowel) – excised

	• Rectopexy Need to add: • non-mesh comparators • approach and type	• Rectopexy Need to add: • non-mesh comparators • approach and type	21. Burial of mesh (no mesh removed) 22. Localised excision and closure of mesh exposure 23. Total excision of mesh 24. Total removal of transobturator tape 25. Abdomonal removal sacrocolopexy mesh 26. Abdomonal removal sacrohysteropexy mesh 27. Abdomonal removal sacrocervicopexy mesh Rationalisation of mesh complication procedures needed
Concomitant Procedure	M Options: • Retropubic Midurethral Tape (for incontinence) • Transobtrurator Mideurethral Tape (for incontinence) • Vaginal Mesh (for prolapse) • Sacrocolpopexy • Sacrohysteropexpy / sacrocervicopexy • Rectopexy Need to add: • non-mesh comparators • approach and type	M Options: • Retropubic Midurethral Tape (for incontinence) • Transobtrurator Mideurethral Tape (for incontinence) • Vaginal Mesh (for prolapse) • Sacrocolpopexy • Sacrohysteropexpy / sacrocervicopexy • Rectopexy Need to add: • non-mesh comparators • approach and type	M
Mesh Unique Device Identifier (UDI)	M	M	M
Mesh Material	M	M	M
Mesh Manufacturer	M	M	M
Device Catalogue Reference Number (if no UDI)	O	O	O
Device Lot Number (if no UDI)	O	O	O
Type of Sutures	M	M	M
Indication for surgery	Options: • Incontinence • Vaginal/uterine prolapse • Rectal prolapse	Options: • Incontinence • Vaginal/uterine prolapse • Rectal prolapse	Options: • Pain • Dyspareunia / sexual dysfunction • Mesh erosion/extrusion • Voiding difficulty

	• Obstructive defaecation	• Obstructive defaecation	• To relieve urinary urgency • Urinary incontinence • Urinary tract infections • Patient request • Abscess/mesh related infection • Other (free text)
Classification of Mesh complication	n/a	n/a	Intra-operative mesh/graft complication score (ICS-IUGA https://www.ics.org/complication)
Discussed at MDT	M	M	M
Pelvic floor exercises offered	O	O	O
Pre-operative urodynamics performed	O	O	O
Pre-operative urodynamic diagnosis	O	O	O
Does patient require catheters pre-operatively?	O	O	O
Pre-op Brief Pain Inventory – short form or Visual Analogue Scale for Pain	O	O	O
Pre-op UTI Symptoms Assessment Questionnaire	O	O	O
Pre-op Sexual health questionnaire, such as ePAQ-PF or PIS-Q or Female Sexual Function Index	O	O	O
Pre-Op EQ-5D_5L	O	O	O
Pre-op ICIQ-UI	O	O	O
Pre-op ePAQ-PF	O	O	O
Co-morbidities: • **Diabetes** • **Ehlors Danlos**	O	O	O
Pre-op Smoking Status	O	O	O
Patient height	O	O	O
Patient weight	O	O	O
Past surgical Procedures	O	O	O
Intra-operative ureteric injury	M	O	O
Intra-operative bladder injury	M	O	O
Intra-operative vaginal button holing	M	O	O
Intra-operative	M	O	O

urethral injury			
Intra-operative bowel injury	M	O	O
Intra-operative vascular injury	O	O	O
Intra-operative neurological injury	O	O	O
Intra-operative blood loss>500ml	O	O	O
Peri-operative blood transfusion	O	O	O
Peri-operative thromboembolism	O	O	O
Intra-operative death	M	O	O
Anaesthetic used	O	O	O
Post-operative return to theatre for procedure related event within 72 hrs	M	O	O
Post-operative catheterisation required for more than 10 days post-op	O	O	O
Return to hospital within 30 days for procedure related event	M	O	O
Readmitted to hospital within 30 days for procedure related event	M	O	O
Planned re-admission or emergency	M	O	O
Post-operative review date	O	O	O
Post-op Brief Pain Inventory – short form or Visual Analogue Scale for Pain	O	O	O
Post-op UTI Symptoms Assessment Questionnaire	O	O	O
Post -op Sexual health questionnaire, such as ePAQ-PF or PIS-Q or Female Sexual Function Index	O	O	O
Post -Op EQ-5D_5L	O	O	O
Post -op PGI-I (for prolapse)	O	O	O

Post -op PGI-I (for incontinence)	O	O	O
Post -op ICIQ-UI	O	O	O
Post -op ePAQ-PF	O	O	O
Post op change in stress urinary incontinence	O	O	O
Post-op change in stress urinary incontinence	O	O	O
Post-op change in urgency/urge incontinence	O	O	O
Does patient require catheters post operatively?	O	O	O

Evidence-to-recommendation rationale for recommendation 7: It is proposed that the interim dataset be capable of linking to other national datasets to augment with further information on readmissions, attendance at other services (e.g. pain clinics, physiotherapy, occupational therapy, rehabilitation) and cross sector (NHS and independent) and cross boarder treatment. Identifiers have therefore been included within the proposed minimum dataset. However further exploration and agreement on which national datasets to link to for England and devolved nations are required.

The interim database should be capable of performing a mesh implant track and trace function and this process will need to be established. The Breast Implant Registry process can be used as a guide whereby in the event of a recall, NHS Digital identifies affected individuals and traces current addresses, these are then supplied to the organisation that carried out the surgery so that they can make contact and arrange an assessment and next steps. It should be noted that currently device recall for the Breast Implant Registry is only possible based upon manufacturer since there are currently no validity rules available for device identifier, serial numbers, catalogue reference numbers and lot numbers. Further exploration into establishment of a similar process within devolved nations is required.
Each society database should build in a link to the MHRA yellow card system to allow clinician reporting of adverse incidents (replicate what has already been done for BSUG to BAUS and TPFS).

The interim database should be capable of processing third party data access requests to make data available to support wider research and service evaluation.

Information governance work (as below in recommendation 7) should be undertaken to establish a legal basis to link to other data sources.

Recommendation 7: Data flows and linkage

Recommendation 7.1: Ensure that the new interim database is capable of:

- Linking to other national datasets (including devolved nation) and data sources via an established legal basis
- Performing a mesh implant track and trace function (for example using the Breast Implant Registry process as a guide)
- Building in a link to the MHRA yellow card system to allow clinician reporting of adverse incidents (for example replicate what has already been done for BSUG to BAUS and TPFS).
- Processing third party data access requests (for example to make data available to support wider research and service evaluation).

Recommendation 7.2: Undertake further exploration and agreement on which national datasets to link to for England and the devolved nations.

Evidence-to-recommendation rationale for recommendation 8: Exploratory work highlighted that a robust legal basis is required for the interim database which will provide the ability of collect identifiable and confidential data and to undertake data linkage and transfer. The technical workshop identified patient consent as the most appropriate legal basis to meet the common law duty of confidentiality, since section 251 exemption (or equivalent legal exemption) is not available across all devolved nations. The workshop also identified that expert IG support is required by all Societies to implement a successful data protection and information governance compliance programme.

It is unlikely that TPFS database, as it currently exists, has sufficient information security or information governance set up to support the collection of identifiable confidential patient information. Should TPFS be included within the interim database resource must be invested to achieve sufficient compliance.

Recommendation 8: Information governance

Ensure that patient consent is sought as the most appropriate legal basis to meet the common law duty of confidentiality across England and devolved nations. Expert information governance resource to support the following activities should include:

- Assessment of data flows, data controllership and legal basis for each element of processing under GDPR (article 6 and article 9), with a register of processing activities to be maintained.
- Data Protection Impact Assessment.
- Appointment of a Data Protection Officer.
- Development of transparency documentation and consent documentation (privacy notice, patient leaflets, posters, consent capture form and consent leaflet)
- Assessment and establishment of any required data sharing agreements to permit data collection across England and devolved nations
- Review of data subject rights and establishment of individual rights and opt out policy and process. This should include the development of a clear patient access policy and process.
- Information security arrangements to be reviewed, this may require completion of NHS Digital Data Security and Protection Toolkit (DSPT)
- Mapping and development of required information governance policies.

Evidence-to-recommendation rationale for recommendation 9: Analytical and statistical expertise is currently missing within the BSUG, BAUS and TPFS databases. In order for the interim database to produce statistically robust and reliable results/outputs this expertise will need to be provided by a partner organisation (see options in section 7).

The feasibility of obtaining case ascertainment figures/denominator data from PHIN for privately funded procedures undertaken within the independent sector should be explored.

A long term registry should take forward the development of an appropriate methodology to follow up patients for a minimum of 5 years to enable the capture of good and bad outcomes for mesh and comparator procedures.

An appropriate follow up period and methodology for the interim database has yet to be established and agreed and a consensus agreement should be reached between the Societies.

The collection of patient outcomes directly from patients is desirable and should be incorporated into the long term registry; however the feasibility of establishing this for the interim database (given the short timescale to establish an interim database to meet the pause recommendations) makes it unlikely that this could be achieved in the short term.

Recommendation 9: Data collection and data quality

Recommendation 9.1: Ensure that data quality and completeness is improved by:

- Identifying dataset mandatory fields (for example, see suggested dataset)
- Modifications to incorporate built in validation rules and checks to the BSUG/BAUS/TPFS data collection platforms (for instance to prevent values that are implausible and to ensure mandatory fields are not omitted)
- A clear data collection schedule to be established for each database which allows a period of validation by providers and clinicians before data submitted is locked down for cleaning and analysis
- Publication of % data completeness by provider
- Case ascertainment to be checked against national data sources (such as HES,PEDW and other devolved nations datasets) and published at provider and national level.

Recommendation 9.2: Reach consensus from BSUG, BAUS and TPFS regarding an appropriate follow up period and methodology for the interim database.

Evidence-to-recommendation rationale for recommendation 10: Exploratory work and workshops highlighted that outputs should align to the aims and objectives of the audit. Expert statistical expertise is required to produce robust outputs, especially if outlier analyses required. Table 8 considers the outputs stakeholders would like an interim database to produce.

Recommendation 10: Outputs

Recommendation 10.1: Reported results at the following levels (as a minimum):

- Individual surgeon (Consultant level outcomes to be published on professional society websites and NHS Choices/My NHS, for England, to aid transparency to patients)
- Hospital provider (NHS and independent)
- Regional
- National (England, Scotland, Wales, Northern Ireland).

Recommendation 10.2: Publish national reports annually and include:

- Comparisons in outcomes and safety between mesh and non-mesh (comparator) procedures
- Benchmarked outcomes and complications at hospital provider, regional and national level
- Benchmarked outcomes and complications by manufacturer, device type and material
- Data quality statement/assessment which includes % participation, case ascertainment levels and % data completeness
- A lay summary for patients to aid transparency.

Recommendation 10.3: Explore the feasibility of establishing a risk adjustment model for the interim database and consider risk adjusting results.

Recommendation 10.4: Produce a summary extract for patients (as per NICE guidance) that contains important information about their procedure and the device inserted.

Recommendation 10.5: Establish a method of data access for manufacturers for the long term registry. Undertaken further work to determine the data mesh manufacturer's inputs to improve quality and safety.

10 Conclusion

This report will be submitted to the funding body, the DHSC, for consideration of:

1. The preferred model from section 7 to be used to establish an interim database
2. The preferred option from section 8 to meet pause recommendation 4 'Reporting of complications via MHRA is linked to the register'
3. Implementation of recommendations within section 9 to establish an interim database

HQIP thanks and acknowledges the support and time afforded by patients, patient support groups, the Societies (BSUG, BAUS and TPFS), technical teams, clinical teams, attendees and the Chairs of both workshops (Professor Keith Willett, NHS England Director for Acute Care and Emergency Preparedness and Annie Laverty, Chief Experience Officer at Northumbria NHS Foundation Trust).

11 Appendix A: Primary Surgical Procedures collected by current BSUG and BAUS databases

BSUG Incontinence Procedures

1. Anterior repair (AR) + BNB
2. Artificial urinary sphincter
3. Cystoscopic BNI Macroplastique
4. Cystoscopic BNI Collagen
5. Cystoscopic BNI Contingen
6. Cystoscopic BNUI Tgress
7. Cystoscopic BNI Bulkamid
8. Cystoscopic Botulinum Injection
9. Coaptite injectable implant
10. Periurethral BNI
11. Non-Cystoscopic BNI Zuidex
12. Non-Cystoscopic BNI Durasphere
13. Non-Cystoscopic BNI MIS
14. Non-Cystoscopic BNI Other
15. Colposuspension Open
16. Colposuspension Laparoscopic
17. MMK
18. Retropubic MUS TVT
19. Retropubic MUS TVT exact
20. Retropubic MUS Sparc
21. Retropubic MUS IVS
22. Retropubic MUS Uretex
23. Retropubic MUS Retroarc
24. Retropubic MUS Safyre
25. Retropubic MUS Advantage
26. Retropubic MUS Advantage Fit
27. Retropubic MUS Align
28. Retropubic MUS Pelvilace
29. Retropubic MUS I Stop
30. Retropubic MUS Kim
31. Retropubic MUS Bioarc SP
32. Retropubic MUS Lynx
33. Retropubic MUS Other
34. TVT Obturator
35. TVT Abbrevo
36. TOT Monarc
37. TOT Aris
38. TOT Uretex TO
39. TOT Pelvilace TO
40. TOT Safyre t
41. TOT Obtryx
42. TOT Align TO
43. TOT I Stop
44. TOT KIM
45. TOT Other
46. TOT Bioarc
47. Single excision tape TVT Secur
48. Single excision tape MiniArc
49. Single excision tape Miniarc Precise
50. Single excision tape Adjust
51. Single excision tape Needleless
52. Single excision tape Solyx
53. Single excision tape Zippere
54. Single excision tape Other
55. Laparoscopic Urethropexy
56. Sling BioArc Suprapubic
57. Sling Infast Ultravaginal
58. Sling Rectus Sheath
59. Sling Combined A/V Aldridge
60. Sling Adjustable TRT/Remeex
61. Sling Adjustable AMI/TOA
62. Sling Adjustable AMI/TVA
63. Sling Autologous Spiral
64. Urethral Diverticulectomy
65. Vaginal Closure Fistula
66. Abdominal Closure Fistula
67. Insertion Long Term Suprapubic Catheter
68. Adjustable Continence Therapy (ACT)
69. Discontinued TOT Needleless
70. Discontinued Stamey Procedure
71. Discontinued Flexible Cystoscopy

BSUG Pelvic Organ Prolapse Procedures

1. Anterior Repair (AR)
2. AR + graft
3. Manchester Repair
4. Vaginal Hysterectomy
5. Vaginal hysterectomy + AR
6. LAVH (Laparoscopically assisted vaginal hysterectomy)
7. LAVH + BSO
8. TOAR (transobturator AR) perigee
9. TOAR Avaulta (solo)
10. TOAR Avaulta (plus)
11. TOAR Elevate
12. TOAR Uphold

13. TOAR Pinnacle
14. TOAR Other
15. Needlessness Repair Pinnacle (anterior)
16. Posterior Repair (PR)
17. PR + graft
18. PR + perineorrhaphy
19. PR + perineorrhaphy + graft
20. Recto-enterocoele repair + graft
21. MPR (mesh Posterior repair) Apogee
22. MPR (mesh Posterior repair) Avaulta
23. MPR (mesh Posterior repair) Other
24. Needleless Repair Pinnacle (posterior
25. Needleless Repair Elevate
26. Uphold vaginal support system
27. Posterior IVS
28. Infracoccygeal mesh hysteropexy
29. Infracoccygeal vault mesh suspension
30. TVM Apogee + Perigee
31. TVM Avaulta (solo)
32. TVM Avaulta (plus)
33. TVM other
34. Paravaginal repair vaginal
35. Paravaginal repair abdominal
36. Paravaginal repair laparoscopic
37. Sacrocolpopexy open
38. Sacrocolpopexy laparoscopic
39. Sacrocolpopexy bilateral open
40. Sacrocolpopexy bilateral laparoscopic
41. Sacrospinous fixation
42. Sacrospinous fixation capio
43. Sacrospinous hysteropexy
44. Sacrospinous hysteropexy capio
45. Iliococcygeal fixation
46. Iliococcygeal fixation Capio
47. Sacrocolpohysteropexy open
48. Sacrocolpohysteropexy laparoscopic
49. Sacrocolpocervicopexy open
50. Sacrocolpocervicopexy laparoscopic
51. Sacrocervicopexy bilateral open
52. Sacrocervicopexy bilateral laparoscopic
53. Laparoscopic suture hysteropexy
54. Laparoscopic uterosacral plication
55. Vaginal uterosacral plication
56. Moscowitz
57. Halban
58. Colpoclesis
59. Total Colpectomy
60. Ventral Mesh Rectopexy Open
61. Ventral Mesh Rectopexy Laparoscopic
62. Ventral Mesh Rectopexy Robotic
63. Discontinued total vaginal mesh (TVM) prolift
64. Discontinued TVM prolift M
65. Discontinued Needleless Repair
66. Discontinued IMPR Prolift M
67. Discontinued IMPR Prolift
68. Discontinued TOAR Prolift M
69. Discontinued TOAR Prolift

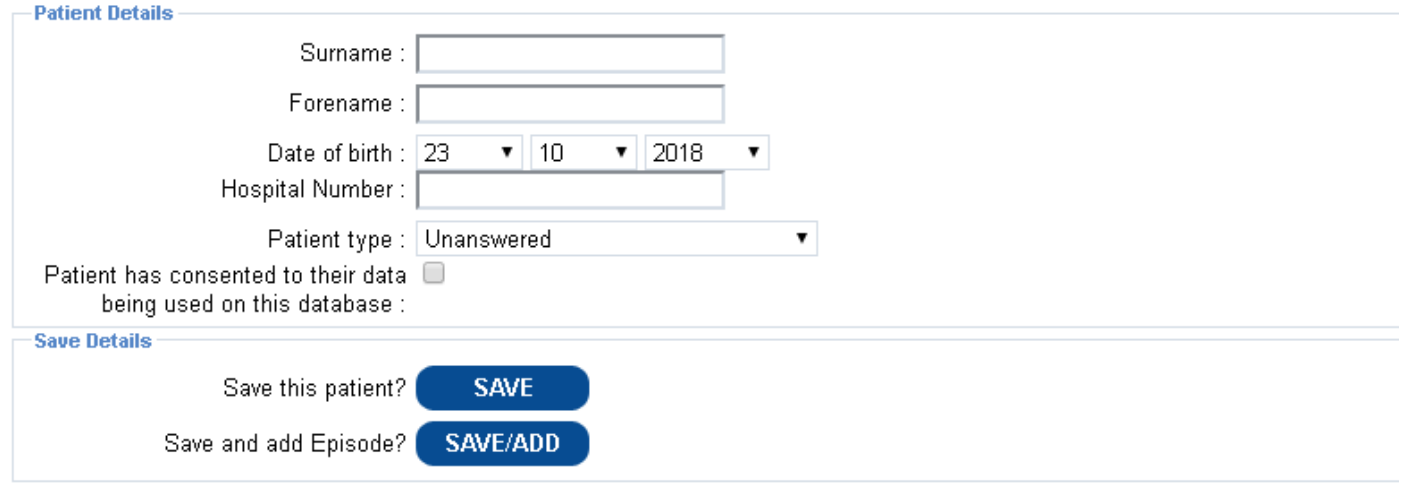
BSUG MESH/Graft complication procedures

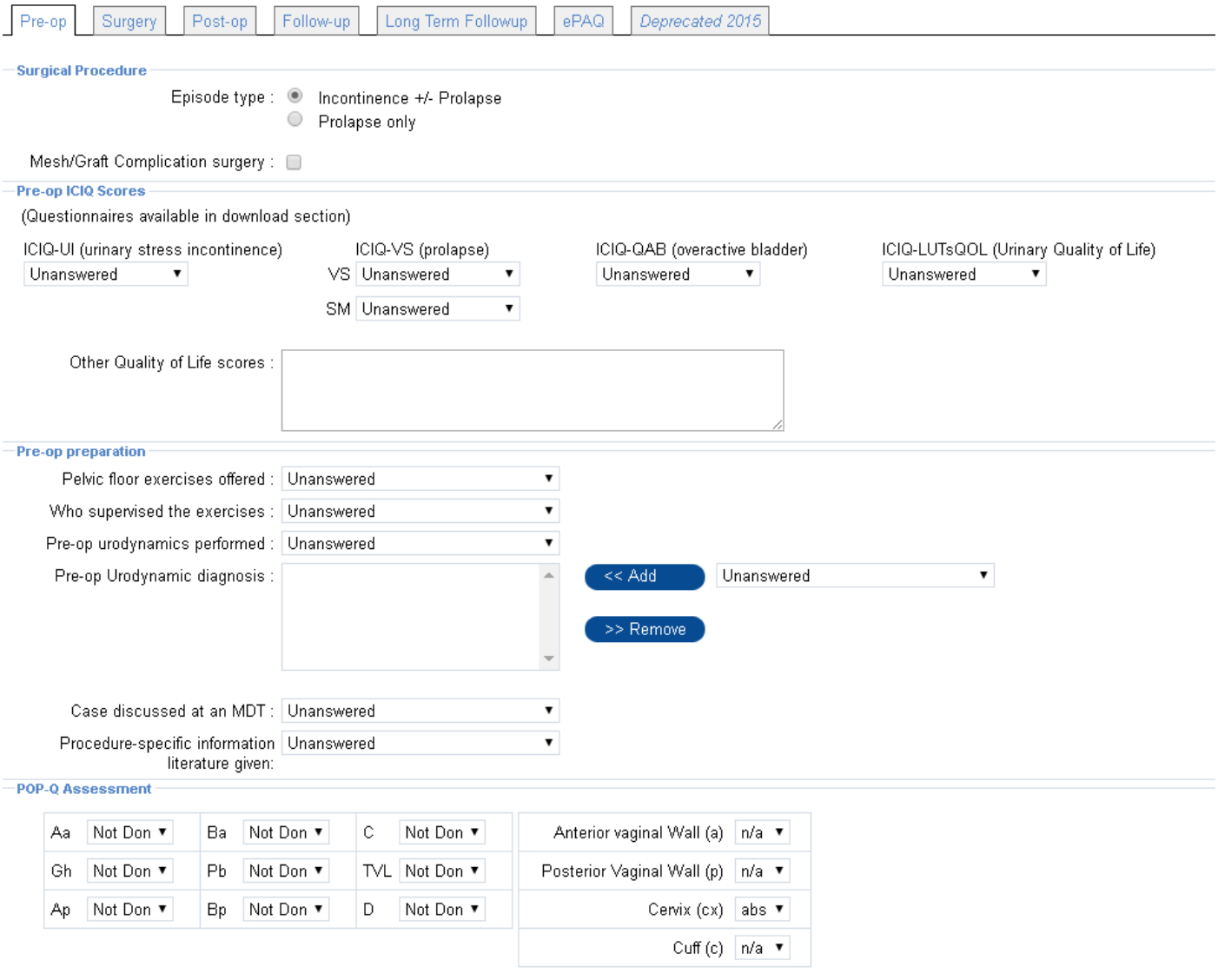
1. Suburethral tape stretched
2. Suburethral tape divided
3. Excision vaginal part of MUT
4. Partial removal retropubic tape open/laparoscopic/robotic
5. Total removal retropubic tape open/laparoscopic/robotic
6. Mesh erosion excised urethral
7. Mesh erosion excised bladder
8. Mesh erosion excised bowel
9. Burial of mesh (no mesh removed)
10. Localised excision and closure of mesh exposure
11. Total excision of mesh
12. Total removal of transobturator tape
13. Abdomonal removal sacrocolopexy mesh
14. Abdomonal removal sacrohysteropexy mesh
15. Abdomonal removal sacrocervicopexy mesh

BAUS SUI Procedures

11. Retropubic tape trocar passed bottom-to-top (TVT)
12. Transobturator tape - trocar passed outside-to-inside (TOT)
13. Transobturator tape - trocar passed inside-to-outside (TVTO)
14. Mini tape
15. Other tape
16. Colposuspension
17. Peri-urethral bulking agent
18. Autologous sling
19. Artificial urinary sphincter
20. Autologous transobturator Sling
21. TVT excision
22. AUS
23. Bladder neck AUS
24. Bladder neck AUS (whole device)
25. Bladder neck AUS cuff
26. Bladder neck closure
27. Bladder neck closure and martius
28. Bladder neck closure and partch
29. Bladder neck closure monti-mitro
30. Colposuspension
31. Durasphere injection to Mitrofanoff
32. Excision TVT mesh, colposuspension
33. Female AUS
34. Female sphincter cuff and cystoplasty
35. Insertion bladder neck AUS cuff
36. Insertion of artificial urinary sphincter
37. Insertion of AUS parts
38. Not recorded/Other
39. Replacement of AUS
40. Revision artificial urinary sphincter
41. Urethral closure and martius flap
42. Vaginal closure of urethra/formation

12 Appendix B: BSUG Current Dataset





Past History

Previous surgery : << Add | << Add | >> Remove | None

Parity : Unanswered

Pre-op | Surgery | Post-op | Follow-up | Long Term Followup | ePAQ | *Deprecated 2015*

Surgery

Operation date : 23 10 2018

Main Incontinence surgery : Unanswered

Incontinence Surgery Type: Unanswered

Concomitant surgery : << Add | << Add | >> Remove | None

Concomitant Prolapse Graft Used : None

BMI Calcalculator (enter Height and Weight)

Height(m) : 0 Weight(Kg) : 0 BMI : 0

Anaesthetic/surgeon

Anaesthetic used : Unanswered

Senior surgeon present : Unanswered

Grade of operator : Unanswered

Intra-operative Graft Complication

Graft Complications : Unanswered

Intra-operative information

Make all 'No'

Ureteric injury : Unanswered

Bladder injury : Unanswered

Vaginal Button-holing : Unanswered

Urethral Injury: Unanswered

Bowel injury : Unanswered

Vascular injury : Unanswered

Neurological injury : Unanswered

Blood loss > 500ml : Unanswered

Peri-operative blood transfusion : Unanswered

Peri-operative Thromboembolism : Unanswered

Death : Unanswered

Estimated blood loss (ml) :

Operation Duration : minutes.

Length of stay

Length of stay Post Op: Unanswered

Pre-op | Surgery | Post-op | Follow-up | Long Term Followup | ePAQ | *Deprecated 2015*

Post-op morbidity

Return to theatre for procedure-related event within 72 hrs : Unanswered

Make all 'No'

Catheterisation required for more than 10 days post-op : Unanswered

Return to hospital within 30 days for procedure related event : Unanswered

Readmitted to hospital within 30 days for procedure related event : Unanswered

Long term problem identified :

Post-op/Follow-up

How was follow-up carried out : Unanswered

What is the follow-up interval : Unanswered

Global Impression of Improvement

for Incontinence : 0-Unanswered

for Prolapse: 0-Unanswered

Post-op ICIQ Scores

(Questionnaires available in download section)

ICIQ-UI (urinary stress incontinence) Unanswered

ICIQ-VS (prolapse) VS Unanswered SM Unanswered

ICIQ-QAB (overactive bladder) Unanswered

ICIQ -LUTsQOL (Urinary Quality of Life) Unanswered

Other Quality of Life scores :

POP-Q Assessment

Aa	Not Don	Ba	Not Don	C	Not Don	Anterior vaginal Wall (a)	n/a
Gh	Not Don	Pb	Not Don	TVL	Not Don	Posterior Vaginal Wall (p)	n/a
Ap	Not Don	Bp	Not Don	D	Not Don	Cervix (cx)	abs
						Cuff (c)	n/a

Post-op/Follow-up

Change in Stress Urinary Incontinence (i.e. leakage with activity) : Unanswered

Change in Urgency / Urge Incontinence : Unanswered

Does patient require catheters : Unanswered

If Yes, were they required pre-op : Unanswered

Post-op Graft Complication

Graft Complications : Unanswered

Pre-op | Surgery | Post-op | Follow-up | Long Term Followup | ePAQ | *Deprecated 2015*

Acquisition

Followup date : 1 | 1 | 1918

Post-op/Follow-up

How was follow-up carried out : Unanswered

What is the follow-up interval : Unanswered

Global Impression of Improvement

for Incontinence : 0-Unanswered

for Prolapse: 0-Unanswered

Follow-up ICIQ Scores

(Questionnaires available in download section)

ICIQ-UI (urinary stress incontinence)	ICIQ-VS (prolapse)	ICIQ-QAB (overactive bladder)	ICIQ -LUTsQOL (Urinary Quality of Life)
Unanswered	VS Unanswered	Unanswered	Unanswered
	SM Unanswered		

Other Quality of Life scores :

POP-Q Assessment

Aa	Not Don	Ba	Not Don	C	Not Don	Anterior vaginal Wall (a)	n/a
Gh	Not Don	Pb	Not Don	TVL	Not Don	Posterior Vaginal Wall (p)	n/a
Ap	Not Don	Bp	Not Don	D	Not Don	Cervix (cx)	abs
						Cuff (c)	n/a

Post-op/Follow-up

Change in Stress Urinary Incontinence (i.e. leakage with activity) : Unanswered

Change in Urgency / Urge Incontinence : Unanswered

Does patient require catheters : Unanswered

If Yes, were they required pre-op : Unanswered

Post-op Graft Complication

Graft Complications : Unanswered

Notes

Did Not Attend :

Pre-op | Surgery | Post-op | Follow-up | Long Term Followup | ePAQ | *Deprecated 2015*

Problems Identified

Time from surgery : ____ months.

Prolapse

Same site recurrent prolapse requiring conservative therapy : ☐
Same site recurrent prolapse requiring surgery : ☐
New site prolapse : ☐

Bladder

Recurrent incontinence treated conservatively : ☐
Recurrent incontinence requiring surgery : ☐
New incontinence treated conservatively : ☐
New incontinence requiring surgery : ☐
Recurrent Cystitis / UTIs : ☐
Voiding difficulty : Unanswered ▼

Bowel

New onset constipation : ☐
Obstructive defaecation : ☐

Sexual activity

De novo dyspareunia : ☐

Mesh

Vaginal narrowing secondary to mesh retraction : ☐
Mesh erosion : Unanswered ▼

Chronic Pain

Pelvic : ☐
Vaginal : ☐
Bladder : ☐
Urethral : ☐

Long Term Graft Complication

Graft Complications : Unanswered ▼

Pre-op | Surgery | Post-op | Follow-up | Long Term Followup | ePAQ | *Deprecated 2015*

	Pre Op	Post Op
Urinary		
Pain :	Unanswered	Unanswered
Voiding :	Unanswered	Unanswered
Overactive Bladder :	Unanswered	Unanswered
Stress Urinary Incontinence :	Unanswered	Unanswered
Quality of Life :	Unanswered	Unanswered
Bowel		
Irritable Bowel :	Unanswered	Unanswered
Constipation :	Unanswered	Unanswered
Evacuation :	Unanswered	Unanswered
Continence :	Unanswered	Unanswered
Quality of Life :	Unanswered	Unanswered
Vaginal		
Pain & Sensation :	Unanswered	Unanswered
Capacity :	Unanswered	Unanswered
Prolapse :	Unanswered	Unanswered
Quality of Life :	Unanswered	Unanswered
Sexual		
Urinary & Sex :	Unanswered	Unanswered
Bowel & Sex :	Unanswered	Unanswered
Vagina & Sex :	Unanswered	Unanswered
Dyspareunia :	Unanswered	Unanswered
General Sex Life :	Unanswered	Unanswered

13 Appendix C: Current BAUS SUI Dataset

The British Association of Urological Surgeons
Female stress urinary incontinence surgery registry
Operation dataset; Page 1; Version 1.2 (16 Jan 2017)

Basic demographic data

Question titles in **red** denote a mandatory questions.

Unique patient identifier	
Date of birth	dd/mm/yyyy

Registry data

Basic details

Has the patient consented to data entry	○ No ○ Yes
Funding category	○ NHS ○ Private
Hospital centre	
Main consultant	
Kind of surgery	○ Primary ○ Recurrent SUI
Operation performed	○ Retropubic tape trocar passed bottom-to-top (TVT) ○ Transobturator tape - trocar passed outside-to-inside (TOT) ○ Transobturator tape - trocar passed inside-to-outside (TVTO) ○ Mini tape ○ Other tape ○ Colposuspension ○ Peri-urethral bulking agent ○ Autologous sling ○ Artificial urinary sphincter ○ Other operation

Prior operations (for procedures for recurrent SUI)

Date of prior operation	dd/mm/yyyy
What kind of operation was performed previously	○ Tape ○ Colposuspension ○ Autologous sling ○ Peri-urethral bulking agent ○ Other
Please specify tape product for previous operation	
Please specify other previous operation	

The British Association of Urological Surgeons

Female stress urinary incontinence surgery registry

Operation dataset; Page 2; Version 1.2 (16 Jan 2017)

Unique patient identifier

Date of operation dd / mm / yyyy

Pre-operative assessment

Height m

Weight kg

Body mass index kg m^{-2} (calculated outside of the system and hand entered)

enter the body mass index only when the height and weight data are not available

Charlson comorbidities

- ○ None
- ☐ Myocardial infarction
- ☐ Congestive heart failure
- ☐ Peripheral vascular disease
- ☐ Dementia
- ☐ COPD
- ☐ Connective tissue disease
- ☐ Slight diabetes
- ☐ Peptic ulcers
- ☐ Mild liver disease
- ☐ Hemiplegia
- ☐ Pre-operative catheter dependence
- ☐ Moderate/severe kidney disease
- ☐ Diabetes with organ damage
- ☐ Tumours (within 5 years)
- ☐ Leukaemia
- ☐ Lymphoma
- ☐ Moderate / severe liver disease
- ☐ Metastatic solid tumours
- ☐ AIDS
- ☐ Neuropathic bladder

Neurological co-morbidity ○ No ○ Yes

Congenital co-morbidity ○ No ○ Yes

Previous radiotherapy ○ No ○ Yes

Voiding dysfunction ○ No ○ Yes

Previous complex pelvic surgery ○ No ○ Yes

Symptoms ○ Pure stress incontinence ○ Mixed stress incontinence

Pre-operative urodynamics performed ○ No ○ Yes

Results of pre-operative urodynamics

- ○ Normal
- ○ Urodynamic urinary stress incontinence
- ○ Urodynamic detrusor over-activity / incontinence
- ○ Urodynamic mixed urinary incontinence
- ○ Other

Other urodynamics result

Patient-reported severity of incontinence

- ○ 0-1 pads per day
- ○ 2-3 pads per day
- ○ 4-5 pads per day
- ○ >5 pads per day

Was case discussed at MDT meeting or within agreed protocol

- ○ No
- ○ Yes

The British Association of Urological Surgeons

Female stress urinary incontinence surgery registry

Operation dataset; Page 3; Version 1.2 (16 Jan 2017)

Unique patient identifier

Date of operation dd / mm / yyyy

EQ-5D_5L

Mobility
- ○ I have no problem in walking about
- ○ I have slight problems in walking about
- ○ I have moderate problems in walking about
- ○ I have severe problems in walking about
- ○ I am unable to walk about

Self care
- ○ I have no problems washing
- ○ I have slight problems washing or dressing myself
- ○ I have moderate problems washing or dressing myself
- ○ I have severe problems washing or dressing myself
- ○ I am unable to washing or dress myself

Usual activities
- ○ I have no problems doing my usual activities
- ○ I have slight problems doing my usual activities
- ○ I have moderate problems doing my usual activities
- ○ I have severe problems doing my usual activities
- ○ I am unable to do my usual activities

Pain / discomfort
- ○ I have no pain or discomfort
- ○ I have slight pain or discomfort
- ○ I have moderate pain or discomfort
- ○ I have severe pain or discomfort
- ○ I have extreme pain or discomfort

Anxiety / depression
- ○ I am not anxious or depressed
- ○ I am slightly anxious or depressed
- ○ I am moderately anxious or depressed
- ○ I am severely anxiously or depressed
- ○ I am extremely anxious or depressed

Your own health score today on a scale of 0 (worst imaginable health state) - 100 (best imaginable health state)

Unique patient identifier

Date of operation dd / mm / yyyy

ICIQ-UI short form

How often do you leak urine

- ○ Never
- ○ About once a week or less often
- ○ Two or three times a week
- ○ About once a day
- ○ Several times a day
- ○ All the time

How much urine leaks

- ○ None
- ○ A small amount
- ○ A moderate amount
- ○ A large amount

How much does leaking urine interfere with your everyday life

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10

When does urine leak

- ○ Never - urine does not leak
- ☐ Before you can go to the toilet
- ☐ When you cough / sneeze
- ☐ When you are asleep
- ☐ When you are physically active / exercising
- ☐ When you have finished urinating and are dressed
- ☐ For no obvious reason
- ☐ All the time

The British Association of Urological Surgeons

Female stress urinary incontinence surgery registry

Operation dataset; Page 5; Version 1.2 (16 Jan 2017)

Unique patient identifier	
Date of operation	dd / mm / yyyy

Current operation

Date of operation	dd / mm / yyyy
Kind of surgery	○ Primary ○ Recurrent SUI
Operation performed	○ Retropubic tape trocar passed bottom-to-top (TVT) ○ Transobturator tape - trocar passed outside-to-inside (TOT) ○ Transobturator tape - trocar passed inside-to-outside (TVTO) ○ Mini tape ○ Other tape ○ Colposuspension ○ Peri-urethral bulking agent ○ Autologous sling ○ Artificial urinary sphincter ○ Other operation
Details of tape product	
Mesh Identification Number	
ASA grade	○ Grade 1 ○ Grade 2 ○ Grade 4 ○ Grade 3 ○ Grade 5
Details of other operation	
Other synchronous procedures	○ No ○ Yes
Please specify other synchronous procedures	
Peri-operative complications	○ None ☐ Bladder perforation ☐ Procedure abandoned ☐ Urethral perforation ☐ Other
Reason procedure abandoned	
Please specify other peri-operative complications	

Unique patient identifier

Date of operation dd/mm/yyyy

Post-procedure data

Did the patient leave theatre with catheter in situ
- ○ No
- ○ Yes

Trial without catheter performed
- ○ <6 hours after operation
- ○ 6-24 hours after operation
- ○ >24 hours after operation

for patients who leave theatre with a catheter in situ

Time catheter was in situ min

Patient able to void after tape insertion
- ○ No
- ○ Yes

At discharge is the patient
- ○ Voiding
- ○ Performing de novo ISC
- ○ De novo catheterisation
- ○ Intentional ISC
- ○ Intentional catheterisation

Did patient start unintended CISC
- ○ No
- ○ Yes

Other management offered

Patient status
- ○ Alive
- ○ Died on the table
- ○ Died in hospital

Discharge date known
- ○ No
- ○ Yes

Estimated date of discharge dd/mm/yyyy

Date of discharge/death dd/mm/yyyy

Additional comments relevant to this case

Unique patient identifier	
Date of follow up	dd / mm / yyyy

Follow up

Actual date of discharge	dd / mm / yyyy

PROMS

Patient-reported severity of incontinence	○ 0-1 pads per day ○ 2-3 pads per day	○ 4-5 pads per day ○ >5 pads per day
Since surgery, is the patient dependent on a catheter or CISC	○ No ○ Yes	
Patient-reported complications: UTI	○ No	○ Yes
Antibiotics given	○ No	○ Yes
Positive microscopy	○ No	○ Yes

Over-active bladder symptoms

New / de novo urgency	○ No	○ Yes
Pre-existing urgency change	○ Worse ○ No change	○ Better
Anti-cholinergic drug given	○ No	○ Yes
Specify any other treatment		

Complications

Tape extrusion	○ No	○ Yes
Location of extrusion	○ Vaginal ○ Bladder	○ Urethral
Intervention for extrusion	○ No	○ Yes
Intervention required	○ Topical oestrogen ○ Mucosal apposition with sutures ○ Excision of tape ○ Endoscopic laser excision of tape ○ Open excision of tape ○ Other	
Persistent pain after surgery	○ No	○ Yes
Site of any pain		
Clavien Dindo grade of complications	○ No complications ○ Grade I ○ Grade II ○ Grade IIIa	○ Grade IIIb ○ Grade IVa ○ Grade IVb

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The British Association of Urological Surgeons

Female stress urinary incontinence surgery registry

Follow up dataset; Page 8; Version 1.2 (16 Jan 2017)

Unique patient identifier

Date of follow up dd / mm / yyyy

EQ-5D_5L

Mobility
- ○ I have no problem in walking about
- ○ I have slight problems in walking about
- ○ I have moderate problems in walking about
- ○ I have severe problems in walking about
- ○ I am unable to walk about

Self care
- ○ I have no problems washing
- ○ I have slight problems washing or dressing myself
- ○ I have moderate problems washing or dressing myself
- ○ I have severe problems washing or dressing myself
- ○ I am unable to washing or dress myself

Usual activities
- ○ I have no problems doing my usual activities
- ○ I have slight problems doing my usual activities
- ○ I have moderate problems doing my usual activities
- ○ I have severe problems doing my usual activities
- ○ I am unable to do my usual activities

Pain / discomfort
- ○ I have no pain or discomfort
- ○ I have slight pain or discomfort
- ○ I have moderate pain or discomfort
- ○ I have severe pain or discomfort
- ○ I have extreme pain or discomfort

Anxiety / depression
- ○ I am not anxious or depressed
- ○ I am slightly anxious or depressed
- ○ I am moderately anxious or depressed
- ○ I am severely anxiously or depressed
- ○ I am extremely anxious or depressed

Your own health score today on a scale of 0 (worst imaginable health state) - 100 (best imaginable health state)

The British Association of Urological Surgeons

Female stress urinary incontinence surgery registry

Follow up dataset; Page 9; Version 1.2 (16 Jan 2017)

Unique patient identifier

Date of follow up dd / mm / yyyy

ICIQ-UI short form

How often do you leak urine

- ○ Never
- ○ About once a week or less often
- ○ Two or three times a week
- ○ About once a day
- ○ Several times a day
- ○ All the time

How much urine leaks

- ○ None
- ○ A small amount
- ○ A moderate amount
- ○ A large amount

How much does leaking urine interfere with your everyday life

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10

When does urine leak

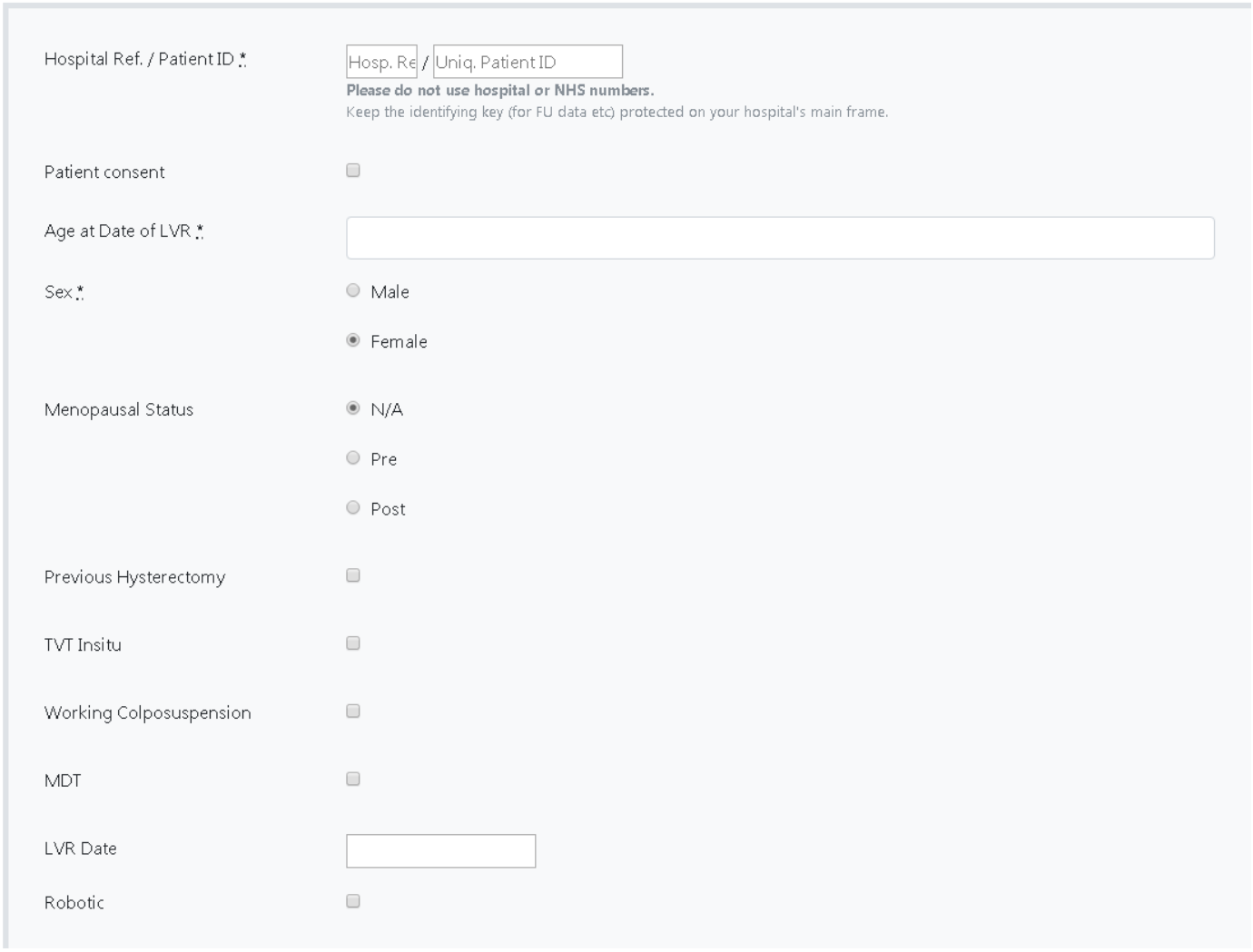
- ○ Never - urine does not leak
- ☐ Before you can go to the toilet
- ☐ When you cough / sneeze
- ☐ When you are asleep
- ☐ When you are physically active / exercising
- ☐ When you have finished urinating and are dressed
- ☐ For no obvious reason
- ☐ All the time

Patient satisfaction

Are you happy with the outcome of your surgery

- ○ Very satisfied
- ○ Satisfied
- ○ Neutral
- ○ Unsatisfied
- ○ Very unsatisfied

14 Appendix D: Current TPFS Dataset



Hospital Ref. / Patient ID *

Hosp. Re / Uniq. Patient ID

Please do not use hospital or NHS numbers.

Keep the identifying key (for FU data etc) protected on your hospital's main frame.

Patient consent

Age at Date of LVR *

Sex *

- Male
- Female

Menopausal Status

- N/A
- Pre
- Post

Previous Hysterectomy

TVT Insitu

Working Colposuspension

MDT

LVR Date

Robotic

Indication	☐ ODS
	☐ FI
	☐ Prolapse
	☐ SRUS
	☐ Pain
	☐ Middle Compartment Prolapse
Mesh Type Used	○ Polypropylene
	○ TiLoop
	○ Biodesign
	○ Permacol
	○ Strattice
	○ Dynamesh
	○ Other
Product Code	
Batch Code	
Suture Material 1	○ PDS
	○ Other

Fixation	○ Staples ○ Sutures
Sutured to Peri Utero Facial Ligaments	☐
Suture Material 2	○ PDS ○ V-Lock ○ QUIL ○ Other
Length of Stay	
Complications	
Readmission Date	
Readmission Reason	
Primary Outcome	○ Success ○ No Change ○ Deterioration
Last Seen Date	
Date of Symptom Relapse	

Revision Procedure	◉ None
	○ RAR
	○ STARR
	○ Haemorrhoidectomy
	○ Post-Rectopexy
	○ Redo LVMR
	○ SNS
	○ TVT
	○ Other
Revision Date	
Revision Outcome	○ Success
	○ No Change
	○ Deterioration
Mesh Complications	○ None
	○ Disattachment
	○ Vault Erosion
	○ Vaginal Erosion
	○ Vaginal Extrusion
	○ Rectal Erosion
	○ RV Fistula
	○ Rectal Stricture
	○ Rectal Extrusion
	○ Bladder Erosion
	○ Vaginal Pain
Complication Date	

Surgery for Complications	○ None
	○ Local Vaginal Surgery
	○ LAP Removal
	○ LAP Remove Mesh and re-do LVMR
	○ LVMR With Biologic
	○ Per-Rectal Removal
	○ Vaginal Removal
	○ Anterior Resection
	○ Colopouch
Complications - Date of Surgery	
Ongoing Problems	◉ None
	○ ODS
	○ FI
	○ SRUS
	○ Pain
	○ USI
	○ UUI

Recurrent Prolapse	○ External Prolapse
	○ Vault Prolapse
	○ Cystocele
Reccurence Date	
Reccurence Stoma	

15 Appendix E: Proposed BSUG Minimum Dataset

PROPOSED REVISED MINIMUM DATASET (HQIP 2018)

Suggested minimum data collection

Name of Patient

Date of Birth

NHS Number

PRE-OPERATIVE PREPARATION

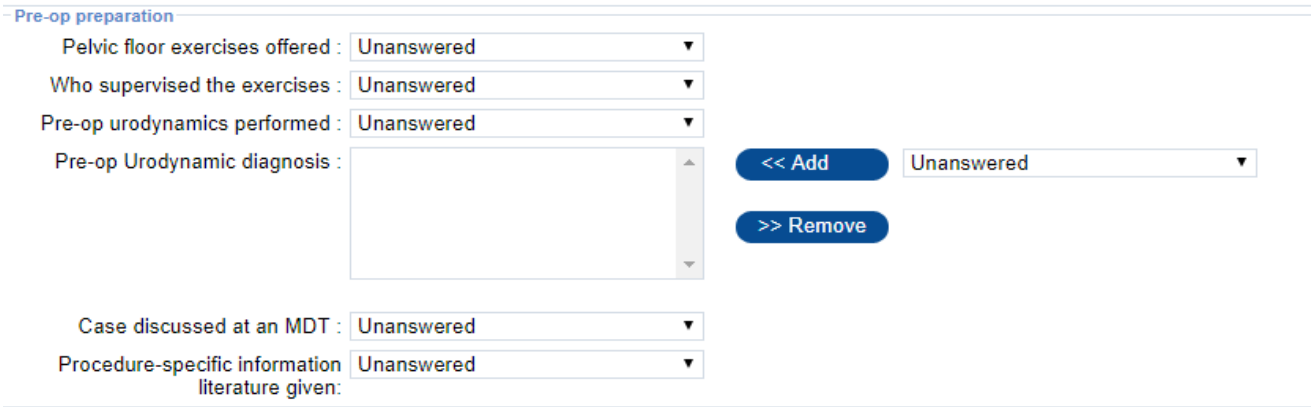
List of options could vary with type of procedure:

(e.g.) Incontinence, Vaginal / Uterine prolapse, Rectal prolapse, Obstructive defaecation

Need to record:

1) Indication for surgery (e.g.) Urinary incontinence, prolapse, dyspareunia / sexual dysfunction, bowel symptoms, etc
2) Discussion at MDT,
3) Agreed information provided (all the information below may not be necessary for interim database / registry)

Box could be a modified version of the below:



Baseline Questionnaires

Options: Epaq, ICIQ, EQ-5D_5L, EQ5D, UTI assessment,

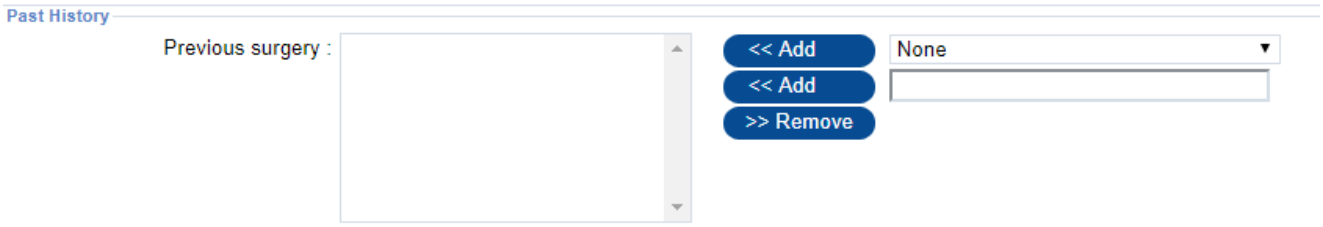
Sexual function questions: Already included in Epaq, ?PISQ – mainly used for research, Arizona Sexual Experience Scale (doesn't include dyspareunia)

Baseline vaginal / rectal / bladder / pelvic pain score:

May need to include details of patients Past Medical History which may affect outcome

Examples – Diabetes, Ehlors Danlos, Smoking, Steroid use etc, etc

Also need past surgical history:



SURGERY

List of different options: (Could also have a section for Mesh complication surgery)

1) **Retropubic Midurethral Tape (for incontinence)**
2) **Transobtrurator Mideurethral Tape (for incontinence)**
3) **Vaginal Mesh (for prolapse)**
4) **Sacrocolpopexy**
5) **Sacrohysteropexpy / sacrocervicopexy**
6) **Rectopexy**

Surgeon details including GMC number

Unit details

Mesh type

Suture type

Manufacturer **Product name** **Product Code**

Suggested Intraoperative Complications as below:

Some of the fields could be taken out or more could be added in

Surgery

Operation date : 10 10 2018

Main Incontinence surgery : Unanswered

Incontinence Surgery Type: Unanswered

Concomitant surgery :

<< Add None

<< Add

>> Remove

Concomitant Prolapse Graft Used : None

BMI Calcalculator (enter Height and Weight)

Height(m) : 0 Weight(Kg) : 0 BMI : 0

Anaesthetic/surgeon

Anaesthetic used : Unanswered

Senior surgeon present : Unanswered

Grade of operator : Unanswered

Intra-operative Graft Complication

Graft Complications : Unanswered

Intra-operative information

Make all 'No'

Ureteric injury : Unanswered

Bladder injury : Unanswered

Vaginal Button-holing : Unanswered

Urethral Injury: Unanswered

Bowel injury : Unanswered

Vascular injury : Unanswered

Neurological injury : Unanswered

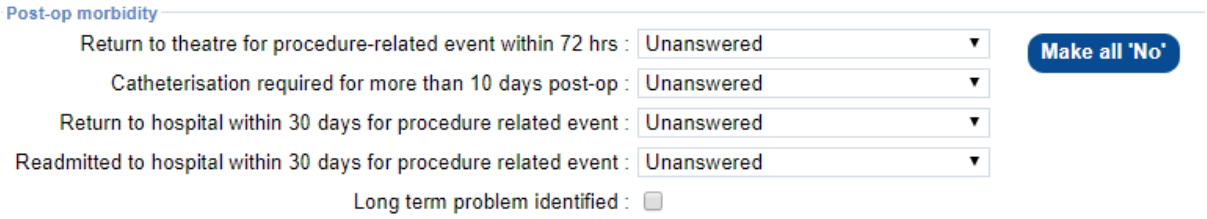
Blood loss > 500ml : Unanswered

Peri-operative blood transfusion : Unanswered

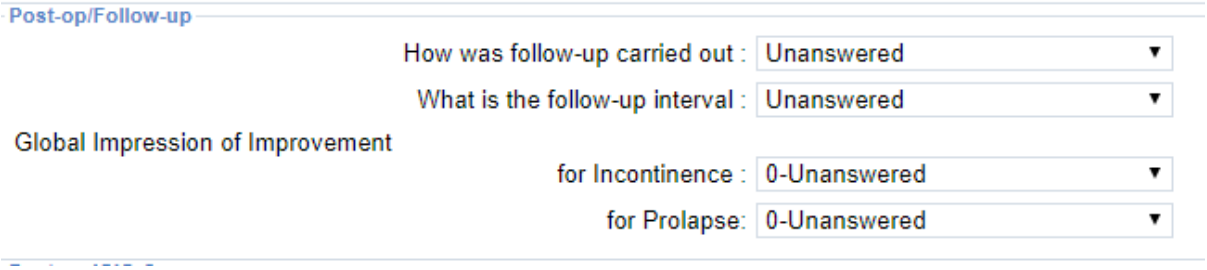
Peri-operative Thromboembolism : Unanswered

Death : Unanswered

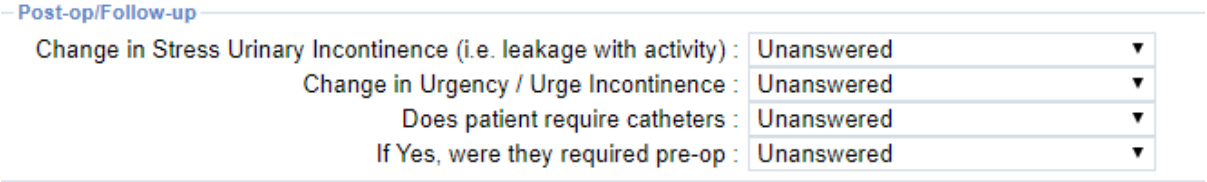
POST-OPERATIVE FOLLOW UP

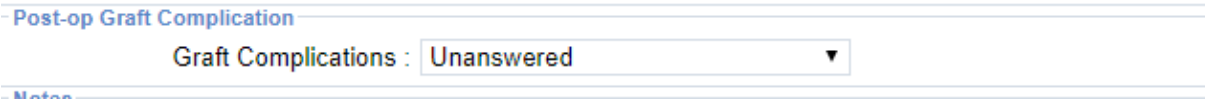


Need to record if planned re-admission (perhaps for trial without catheter) or emergency



Completion of required questions: ICIQ, Global Impression of improvement, Sexual function, UTI's, pain scores etc (to be agreed)





Detail regarding type of complication (e.g.) Erosion, Infection, Dyspareunia, etc

Record that the case has been reported to the MHRA

16 Appendix F: Minutes of Technical workshop

Tuesday 13th November, 13.00-17.00, Upper Hall, Bishopsgate Institute, 230 Bishopsgate, London, EC2M 4QH

1. Introduction, declarations of interest and background

KW thanked the group for the attending the meeting and introduced each of the stakeholders. KW outlined the purpose of the meeting and highlighted the intense political interest in this area. KW noted that the interest bought up opportunities for change and development in recording data in these areas especially around complications and outcomes. KW acknowledged there was a wide range of views in this area and vested interests which need to be accounted. KW thanked everyone for completing a declaration of interest prior to the meeting which have been reviewed.

The current situation is that a pause is in place, until March 2019, in the use of procedures utilising surgical mesh for prolapse and stress urinary incontinence. The purpose of this meeting was to try and identify what data needs to be collected from the established three databases in the interim, to establish a minimum dataset. KW emphasised the requirement for there to be an honest review of what is capable in the short term to satisfy scrutiny in this clinical area. KW emphasised that there must be a conclusion at this meeting about agreeing an interim position.

Summary of briefing paper, objectives of the meeting and timelines

SH explained the work that HQIP are commissioned to undertake on behalf of the Department of Health, which was a short feasibility study to look at the possibility of the interim data solution which would collect a minimum dataset and would produce a report in the interim period. It was explained that developing a registry would take 12 months to procure, 12 months for the registry to be set up and a further 12 months prior to producing outputs from the collected data. SH explained the objectives of the meeting and the work that has been carried out to date. It was highlighted that notes are being taken for internal use a high-level summary would be circulated to the attendees of the meeting in January/ February 2019.

Presentations by:
The British Society of Urogynaecology (BSUG)

AH provided a summary of the BSUG database which is hosted by the society which is registered as a charity. The database is run on the N3 network which requires a username and password. Both clinicians and units can review their individual and unit data to look at their own procedures in comparison to the national results. In the last three months, they have had 259 active users.

The main barriers to participation are that clinicians have to be on an N3 connection and the participation in the database in not mandated. It was highlighted that the participation rose significantly in 2013 when the data was mandated by HQIP to participate in the NHS England Clinicians Outcomes Programme (COP). There are additional barriers with participation in Scotland due to data sharing issues which need to be resolved. It was also highlighted that the database does not currently collect the NHS number; however, they can do in the future to allow for linkages and tracking the patient outcomes.

The database currently collects data on the following; incontinence, prolapse and mesh complications of surgery. The ICS/ IUGA complication details are recorded. This also directs patients to report directly to the yellow card system.

AH noted that from the three data recommendations following the review the database they met 2 of the recommendations:

- Recommendation 3- a register of operations is maintained to ensure every procedure is notified and the women identified, and the women identified who has undergone the surgery
- Recommendation 4- reporting of complication s via MHRA is linked to the register

The recommendation which is not met is the following:

- Recommendation 2-surgeons report every case to a national register

AH noted that they have proposed six procedures which should be included in the minimum dataset, it was also recommend that BSUG felt the interim data solution needed to capture the type of mesh, manufacturer and the code.

The chair thanked AH and BSUG and opened questions to the group. There was a query about whether the database was linked to scan for safety, it was confirmed that data was currently being manually entered by the clinicians.

There was also discussion about PROMs tools and it was noted that Professor Radley is leading on the electronical Personal Assessment Questionnaire (ePAQ) in Sheffield. It was queried whether these PROMs would be acceptable to the mesh patients and whether there was a viable PROM which could be incorporated into the interim solution which patients could have sight of to ensure the outcome data reflected their experience. BSUG confirmed that currently PROMs are clinician entered for clinician use to support appraisals and revalidation. BSUG do publish national results on their website. AH noted that there are questionnaires available for patients currently, and this could be updated to what was agreed more appropriate tools. SM highlighted that following the interviews with the mesh patients, it was clear that the questionnaires for incontinence were not appropriate for the additional complications they experienced. There was discussion about the information governance restrictions would need to be managed if patient were to access their data and the ensuring trusts Caldecott Guardians were aware of patients accessing data.

DK highlighted mandating audits would be the responsibility of the medical director at a trust level to ensure the data is captured per consultant who is operating within the trust.

There was discussion about the benefit of collecting patient identifiable data in being able to link data to third party data sources; this would also provide assurance about all cases being captured as HES data could be used for case ascertainment. It was noted that HES was England only and alternative models would have to be examined to ensure case ascertainment for the devolved nations. AW mentioned Surgical Workload Outcomes Audit Database (SWORD) producing aggregated numbers of procedures; however, there is less value to the patients and public the data not being available on a more granular basis.

The British Association of Urological Surgeons (BAUS)

CH provided a summary of the BAUS database; he noted that they are currently developing their strategic plan up to 2020 to drive forward quality improvement. It was highlight that the BAUS database was more procedure based and focused on clinical questions for stress urinary incontinence and covered both primary procedures and redo procedures, which was around an 80/20 spilt. It was explained that this database is open to anyone and was originally set up for revalidation purposes and is open to members of the society and 95% of UK urologists were members of BAUS.

The dataset for PROMs is concise, however, it was broad and covered the following; pain, ability to carry out household tasks. It was highlighted, BAUS were conscious the tool did not cover sexual function and it is been highlighted by patient groups that it is of high importance for this to be captured.

Participation and engagement within the independent sector has been attempted but has been challenging due clinical coding. It was also highlighted another challenge has been capturing the data for the follow up which is around 40%. It was noted that it was felt that the follow up collected by BAUS was not long enough, currently it was

being collected at 3- and 6-months post procedure. It was been highlighted that complication can occur years post the procedure. It was noted that the upcoming NICE guidelines recommended a minimum of a five year follow up.

CH highlighted some additional challenges such as the patient community losing the trust of the surgeons and not satisfied with surgeon entered data on the database. It was emphasised that the entry to the database needs to be mandated. It was also suggested that there are external validations to provide assurance the data that are entered is accurate.

It was summarised what BAUS suggestions would be ongoing forwards; there was agreement they also wanted the data collection to be mandated. It was also suggested that it should be externally inputted by a data manager within the trust. They recommended that comparator data would also be captured in addition to mesh surgery. It was highlighted the follow up period needed to be increased to capture data about the operations success and complication rates. It was also highlighted that it was required to include data about mesh salvage surgery and the success and complication rates. It was recognised that linkage to 3rd party data sources are important to ensure all cases are captured.

It was also noted that the funding model would need to be examined as a lot of this work is currently being carried out voluntarily and it needed a sustainable funding model.

The chair thanked CH and BAUS and opened questions to the group. It was asked how problematic it would be for BAUS to open up the database to non-members such as specialist nurses to input the data, CH confirmed this was feasible.

There was discussion about the follow up period and acknowledging the 5-year minimum which will be recommended by NICE and to ensure patients who have successful procedures are also captured and entered onto the database. It was recognised that the typical response rate was 30% if just contacted by email and response is increased if the patient is phone, emailed and then phone again if necessary. It was also noted that there are a shortage of clinical nurse specialists and recommendations about workforce need to be cognizant of the staffing model in place within trusts that are performing the operations and the workforce is less resourced than other areas, i.e. cancer care.

It was noted that identifying patients to measure successful outcomes would be problematic due to them not being seen in an outpatient clinic.

There was discussion about capturing comparators for mesh and being able to also track these surrogate makers both with their clinical and patient outcomes. It was highlighted there was no evidence base for alternative procedures so felt it was important for this to be captured.

The Pelvic Floor Society (TPFS)

AW provided a summary of the database which collects data on rectopexy procedures. They are a newly established group and are a sub group under The Pelvic Floor Society, this was a member only group which is funded by industry. The clinicians directly enter onto the database and do not link to other datasets. It was noted they do not have the legal basis to collect patient identifiable data. It was highlighted that certain types of surgery are under review in a national study and the recommendations are in the public domain. It has been suggested that one method of repair cannot be concluded to be more effective than another method.

It was noted like the other societies they would recommend that data entry should be mandated and the patient identifiable data must be collected. The current position is the data is variable and not fit for purpose to robust report efficiency or outcome and there is a risk that the data are not accurate. It was also mentioned it would be of great benefit for there to be a pelvic floor service established to have oversight of the patient pathway and to be able to effectively capture patients who would be applicable to be entered on the database.

AW highlighted they feel it would be of benefit to be able to track the different types of mesh, there is concern that certain materials are more effective than others, i.e. polyester is felt to have an increased risk of complications. It was felt that it would be of value to be able to be able to track the complications to the yellow card system to ensure all complications are captured in the database.

It was mentioned that from their perspective PROM data would be of benefit having something simplistic to encourage participation such as the following; success no change, some deterioration and ongoing problem. It was noted that TPFS are working with Oxford University about developing PROMs which will be app based, the Pelvic Floor Society are considering purchasing this software. It was felt that this will allow patients to enter their own data and to be updated multiple times with different symptoms. An app-based solution would allow patients to trust and control their data; it was also felt that a lot of people are phone literate so the take up would be high.

It was noted that the trust was lost for the society due to the issues with one consultant, who is no longer operating, however, work has had to be done to disassociate with this consultant and rebuild trust.

It was highlighted that due to the requirements for robust information governance; there would need to be expertise and support provided to the society to help them meet the requirements in being able to collect patient identifiable data.

KW thanked AW and opened up the questions to the group. CH asked whether during the review there were many patients reporting complications following ventral mesh rectopexy and whether this group are being represented from a patient perspective. SM responded by highlighting the review was open to all patients affected and they were not able to control who came forward.

There was also discussion about ensuring the independence of the database; it was acknowledged that the issues around mesh might expand to other areas such as hernia. The funding of the database was discussed, and DK noted that the National Joint Registry (NJR) are funded by industry and risks around lack of trust are mitigated by having a robust governance system in place to ensure there is confidence in independent oversight of the NJR.

It was strongly recommended that the type of mesh needed to be recorded on the database to be able to track, as multiple types are being used for the different procedures. It was suggested that the following things are also recorded; mesh serial number, batch number and the type of product. There was discussion about there being no evidence base for which type of mesh is the most effective. It was noted that some believe collagen mesh is the most effective; however, there is no evidence to support this. It was also noted that different surgeons have different techniques which may be a factor in contributing to the success of a procedure.

There was discussion about whether Scan 4 Safety would be able to support the database and flow device details which should be recorded by this initiative. SG highlighted that currently there is no known roll out date, so could not be able to be utilised for the interim database. DM highlighted that from 2024 it would become mandatory for every device to have a unique identifier, however, whether this will be able to be scanned in hospitals is unknown. KW advised that the new NICE guidelines would recommend a patient is provided with details of which device was used for their procedure.

KW provided a summary of the conversations so far in the meeting and reminded that the purpose of the meeting was to come to a decision about setting up an interim database following the recommendations from the review. The minimum dataset will need to be currently provided by the current three databases in place which would be hosted by an independent organisation to provide assurance of the data. It was agreed that funding would need to be in place and there would be information governance requirements which would need to be met to ensure patient identifiable data is collected. There was also agreement that comparators in addition to mesh would need to be collected. It was recommended that extracts from the databases are taken in the interim and there needed to be agreement on what the minimum dataset would include and the comparators. There would also need to suggestions about the more effective and feasible way to share this with patients.

It was summarised the following information would need to include the following:

- Patient identifiable data
- Pre-operative information
- Type of surgery
- Type of device
- Name of hospital where the performed was undertaken
- PROMs

AW highlighted that ventral mesh rectopexy procedure should be included. SJ noted that there are four main alternatives to prolapse surgery and AC stated he felt there are three alternatives for incontinence. It was highlighted that the balance of inclusion of a lot of procedures rather than focusing on the core concerns for the interim solution. It was suggested that a patient perspective should be considered in what procedures they wanted to know the outcomes and complications for.

There was discussion about linking to other data such as the MHRA yellow card system, DM noted that the data from the yellow card cannot be shared with a database without consent from any identifiable element due to legislation restrictions. There was discussion about the impact of this for pause recommendation four. It was agreed the review team and the MHRA would discuss this further outside of the meeting.

It was also agreed a follow up meeting was required with NHS Digital.

What are the data and reporting requirements of key stakeholders (including NHS England, Department of Health, NHS Improvement, and Devolved Nations, MHRA, NICE, PHIN, hospital providers and clinical groups)?
KW opened up the discussion about what each stakeholder would require from the outputs in the next 2 to 3 years from the interim database. DM answered from an MHRA perspective they would require it by device type. AC stated from a CAG perspective it would be helpful to have a report on the operation type and to understand what the rate of complications per procedure would be. There was agreement about this from CH and AW who mentioned that it would be useful for clinicians to see what the complication rates for certain procedures are for mesh surgery and the alternatives. It was also noted that case ascertainment data would be helpful to ensure clinicians are recording the data for all the procedures they are performing.

TOK mentioned from a governmental perspective it would be helpful to have data over time to be able to identify trends and to see what procedures are safe. SM mentioned it would be helpful to capture if patients have had previous procedures. HP highlighted the importance of having clear objectives for any database that encompass the clinical priorities, to ensure that only data which answers the objectives are collected.

There was further discussion about the PROMs data and it was highlighted that sexual function and pain must be collected within the PROMs. It was discussed whether the complications data are collected currently via the MHRA yellow card system, DM suggested that the rate of complications reported are around 10% and the data recorded are qualitative and they do not have the legal basis to share this data with other organisations. It was suggested that for the long term registry this could be examined to try and utilise the data captured by MHRA. There was general consensus that data from industry would be useful to capture to ensure transparency and all parties have shared access to the data to ensure safety and to improve quality.

It was discussed what would be feasible for follow up and the frequency of the reports. It was noted that 94% of patients are not readmitted back to hospital as an inpatient, so complications are known when they attend a clinic such as a pain clinic which the performing clinician may not be aware of, this again emphasised the need to collect NHS number to be able to identify which other services the patient has attended. There was wider discussion about whether it should be an annual follow up, there were concerns about how patients would be followed up as attendance to a clinic for up to five years would not be practical with the current infrastructure of services. It was

suggested trying to align it with other women's health initiatives such as a mammogram or cervical smear test. It was also noted that this would result in a significant number of patients to follow up and whether detailed data needed to be captured for patients who experienced complications rather than the whole cohort of patients who had the procedure.

TOK suggested widening the databases to the multidisciplinary team (MDT) so other staff members can enter data such as specialist nurses, the group welcomed this idea, however, mentioned that the reality is there is not always an MDT team in place and there are a limited number of hospitals which have a specialist nurse post. It was queried what minimum number of procedures clinicians should be undertaking, it was generally agreed that this should be a minimum of 20 procedures per year. KW noted that the upcoming NICE guidelines provide no recommendation for the number of procedures and it will be to the discretion of the hospital. It was added that there is further complexity as some of the procedures are commissioned under specialist commissioning, which is current under consultation, though this only affects England.

Minimum mesh dataset, consensus to be reached

The societies were in general agreement the BSUG suggestion would be suitable for the interim database for the clinical data. It was recommended the outcome data from patients required additional work, it was confirmed that BSUG would welcome working with patients to adapt their outcome tools to ensure the correct information was being captured.

It was queried whether patients would be able to change submitted outcome data if they did not agree with the clinician's decision. This led to the discussion about the importance of ensuring the PROM used was a validated tool, it also needed to ensure it covered all patient groups and the complexity this would pose to ensure streamlining. It was felt the specialist societies needed the opportunity to review and comment upon what PROMs tools are to be used. It was also felt that funding to ensure good outcome data was factored into the interim database and the future registry, to ensure the data are captured and complete.

AW suggested that all mesh operations should be included, and the PROMs should filter down into the appropriate tool and should ask simplistic questions to ensure completion, such as would you have it again and would you recommend it to a family or friend. KW confirmed that the new NICE guidelines would also recommend data about mesh removals should be captured.

SM mentioned that from the information gathered for the reviews the common concerns from patients were the following; recurrent urinary infections, antibiotic resistance and fear of sepsis, impact on sexual function. It was agreed that any proposed tools would be taken to the Stakeholder Workshop on the 28th November for discussion.

The legal basis was discussed, and the group suggested it should be based on a consent model rather than s251, it was felt by the societies that HQIP should support this to ensure a coordinated approach between the societies as they do not currently have the funding to put this in place.

Summary and close

It was felt that NHS Digital should hold the data for the interim database and further discussions were required to determine the logistics of the current three databases sending them extracts of data. It was noted, NHS Digital was an England only organisation, so a compromise may be required for the devolved nations.

It was agreed that the interim database should have an independent governance model to ensure independence and transparency which should also have patient representatives.

There was agreement that the long-term registry should have one database for all procedures and comparators which would also capture the patients who sought treatment from independent providers.

KW thanked everyone and closed the meeting.

17 Appendix G: Minutes of Stakeholder Workshop

Wednesday 28th November, 13.00-17.00, The Wesley Hotel Euston, 81-103 Euston Street, London NW1 2EZ

1. Introduction, declarations of interest and objectives

AL thanked the group for attending the meeting and explained the background to the meeting and that the purpose was explore the outcomes important for patients to be captured for either an interim data solution and a longer term registry.

AL went around the group and invited each individual to share what their interests were in the area of urogynaecological mesh and what they wanted to achieve from the meeting. The responses from the group were the following; ensuring outcomes are captured from a physiotherapy perspective, to ensure data is collected to enable reporting on safety and efficiency of mesh procedures, to assist the development of a tool for patients and clinicians to support decisions of which treatments to offer and choose. Some of the group highlighted the previous work they have done in this area, such as development if guidelines on a global basis, national reviews, development of a care pathways (such as a pelvic wellbeing in Wales which encompasses stress urinary incontinence (SUI) and pelvic organ prolapse (POP)). There was agreement from the group that a main aim of the meeting would be to recommend a viable way to measure and capture outcomes and complications. The importance of capturing other relevant co-morbidities and past medical history was highlighted, for instance patients with fibroids are more likely to develop SUI. The significant impact of mesh related complications was emphasised, for instance it was stated that 7/10 women are no longer able to have intercourse and 53% of patients with complications will have a divorce. It was also noted that representatives from women's groups felt that partial mesh removal should not be an option. There was acknowledgment that women have lost trust in the healthcare system which needed to be rebuilt.

2. Background, timelines and summary of exploratory work undertaken so far

SH explained the work that HQIP are commissioned to undertake on behalf of the Department of Health, which was a short feasibility study to look at the possibility of establishing an interim database which would collect a minimum dataset and would produce a report in the interim period. It was explained that developing a registry would take 12 months to procure, 12 months for the registry to be set up and a further 12 months prior to producing outputs from the collected data. SH explained the objectives of the meeting and the work that has been carried out to date. It was highlighted that notes are being taken for internal use and summary feedback would be circulated to attendees of the meeting in January/ February 2019.

SH invited the group to ask questions, it was queried whether the database would just collect data for SUI and POP or whether there would be comparators included. SH responded that there was agreement at the technical workshop that it should include comparator procedures, the group agreed with this recommendation. There was a question about whether rectopexy procedures would be collected and the issue of this not being coded. It was clarified that the cases are identified by the clinician entering the data but The Pelvic Floor Society (TPFS) database which covers rectopexy procedures does not link to NHS Digitals HES data to check case ascertainment. It was also raised that not all current three databases collect patient identifiable data which enables them to link with other data sources and follow patients however the recommendation would be this information is captured both in the interim database and the full registry. It was stated by the patient groups they do not have confidence in the three current society run databases, it was felt that a limited amount of patient information is currently captured, i.e.

BSUG are reporting on around 30% of all eligible cases, and they felt the interim database should be hosted by an independent organisation. It was felt that the low participation was due to it not being mandated and being reliant on the goodwill of the clinician to enter this data.

3. Summary of the technical workshop discussions

KW provided a summary of the Technical Workshop held on the 13 November 2018 and the stakeholders who attended this meeting. KW highlighted that there were discussions about where the data would be held, and it was suggested that NHS Digital could store the data provided from the databases in the interim and potentially link to the coded HES data which would provide case ascertainment information. It was noted that this could be an interim solution until a full registry was commissioned. KW explained the challenges of the current three databases; there is no mandate for clinicians to enter data, clinicians who do enter data are doing so solely based on goodwill and the databases have limited funding and are largely based on subscriptions paid to the societies as part of their membership. It is anticipated to have the interim database in place by spring 2019. In parallel would run the process to independently commission and develop the specification for a registry. KW emphasised, that there was a requirement from the Independent Medicine and Medical Devices Safety review to have a database to fulfil three of their recommendations, so the pause can be lifted from April 2019. KW noted that during the technical workshop there was general agreement about what the minimum dataset should contain, and the workshop today would be able to influence and recommend what outcomes should be collected for the interim database.

KW highlighted some of the complexities which were raised at the technical workshop about collecting outcome data, such as at what point are patients followed up and whether this could be aligned to other women's health initiatives such as mammograms and/ or cervical screening. The ability for patients to enter their own data was discussed at the technical workshop, it was a strong aspiration for the full registry, but it was felt that it would not be feasible for the interim database.

It was queried how the data would be transferred to the independent host organisation, KW responded that it would be a secure data extract. It was noted that if NHS Digital were the host organisation then there would be the potential to also link to HES data.

There was a query as to whether the clinicians would have to enter the data to the current database and then the interim database, it was confirmed clinicians would have to enter the data once. It was again highlighted that clinicians need to be mandated to enter data, as currently the case ascertainment is variable.

There was a discussion about the full registry and it was confirmed it would go through an independent procurement process via EU procurement requirements. KW outlined the procurement process HQIP runs by inviting key stakeholders to a specification meeting, HQIP then develop a specification which is put out to market for all potential bidders. It was noted that HQIP commissioned projects are required to publish reports with process and outcome data to the public. KW also mentioned some of the projects having dependencies such as best practice tariff to drive improvements in care.

It was highlighted that it was important to understand what data items should to be collected for patient follow up, initial thoughts from the group to include chronic pain and low-grade infections. It was also highlighted how important patient identifiable data would be to ensure patients are tracked and multiple procedures are reported.

4. Discuss symptoms, complications, outcomes and adverse events that are important to patients

There was discussion about what was important to collect whilst being mindful that the larger the database the harder to ensure data quality and completeness. TOK mentioned that from a governmental perspective it would be helpful to understand the variations in care and what might pose a patient safety concern and whether some surgeons and hospitals have better outcomes.
BY emphasised that following her work with patients, it is crucial to capture pre and post procedure information to understand how symptoms have changed and having data which captures why the mesh was inserted, i.e. whether it inserted to treat incontinence or following a hysteroscopy.

Following a conversation with patients, it was noted that the following are reoccurring themes of importance to them:

- Pain
- Loss of sexual life/ dyspareunia
- Urinary tract infections
- Erosion of mesh
- Antibiotic resistance which affects 8% of women

It was also highlighted that using terminology that could be understood by patients would be recommended, it was noted that terms like dyspareunia are not always accessible to patients unless they are very informed.

There was discussion about the symptoms which need to be captured. It was mentioned that the level of pain needs to be differentiated and where the pain is located, such as in the leg, and whether it was chronic, heavy, grinding and how much of the leg was affected, buttock pain, calf pain, nerve damage pain, vaginal pain and whether this was a slicing, burning and/ or stabbing sensation. There was also experience of hip pain and lower back pain. It was noted that some of these symptoms may occur instantly or might be delayed and therefore not necessarily associated with the procedure due to the time lag in experiencing these symptoms.

The group discussed whether there was a validated outcome measure which would pick up these complex outcomes, it was noted that the societies have provided their thoughts about which outcomes tools could be used.

The tools proposed by the societies which were tabled for the meeting were discussed.

- EQ-5D_5L
- ICIQ-UI
- (PGI-I) Global Impression of improvement
- EPAQ-PF (pelvic floor)
- UTI symptoms assessment Questionnaire
  Arizona Sexual Experiences Scale

It was noted that the ICIQ tool has been suggested by NICE for incontinence, however, it was felt this does not cover all the issues. The PG-I tool has been noted as being good from a patient perspective but has been said to be vague and unspecific and does not capture organ damage. There was discussion the tool needed to capture information about being able to perform physical activities. It was noted that the PISQ tool has been validated for sexual function and is not too onerous to complete. It was mentioned that the EQ-5D-5L has been based on health economics. It was noted that the ICIQ-UI was derived by patients.

It was highlighted that the tool need not be related to the original condition, i.e. the tool chosen for sexual function does not need to capture whether the symptoms of incontinence are improved. It was also emphasised that the tool needed to be sensitive to the nature of the complications patients report and needed to capture how severe and

debilitating the pain can be. It was also noted that the validated tools do not capture the impact of having recurrent UTI's for several days. It was also felt important to know whether the mesh had eroded but that could only be reported by a clinician.

It was suggested whether tools which capture pain score for other conditions, such as endometrioses, could be used. There was discussion on the importance of being able to collect robust outcome data using validated PROMS to enable reporting on outcome data for devices and the clinical indication for procedure. It was mentioned that the Scan 4 Safety would eventually be able to link to the register, so this information would be collected by this mechanism in time.

There was the suggestion that a bespoke tool would be more appropriate due the nature of what needs to be captured, which was felt could be worthwhile, however, would take a minimum of four years prior to being validated. It was felt that for the interim database, something needs to be in place to provide assurance and more sophisticated tools can be developed and incorporated into the full registry.

It was also mentioned that the outcome tools would also need to be relevant to the comparator (non-mesh) procedures captured by the interim database and whether a more simplistic tool was required which collected data about pain, impact on life, sexual function, incontinence and mesh erosion. It was also suggested if complications were identified then a more drilled down tool would then be used. The interim can be used to get an understanding of whether it is capturing meaningful data.

There was also discussion on the following outcome data being helpful to be captured; over active bladder, obstructive and whether the mesh entered the bladder, vaginal pain, bladder pain, abscess, foreign bodies, sensitivity and small bowel injuries. It was suggested more than one outcome needs to be captured.

There was discussion about whether the tool needed to be validated and it was felt that it would be more effective using a validated tool which was comprehensive. There was discussion about the burden to the patient to complete and to ensure data is captured and was not too time consuming.

5. Discussion of practicalities and possible solutions for other key areas, including:

- **Patient follow up**
- **Patient involvement and project governance**

It was raised about the practicalities of when and how to capture this information, currently the three databases are collecting the data at approx. 3- and 6-months post procedure only. It was highlighted that NICE will recommend this should to be a minimum of a five year follow up. It was also raised about the issues of some patients then seeking care from the independent sector when experiencing complications. It was mentioned that follow up data could be aligned with other women's health care initiatives such as mammograms and cervical screening. It was suggested that the patient could be emailed details at the time of procedure; with information such as the consent form, information about the procedure and any information they need to be aware of following the procedure. It was felt that they could then be emailed for follow up information in the future. It was mentioned that there are current information governance restrictions about sharing NHS and independent sector data. It was highlighted that Scotland do not the details of private patients, CC who works with PHIN said he would follow up on this.

There was discussion about the workforce require to ensure good follow up and whether any administrative support is needed to ensure this is rolled out, patients receive any information in a timely manner and to deal with queries. It was felt that the information needed to be sent electronically as people are more likely to retain the information.

It was suggested that a trigger could be set up on the system linked to prescriptions, patients would not be able to receive prescriptions unless they complete their outcome data. Another suggestion was a text message from the GP prompting a response. It was felt both positive and negative outcomes need to be captured. It was suggested, due to the nature of the data to be collected, this needed to be co designed with the patients to see how they feel they would be more likely to complete the outcome tools. There was a suggestion about the PROM being linked with research grants to roll this out. It was commented that it needed to be clear whether this data would be routine clinical follow up and evaluation or research.

It was highlighted that there needs to be consideration of what happens if patients report complications to the database or registry and whose responsibility it is to follow this up, it was felt that it might be isolating for patients to report complications and negative outcomes and not be contacted by a healthcare professional. There was a query about how long the data will be held for and tracked, there are some stories of women not realising they had mesh related complications until a number of years later. It was also highlighted the cohort of patients is very large and this would need to be managed appropriately or whether it would need to be sampled. There was a suggestion of whether it would be a year follow up and then approached if there was a certain trigger to contact them again, the limitations of being contacted out of the blue was also discussed. It was highlighted the National Joint Registry follow methodology could be explored.

It was felt that the outcomes for every procedure should be captured. There was the discussion about using the operating notes to provide information of the procedure to the patient. The challenges of time and resources were spoken about which might restrict this from working. It was also mentioned about the variability in hospital systems and the coding for these procedures needed to be simplified to ensure accuracy. TOK mentioned something similar is being trialled in Scotland and whether a checklist of information provided to a patient could be recommended.

6. Summary and Close

AL summarised the main part of the discussion, SH noted that she would work up some suggestions following conversation with the societies and circulate this to the group. AL thanked everyone and closed the meeting.

18 Appendix H: Current MHRA Manufacturer Vigilance Report

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA)	Stamp box
Address of National Competent Authority	
Date of this report	
Reference number assigned by the manufacturer	
Reference number assigned by NCA	

Type of report

- ○ Initial report
- ○ Follow-up report
- ○ Combined initial and final report
- ○ Final report

Does the incident represent a serious public health threat?

- ○ yes
- ○ no

Classification of incident

- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ○ All other reportable incidents

Identify to what other NCA's this report was also sent

2 Information on submitter of the report

Status of submitter

- ○ Manufacturer
- ○ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information	new

Name	
Contact Name	
Address	
Postcode	City
Phone	Fax
E-mail	Country
	AT - Austria

4 Authorised Representative Information	new

Name	
Contact Name	
Address	
Postcode	City
Phone	Fax
E-mail	Country
	AT - Austria

5 Submitter's information	new

Name	
Contact Name	
Address	
Postcode	City
Phone	Fax
E-mail	Country
	AT - Austria

6 Medical device information | new

Class

- AIMD Active implants
- MDD Class III
- MDD Class IIb
- MDD Class IIa
- MDD Class I
- IVD Annex II List A
- IVD Annex II List B
- IVD Devices for self-testing
- IVD General

Nomenclature system (preferable GMDN)	Nomenclature code
GMDN	

Nomenclature text

Commercial name/ brand name / make

Model number	Catalogue number

Serial number(s) (if applicable)	Lot/batch number(s) (if applicable)

Software version number (if applicable)

Device Mfr Date	Expiry date

Implant date (For implants only)	Explant date (For implants only)

Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)

Accessories / associated devices (if applicable)

Notified Body (NB) ID-number

7 Incident Information

Date the incident occurred

Incident description narrative

User facility report reference number, if applicable

Manufacturer's awareness date

Number of patients involved (if known)	Number of medical devices involved (if known)
0	1

Medical device current location/disposition (if known)

Operator of the medical device at the time of incident (select one)
◯ Healthcare Professional ◯ Patient ◯ Other
Usage of the medical device (select from list below)
◯ initial use ◯ reuse of a single use medical device ◯ reuse of a reusable medical device ◯ re-serviced/refurbished ◯ other ◯ problem noted prior use

8 Patient information		
Patient outcome		
Remedial action taken by the healthcare facility relevant to the care of the patient		
Gender, if applicable ◯ Female ◯ Male		
Age of the patient at the time of incident, if applicable	**units** ◯ Years ◯ months ◯ days	
Weight in kilograms, if applicable		

9 Healthcare facility information	new

Name of the healthcare facility	
Contact person within the facility	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country** AT - Austria

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

Initial corrective actions/preventive actions implemented by the manufacturer

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

Remedial action/corrective action/preventive action / Field Safety Corrective Action

Time schedule for the implementation of the identified actions

Final comments from the manufacturer

Further investigations

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

○ Yes ○ No

Number of similar incidents

0

If yes, state in which countries and the report reference numbers of the incidents.

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

☐ AT	☐ BE	☐ BG	☐ CH	☐ CY	☐ CZ	☐ DE	☐ DK
☐ EE	☐ ES	☐ FI	☐ FR	☐ GB	☐ GR	☐ HU	☐ IE
☐ IS	☐ IT	☐ LI	☐ LT	☐ LU	☐ LV	☐ MT	☐ NL
☐ NO	☐ PL	☐ PT	☐ RO	☐ SE	☐ SI	☐ SK	☐ TR

Candidate Countries

☐ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

12 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

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