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Introduction

In 2018 the Scottish Government requested that Healthcare Improvement Scotland establish and support an independent multidisciplinary group to monitor the use of transvaginal mesh implants in Scotland. The overall aim of the Transvaginal Mesh Implants Oversight (TVMO) group is to provide a monitoring role to NHSScotland until a clinical network has been established. The TVMO group was set up with the remit to:

- review data on the use of transvaginal mesh implants in NHSScotland
- review adverse event reporting by NHS boards to Incident Reporting and Investigation Centre (IRIC) and Medicines and Healthcare Products Regulatory Agency (MHRA)
- consider how significant new evidence, since the independent review of transvaginal mesh implants, can be incorporated into the agreed NHSScotland pathways of care, and
- ensure that any patient information is up to date and appropriate.

See Appendix 1 for group membership.

The TVMO group was also tasked with developing and issuing a self-evaluation tool (SET) to NHS boards to assess transvaginal mesh implants services and practice.

In September 2018 a halt was called to the use of transvaginal mesh implants in Scotland which resulted in a reduction of the number of mesh procedures. The Scottish Government has established an accountable officers group to look at mesh complications and removal.

In winter 2018/19, the TVMO group developed the SET which was piloted with two NHS boards. All 14 NHS boards in Scotland were asked to complete the SET in spring 2019. This report discusses the TVMO group’s evaluation of the use of transvaginal mesh implants in the 13 NHS boards who completed the SET. All 14 territorial NHS boards received the SET. Submissions were received from 13 NHS boards. NHS Western Isles did not submit a return, due to small case numbers, and is not included in this report.

The report includes information about the quality of care of people at individual NHS board and regional level. The report recognises areas of good or innovative practice within NHS boards and captures challenges and barriers which may inhibit improvement.

The purpose of this report is to provide each NHS board’s accountable officer with a regional overview of stress urinary incontinence (SUI)/pelvic organ prolapse (POP) services.

See Appendix 2 for glossary of terms.
Summary of Findings

13 of the 14 NHS boards returned a completed SET to the TVMO group.

The main observations from the completed SETs are:

- 10 out of 13 NHS boards outlined their key outcome measures which included patient satisfaction, adverse events and waiting times.

- All 13 NHS boards are carrying out work to implement the 2019 National Institute for Health and Care Excellence (NICE) guidance on the management of urinary incontinence and pelvic organ prolapse in women. Further work will be required to ensure there is consistency in approach across Scotland.

- There is variance in the development and implementation of pathways of care with some NHS boards reporting more progress than others.

- There was no direct involvement of patients in pathway development.

- All NHS boards reported a clear consent process with patients and their families. NHS boards also reported that they provided patients with sufficient time to process the information before making a decision about their care.

- All NHS boards obtain consent at a separate appointment scheduled after information is shared.

- Each NHS board has clear mechanisms for patients to provide feedback. The methods used ranged from information on specific websites to feedback cards in patient waiting areas.

- All NHS boards reported using national patient information, including information provided by the British Society of Urogynaecology (BSUG) and the British Association of Urological Surgeons (BAUS).

- The majority of NHS boards reported adverse events on Datix (the national IT system used for clinical and non-clinical incident reporting).

- Every NHS board has mechanisms in place for staff training and development, for example, appraisal, education days and conferences and buddy training.
Review Methodology

The TVMO group developed and issued a SET to NHS boards to establish a clear picture of the SUI and POP services within NHS Scotland.

The TVMO group adopted Healthcare Improvement Scotland’s Quality of Care approach (QoCA) to review SUI and POP services in Scotland.

Quality of care approach

Healthcare Improvement Scotland has developed an approach to assess the quality of care of healthcare services in Scotland. The approach aims to shift the focus from quality assurance of services being done ‘to’ organisations, to an approach that, where possible, quality assurance and any resultant intervention is done ‘with’ them. The emphasis is on regular, open and honest organisational self-evaluation using a common and shared quality framework.

Self-evaluation is a process where organisations and services reflect on their own practice. This encourages teams to identify areas where action can drive improvement in service delivery and ultimately, in outcomes for users of their services. Quality improvement on the basis of self-evaluation can result in greater local ownership of issues and design of more effective solutions than those solely mandated by external agencies. Robust self-evaluations are combined with other data and intelligence available from publically available papers, reports and nationally held datasets. This then forms the basis of supportive improvement-focused review work to diagnose where there are issues or difficulties in initiating, sustaining and spreading improvement within organisations.

The relevant domains from the quality of care framework were:

• Domain 1 – Key Organisational Outcomes.
• Domain 2 – Impact on people experiencing care, carers and families.
• Domain 5 – Delivery of safe, effective, compassionate and person-centred care.
• Domain 7 – Workforce management and support.

Table 1, below, sets out the four domains, with each respective quality indicator. The TVMO group were looking for specific examples of evidence and outcomes for each indicator. Examples of these are also detailed in Table 1.
Table 1: Map of Quality of Care Domain, Indicators and TVMO SET evidence/outcomes

### Domain 1: Key organisational outcomes

To meet the quality indicator, the TVMO group wanted to see evidence that NHS boards were considering data regularly and using this to plan for improvement in a timely way. They also wanted assurance that the NHS boards were adhering to national and statutory duties and guidelines.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Examples of evidence/outcomes for each domain included:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Improvements in quality, outcomes and impact</td>
<td>• NHS boards’ collection, review and reporting of data including the development of action plans for improvement</td>
</tr>
<tr>
<td>1.2 Fulfilment of statutory duties and adherence to national guidelines</td>
<td>• NHS boards’ adherence to national and statutory duties and guidelines, in order to fulfil its local, regional and national functions.</td>
</tr>
</tbody>
</table>

### Domain 2: Impact on people experiencing care, carers and families

To meet the quality indicator, the TVMO group wanted to understand what NHS boards were doing to consider the quality of the experiences of patients receiving transvaginal mesh implants.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Examples of evidence/outcomes for each domain included:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 People’s experience of care and the involvement of carers and families</td>
<td>• NHS boards’ feedback mechanisms to obtain the experiences of patients receiving transvaginal mesh implants</td>
</tr>
</tbody>
</table>

### Domain 5: Delivery of safe, effective, compassionate and person-centred care

To meet the quality indicator, the TVMO group were looking to understand how NHS boards within the region were using, and responding to, local and regional data. In addition, the group were looking for evidence that the data was being considered as a whole to identify any emerging themes or region-wide issues which could be addressed through collective action.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Examples of evidence/outcomes for each domain included:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1 Safe delivery of care</td>
<td>• Local/regional/national data was being used to reduce harm</td>
</tr>
<tr>
<td>5.2 Assessment and management of people experiencing care</td>
<td>• Improvements in patient’s safety and patients being appropriately assessed and managed</td>
</tr>
<tr>
<td>5.3 Continuity of care</td>
<td>• Continuity of care is assured and pathway journeys are seamless</td>
</tr>
<tr>
<td>5.4 Clinical excellence</td>
<td>• Care is delivered to a level of excellence</td>
</tr>
<tr>
<td>5.5 Data for improvement and evidence-based</td>
<td>• Standardised best practice is used through the use of clinical management guidelines (CGMS)</td>
</tr>
<tr>
<td>5.6 Quality improvement processes, systems and programmes</td>
<td>• Processes and systems are in place to support improvement activity</td>
</tr>
</tbody>
</table>
Domain 7: Workforce management and support

To meet the quality indicator, the TVMO group were looking for evidence of how well prepared, managed and supported NHS boards were in their daily role to conduct/support transvaginal/transabdominal mesh implants.

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Examples of evidence/outcomes for each domain included:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1 Staff recruitment, training and development</td>
<td>• Surgical expertise is supported by appropriate contingency planning and staff recruitment</td>
</tr>
<tr>
<td></td>
<td>• Opportunities for continued professional development (CPD) are provided in line with national professional guidelines</td>
</tr>
<tr>
<td>7.2 Workforce planning, monitoring and deployment</td>
<td>• Processes in place to monitor clinical performance</td>
</tr>
<tr>
<td>7.3 Communication and team working</td>
<td>• Mechanisms of support for collaborative/team working</td>
</tr>
</tbody>
</table>
About this review

The TVMO group piloted the draft SET with two NHS boards in late 2018. Following review of the completed SETs, the SET was amended taking into account the key learning from the pilot exercise. This process is described in Appendix 3.

The review included two opportunities to submit data. NHS boards submitted their first SET in April 2019, with additional data to be submitted to Healthcare Improvement Scotland by August 2019.

NHS boards submitted data individually. The SET returns were reviewed to:

- determine the governance arrangements of each service
- understand the performance of NHS boards
- identify areas of good practice and innovation, and
- identify areas where improvement was needed.

The SET submissions were reviewed by the stakeholder subgroup of the TVMO group, which met in April and September 2019. Throughout the process, the TVMO group received regular updates from the subgroup and had final sign off of the self-evaluation report.

NHS board areas

All 14 territorial NHS boards received the SET. 13 NHS boards provided submissions. NHS Western Isles, did not submit a return due to small case numbers and will not be included within this report.

Due to the small numbers of cases within services relating to transvaginal mesh it was agreed that drawing regional comparisons would be more beneficial than examination at individual board level. This allowed more accurate interpretation of the data as it recognised that some co-terminus NHS boards work together to provide services for these patient groups. Therefore the analysis and key findings are presented by region according to each NHS board’s respective regional networks:

- **West of Scotland**
  NHS Ayrshire & Arran, NHS Greater Glasgow and Clyde, NHS Forth Valley and NHS Lanarkshire health boards

- **South East Scotland**
  NHS Borders, NHS Dumfries & Galloway, NHS Fife and NHS Lothian health boards

- **North Scotland**
  NHS Grampian, NHS Highland, NHS Shetland, NHS Tayside and NHS Orkney health boards
Limitations

The following limitations were noted:

- The timescales associated with this work were tight, which meant that Healthcare Improvement Scotland’s Quality Assurance Directorate’s full review methodology could not be followed.
- The timing of the data collection also pre-dated much of the activity of the Scottish Government’s Accountable Officers group on complications and debates about mesh removal.
- The questions within the SET were interpreted by NHS boards differently in some instances.
- SETs were completed by a broad range of NHS board employees at all levels.
Summary of stress urinary incontinence and pelvic organ prolapse services in Scotland

- General practitioners (GP) are the main point of entry to specialist services for patients with SUI and/or POP.

- All NHS boards demonstrated a strong preference to offer conservative interventions at the outset before surgical options are discussed. As one NHS board reported:

  “After the clinical assessment and necessary investigations, the management pathway is agreed with the patient starting with conservative options not previously tried and not contraindicated”

- The conservative options included onward referral to specialist services such as incontinence nurses, pelvic floor physiotherapy and urology/urogynaecology.

- Some local treatments were being offered for POP within primary care, for example, ring pessary insertion.

- Patients assessed as needing surgery undergo a number of physiological tests including urodynamic assessments. Before surgery is undertaken patients receive information on all treatment options to ensure informed consent can be achieved.

- NHS boards approach pre-treatment assessment according to local resource, capacity and patient need. For example:

  “Women with stress incontinence are managed first by their GP and then the pelvic floor physio team. If referral is indicated they are then seen by their GP and a member of the physio team jointly. After extensive counselling, if they wish to proceed down the route of surgery they first undergo urodynamics and are then discussed at the local multi-disciplinary team“.

Another NHS board commented that:

  “If conservative management is not successful, the suitable surgical options are discussed in detail with the patient. Patient information leaflets are provided and the patient is given time to consider options and confirm decision. When a patient confirms their decision to explore and possibly proceed with surgery, the case is discussed in the local / regional MDT meetings as required and the management plan considered and approved if appropriate.“
• All NHS boards outlined their multi-disciplinary team (MDT) involvement in treatment and management decisions.

• Not all NHS boards described fully the composition of their MDTs or their precise use, whether in routine care or in complex cases but all refer to the value and use of an MDT. The mix of specialists available varied from board to board, with no urology involvement in one NHS board.

• Two NHS boards reported having formed a joint MDT due to low patient numbers.

• Demands on time in coordinating and participating in a MDT were specifically highlighted by two NHS boards.

• All NHS boards refer complex surgical cases to tertiary centres. Some local NHS boards undertook procedures for small mesh erosions but the SET did not collect data on non-mesh complications.
West of Scotland - detailed findings

A. Key organisational outcomes (Quality Framework Domain 1)

Improvements in quality, outcomes and impact (Quality Indicator 1.1)

Throughout the self-evaluation process, the TVMO group were provided with evidence that NHS boards across the West of Scotland are working to deliver established key outcomes. Three of the four NHS boards in this region have mechanisms in place to measure these outcomes. One NHS board reported regular sharing of the key outcomes at local operational and clinical governance meetings.

Good Practice:
There are clear, person-centred, key outcomes that the service is working to which include a focus on quality of life, patient safety, satisfaction. There are also robust mechanisms in place to measure these outcomes.

A range of areas were covered in the outcomes outlined by each NHS board including improving patient quality of life, satisfaction, handling patient complaints, safety, efficacy and shared decision making.

Fulfilment of statutory duties and adherence to national guidelines (Quality Indicator 1.2)

Throughout the self-evaluation process, evidence was provided to illustrate that NHS boards have been implementing the recent NICE guidance.

Local, regional and national work has been undertaken to identify and address areas of compliance and non-compliance with NICE guidance. Some NHS boards have reported that aspects of the guidance have not been implemented. The reasons for this included cost implications, clinical opinion and sustainability.

Local and regional work to develop and implement a number of pathways of care has also taken place. The West of Scotland POP/ SUI group have developed and are currently reviewing pathways on:

- Stress urinary incontinence
- pelvic organ prolapse, and
- mesh complications.

Some NHS boards are more advanced in their pathway of care development than others. Existing pathways of care will be updated and reviewed as per NICE guidance.

The TVMO group commended the efforts of West of Scotland in relation to pathway development.

Good Practice:
There is evidence of the development, review and implementation of a number of care pathways in the West of Scotland and adherence to NICE guidance.
B. Impact on people experiencing care, carers and families (Quality Framework Domain 2)

People’s experience of care and the involvement of carers and families (Quality Indicator 2.1)

NHS boards provided evidence on their consent process, use of Quality of Life (QoL) questionnaires, patient feedback and provision of patient information.

Each NHS board within this region has a clear consent process for patients who are undergoing surgery. This involves sharing information with patients and allowing them sufficient time to process the information before making a decision. Within each NHS board, consent is obtained at a separate appointment scheduled after information is shared. One NHS board noted the negative impact that return appointments are having on the service and clinicians workload.

In each NHS board patients are supported to make an informed choice prior to undergoing surgery and are also made aware of their right to withdraw consent until the time of surgery.

Good Practice:

One NHS board provides patients who had experienced complications with information for consideration and time for reflection and support. They work with patients to ensure shared decision making by agreeing a management plan where appropriate.

NHS boards within the region reported making use of the MDT when needed and that patient cases can be referred here for further input.

One NHS board reported the additional impact that mesh removals had on the service, in particular the impact on lengthening waiting times for a range of urogynaecology procedures.

QoL Questionnaires

Three of the four West of Scotland NHS boards reported using QoL questionnaires to obtain information from women on the quality of their experiences.

- There is variance in the way that NHS boards are using QoL questionnaires. This includes timing of issue, consistency in use, and the type of QoL questionnaire used.
- Two NHS boards provided information on when QoL questionnaires were issued, for example, before and after treatment to enable them to assess the need for intervention and the outcome of treatment.
- One NHS board reported that it stores the responses given either through the BSUG or the BAUS databases.
- Different QoL questionnaires exist for SUI and POP, with more questionnaires available for SUI.
- One NHS board reported that the rate of compliance for completion of QoL questionnaires needs could be improved.
Patient Feedback

A range of methods are used to obtain patient feedback, including:

- Details of how a patient can provide feedback is outlined on the website within a number of the NHS boards within this region. The website has a range of information including contact details for patient advice and support services as other resources.
- Use of cards in the clinical area to outline how patients can provide feedback which one NHS board outlined.

From the evidence provided, the TVMO group is satisfied that each NHS board has clear methods for patients to share their feedback.

Patient Information

Evidence was provided of the information leaflets shared with patients, these include:

- International Urogynaecological Association (IUGA), BSUG and BAUS information leaflets.
- NICE decision making tools.
- National transvaginal mesh implants leaflet.\(^5\)
- Locally developed patient information for POP non-mesh procedures, including weblinks for patients who prefer to use an electronic format.

At the time of the review, the boards in this region were developing leaflets for all SUI procedures. One NHS board had taken responsibility of developing three national leaflets for non-mesh surgery.

The TVMO group noted a consistent approach across the West of Scotland with regard to using national patient leaflets. They noted the development of patient leaflets and agreed this was good practice.

**Good Practice:**
Cross-board working to develop consistent patient information.
C. Delivery of safe, effective, compassionate and person-centred care (Quality Framework Domain 5)

Safe delivery of care (Quality Indicator 5.1)

Not all NHS boards in the West of Scotland provided comprehensive responses concerning adverse events management.

- Three of the four NHS boards in this region use Datix.
- Some NHS boards discuss their adverse events at regular gynaecology risk management meetings.
- One NHS board reported their adverse events to the mortality and morbidity (M&M) meeting.
- All NHS boards reported their mesh specific adverse events to IRIC directly.
- Staff were reported as being aware of the yellow card system for medical device adverse incidents but the responses did not go into detail about implementation.

Across the West of Scotland region there is a consistent approach to reporting adverse events in Datix and to IRIC.

Assessment and management of people experiencing care (Quality Indicator 5.2)

Limited evidence was provided on the reporting and handling of adverse events.

Continuity of care (Quality Indicator 5.3)

The SET questions was not designed to fully capture specific evidence on patient’s experiences of continuity of care.

Clinical excellence (Quality Indicator 5.4)

The majority of NHS boards within this region are taking steps to implement the NICE guidance\(^3\) as fully as they can. At present there are no nationally agreed standards or indicators for NHS boards to comply with. The TVMO group were satisfied with the efforts within West of Scotland to support clinical excellence.

Data for improvement and evidence-based learning (Quality Indicator 5.5)

Evidence was provided to show that NHS boards are recording their data into either the BSUG or the BAUS database. This variance in use of either database is consistent across Scotland.

Some NHS boards reported a compliance issue with the reporting of data onto a database. The TVMO group noted this concern.

The TVMO group are aware of ongoing work involving the Scottish Government to develop a UK registry to enable consistent data collection.
Quality improvement processes, systems and programmes (5.6)

Evidence was provided to show that a number of systems are used when collecting data, including:

- Data on adverse events using Datix and Safeguard.
- Data on patient treatment using the BSUG or BAUS databases.
D. Workforce management and support (Quality Framework Domain 7)

Staff recruitment, training and development (Quality Indicator 7.1)

A range of methods are used to ensure that staff have the skills and experience required to carry out their role:

- One NHS board outlined the recruitment of clinical staff is in line with Royal College of Obstetricians and Gynaecologists (RCOG) recommendations.
- All NHS boards detailed the use of training programmes to ensure that staff are competent and maintain their skills. Most NHS boards outlined this as being in line with RCOG.
- One NHS board outlined the use of the BSUG mentoring scheme as a method for ensuring skills are maintained.
- All NHS boards within West of Scotland support and encourage medical staff to attend, for example, educational days and events and conferences to support their development. Clinicians are encouraged to attend conferences and update their continuing professional development (CPD).
- Staff annual appraisals are used to discuss personal and professional development. This is an opportunity for staff to self-identify any training they would like to attend or need to undertake.
- One NHS board has established apprentice style training. This is provided during specialty training (pre-certificate of completion of training)
- Most NHS boards outlined the role of the MDT in agreeing training requirements for medical staff involved with service delivery.
- Few NHS boards referred to the training needs of other members of the MDT, for example, allied health professionals (AHP) or nurses.

Workforce planning, monitoring and deployment (Quality Indicator 7.2)

Clinical performance is managed in a number of ways including auditing against outcomes, monthly MDT meetings, monitoring complaints.

Communication and team working (Quality Indicator 7.3)

Effective communication between staff to ensure safe, effective and person-centred care is encouraged in a number of ways:

- All NHS boards outlined the use of a regular MDT meetings to discuss cases.
- NHS boards described the different disciplines within the MDT, with variation in membership and frequency of meetings and usage.
- Two of the NHS boards work together as a single MDT due to the small number of cases anticipated within these NHS boards.
• There is a West of Scotland regional MDT. No further details were provided around how this operates.
• The MDT is used to share information and knowledge from national and international meetings.
• Learning summaries are used within one board as a method to enhance team communication.
• One NHS board uses face-to-face meetings on a regular basis.
• Another board outlined the need for leadership to foster good communication between staff.
• One board elaborated that it was important to:

  “maintain healthy work environment, evaluate and respect the role of each member, adequate induction and support to all new members and good leadership”.

West of Scotland - Key areas for improvement

- There was no direct involvement of patients in the pathway development process. This could be addressed as pathways are implemented and reviewed.

- One board reported having no key outcome measures for gynaecology/urogynaecology.

- There is scope to improve the use of QoL questionnaires, compliance rates and the consistency of tools used.

- The need for information for patients experiencing mesh complication after surgery should be systematically addressed to ensure accurate information is provided. Patient information resources on post-operative complications involving mesh was lacking or non-existent.

- The use of support groups and websites for people experiencing complications should be quality assured. For example use of information platforms such as NHS Inform could prove valuable.

- A consistent approach is required when taking account of NICE guidance\(^3\).

- It is important to raise awareness of the requirement and process of reporting adverse events to IRIC.

- NHS boards could give more attention to the training needs of the wider MDT including AHPs and nurses, appropriate to roles and responsibilities.
South East Scotland – detailed findings

A. Key organisational outcomes (Quality Framework Domain 1)

Improvements in quality, outcomes and impact (Quality Indicator 1.1)

Throughout the self-evaluation process, the TVMO group were provided with evidence that the NHS boards within South East Scotland have established key outcomes that NHS boards are working toward. It was noted that only two NHS boards provided detail of their key outcomes. Both of these NHS boards outlined the focus of the key outcomes being on a wide range of areas including patient satisfaction, data collection on surgical procedures involving mesh, cure rates and improvement rates.

The South East Scotland region has a range of methods to measure their key outcomes. One preferred method is the use of QoL questionnaires when collecting information on patient satisfaction. Three out of four NHS boards reported the use of QoL questionnaires against their outcomes.

Fulfilment of statutory duties and adherence to national guidelines (Quality Indicator 1.2)

Throughout the self-evaluation process, evidence was provided by NHS boards within South East Scotland to illustrate that they have been implementing the recent NICE guidance3.

From the evidence provided by each NHS board within this region, it is evident that there has been local, regional and national work undertaken to identify and address the areas of difference between the service and the guidance.

In addition to this, there has been local and regional work to develop and implement a number of pathways of care:

- At the time of the review (summer 2019) one board reported they were developing pathways of care for SUI, they expected to complete this work in August 2019.
  - The board provided the TVMO group with their current female urinary incontinence pathway.
  - The board reported using a local pathway for the treatment of POP and reported that a regional pathway was still to be developed.
- One NHS board was reviewing their pathways of care to take into account the NICE guidance3, findings from the Cumberledge report6 and additional national advice5.
- One NHS board reported that they have implemented the high vigilance protocol2 outlined by the Chief Medical Officer (CMO) in September 2018 but provided no further details on pathways of care.
- One NHS board did not provide the TVMO group with any information on their pathways of care.
- NHS boards within the South East Scotland region have developed protocols for the management of SUI and POP.
B. Impact on people experiencing care, carers and families 
(Quality Framework Domain 2)

People’s experience of care and the involvement of carers and families (Quality Indicator 2.1)

The NHS boards across South East Scotland provided evidence on their consent process, use of QoL questionnaires, patient feedback and provision of patient information.

Consent and Decision-making

Each NHS board within this region has a clear consent process for patients who are undergoing surgery. This involves sharing information with patients, allowing them time to process the information and make a decision. Within each NHS board consent is obtained at a separate appointment scheduled after information is shared. One board noted that some patients do not wish to return to hospital to consent to procedures.

Good Practice:
NHS boards have clear consent processes for patients who are undergoing surgery. This involves sharing information with patients, then allowing them time to process the information before making a decision. Consent is obtained at a separate appointment scheduled after information is shared.

Each NHS board outlined that patients are supported to make an informed choice prior to undergoing surgery.

One NHS board within this region made reference to their patient experience pathway. This involves issuing patients with a document on discharge from hospital. The document asks for the patient to, 'tell us 10 things'. Patients are signposted to the correct department depending on the feedback provided.

QoL Questionnaires

The TVMO group noted that all NHS boards within this region reported that they issue patients with a QoL questionnaire:

- One NHS board reported they issue QoL questionnaires pre and post-surgery.
- All NHS boards issue QoL questionnaires to women who undergo treatment for SUI.
- Three NHS boards reported using International Consultation on Incontinence Questionnaire (ICIQ) QoL questionnaires.
- One NHS board outlined the questionnaire used by their physiotherapy department. They reported future plans to evaluate the service based on returns and share the feedback with GPs to highlight the benefits physiotherapy can make.
Good Practice:
Collating information collected in physiotherapy questionnaires is and using it to determine service improvements and measure the impact of the service is good practice. Information was also shared with primary care teams to demonstrate the benefits of physiotherapy.

Evidence demonstrated that NHS boards within South East Scotland use QoL questionnaires to obtain information.

Patient Feedback
As a region, South East Scotland has a range of methods for obtaining patient feedback:

- All NHS boards give patients the opportunity to speak directly to clinicians in primary or secondary care, to raise their concerns and share feedback.
- One NHS board reported they use, ‘Time to Talk’, cards, which patients can use to provide feedback. These cards also outline the various ways that patients can feedback.
- One NHS board reported the use of postal questionnaires as a method to capture feedback.
- One NHS board outlined the use of cards in the clinical area to outline how patients can provide feedback.

From the evidence provided, the TVMO group noted that each NHS board has clear methods for patients to provide their feedback.

Patient Information
NHS boards across South East Scotland provided the TVMO group with evidence of the patient information leaflets they provide. Most NHS boards within this region direct patients to the RCOG, BSUG and/or BAUS websites to obtain patient information. Other information sources include:

- National transvaginal mesh implants leaflet (developed by Scottish Government).
- IUGA patient information.
- National leaflets developed by West of Scotland urogynaecology group.

One NHS board has recently developed a patient information leaflet that is focused on complications post surgery involving mesh.

Good Practice:
Patient information leaflets that are focused on complications post surgery involving mesh.

The NHS boards within this region reported the use of a consistent approach when issuing patient information.
C. Delivery of safe, effective, compassionate and person-centred care (Quality Framework Domain 5)

**Safe delivery of care (Quality Indicator 5.1)**

Not all NHS boards in South East Scotland provided comprehensive responses concerning adverse events:

- This region reported the using Datix when reporting adverse events.
- Some NHS boards within the region provided information that they reported adverse events through the MHRA reporting system.
- Some NHS boards within the region are reporting adverse events directly to IRIC.
- One NHS board uses photography in patient’s notes, with their consent, to keep an accurate record.
- One NHS board reported the use of the BSUG database when recording adverse events.

**Assessment and management of people experiencing care (Quality Indicator 5.2)**

Most NHS boards within South East Scotland reported they are highlighting adverse events to IRIC. One NHS board raised this was a new process and further education was needed on this.

The TVMO group noted that:

- It was reported that BSUG recommends MHRA for reporting adverse events.
- There is inconsistency with reporting, as there may be more than one surgeon involved (implanting and complications) hence one of the surgeons may have access to limited information.
- One NHS board has a named clinician who reports adverse events.

**Continuity of care (Quality Indicator 5.3)**

The SET questions did not fully capture specific evidence on patient’s experiences of continuity of care.

**Clinical excellence (Quality Indicator 5.4)**

NHS boards within South East Scotland, provided the TVMO group with information on the implementation of the recently published NICE guidance\(^3\). Most NHS boards within this region are taking steps to implement these as fully as they can. At present there are no nationally agreed standards or indicators for NHS boards to adhere too. The TVMO group were satisfied with the efforts within this region.

**Data for improvement and evidence based learning (Quality Indicator 5.5)**

Throughout the self-evaluation process evidence was provided by NHS boards that demonstrated South East Scotland are recording data into a database. From the information provided to the TVMO group, the region are using either the BSUG or BAUS databases to collect data. This variance is consistent across Scotland.
One NHS board has a named clinician who reports data. The TVMO group were concerned with sustainability.

The TVMO group are aware of ongoing work involving, Scottish Government, to develop a UK registry to ensure consistent data collection.

**Quality improvement processes, systems and programmes (Quality Indicator 5.6)**

From the information provided, NHS boards across South East Scotland are reporting adverse events in a number of ways:

- RCOG has a trigger list for incident reporting, although it was noted this was not specific to SUI/POP.
- MHRA have advice on reporting adverse events.
- IUGA have guidance on mesh classifications.

One NHS board has local guidance that they follow when reporting adverse events.
D. **Workforce management and support (Quality Framework Domain 7)**

Please note that one NHS board within this region has provided a, ‘not applicable (N/A)’ return to this aspect of the self-evaluation review.

**Staff recruitment, training and development (Quality Indicator 7.1)**

During the self-evaluation review, NHS boards within South East Scotland, submitted evidence to demonstrate their approach to recruitment, training and staff development:

- The region, on a whole, use annual staff appraisals to discuss personal and professional development.
- Most NHS boards support and encourage staff to attend educational events, for example, conferences and educational days to support their development. Clinicians are encouraged to attend conferences and update their CPD.
- One NHS board detailed the use of training programmes to ensure that staff are competent and maintain their skills.
- Some NHS boards reported the use of audit and M&M meetings.
- Two NHS boards reported using a buddy operating system to share knowledge and skills in surgical procedures.
- Few NHS boards referred to the training needs of other members of the MDT, for example AHPs or nurses.

**Workforce planning, monitoring and deployment (Quality Indicator 7.2)**

Throughout the self-evaluation process South East Scotland provided a range of information on how clinical performance is managed. The region employs a range of methods including:

- auditing against outcomes
- appraisals
- job planning, and
- review of adverse events at M&M meetings.

**Communication and team working (Quality Indicator 7.3)**

During the self-evaluation process, NHS boards within South East Scotland, submitted evidence of how they encourage effective communication between staff to ensure safe, effective and person centred care:

- Two NHS boards work together as a single MDT due to the small number of cases anticipated within these NHS boards.
- There are both regional and local MDTs within this region.
- One NHS board reported having fortnightly MDT meetings to allow the free flow of information.
• One NHS board reported that MDTs allow communication within the team. However it was noted that there have been challenges to ensure is a truly multidisciplinary group:

“MDTs can be difficult to organise as to be truly multidisciplinary we need physiotherapy, urology, nurse specialist, urogynaecology. It’s difficult for all in this group to find time to meet regularly enough so as to discuss patients in a timely way. There should be time in all job plans allocated specifically for the MDM.”

• Another NHS board reported that cooperation takes place because of individual’s efforts and extra time.
• One NHS board use M&M meetings to share learning.
• One board elaborated that it was important to have, “compassionate leadership and regional network”.
South East Scotland - Key areas for improvement

- There was no direct involvement of patients in the pathway development process. This could be addressed as pathways are implemented and reviewed.

- Only two out of four NHS boards reported having key outcomes and provided details of these.

- A consistent approach is required when taking account of NICE guidance\(^3\).

- There is a need for consistency within this region, when providing patients with information resources.

- There is a need for awareness of the requirement and process of reporting adverse events to IRIC.

- One NHS board has one named clinician responsible for reporting adverse events. This could cause sustainability issues.

- NHS boards in this region, could give more attention to the training needs of the wider MDT professionals including AHPs, nurses.

- There is a need for greater support to enable MDT working within this region.
North of Scotland – detailed findings

A. Key organisational outcomes (Quality Framework Domain 1)

Improvements in quality, outcomes and impact (Quality Indicator 1.1)

Throughout the self-evaluation process the TVMO group were provided with evidence that NHS boards within the North of Scotland have established key outcomes that NHS boards are working toward. It was noted that all NHS boards within this region have clear key outcomes and mechanisms in place to measure these.

The key outcomes outlined by each board focused on a wide range of areas including patient satisfaction, adverse events, re-admission rates, success rate, waiting times.

NHS boards across the North of Scotland use a number of mechanisms to review the key outcomes they have in place, these include reviewing waiting times at a weekly meeting and using health informatics, such as, Datix and patient feedback.

Fulfilment of statutory duties and adherence to national guidelines (Quality Indicator 1.2)

NHS boards within the North of Scotland illustrated that they have been taking the steps needed to adhere to the recent NICE guidance³.

From the evidence provided by each NHS board within this region, it is evident that most NHS boards do not carry out surgical procedures and women are referred to specialist services in other NHS boards.

Within the North of Scotland region:

- Most NHS boards have implemented the NICE guidance³ in a range of ways including data collection, regular MDT meetings for complex cases, risk management meetings.
- One NHS board noted that if it follow the recommendation set out within the NICE guidance³ MDT meetings would need to take place weekly rather than monthly that this would impact on routine procedures and would not be cost neutral.
- At the time of SET data collection (Summer 2019) one NHS board reported they were reviewing their protocols and had plans to share these with primary care.

From the evidence provided by the North of Scotland region, the TVMO group were able to determine that a number of NHS boards had pathways in place for SUI and/or POP. It was noted that these were at various stages of development and implementation:

- Two NHS boards reported the pathway of care was under final revision.
- One NHS board has developed a local pre-operative checklist that outlines measures to be taken or explored before a patient is listed for surgery.
- One NHS board has reported there is no plan to develop a pathway due to lack of resources.

The variance within this region was noted.
B. Impact on people experiencing care, carers and families  
(Quality Framework Domain 2)

Please note that one NHS board within this region has provided a ‘not applicable (N/A)’ return to this aspect of the self-evaluation review. Another NHS board within this region has reported the board providing treatment would conduct this aspect of care.

**People’s experience of care and the involvement of carers and families (Quality Indicator 2.1)**

NHS boards within this region provided evidence of their consent process, use of QoL questionnaires, patient feedback and provision of patient information.

**Consent and Decision-making**

Each NHS board within this region has a clear consent process for patients who are undergoing surgery. This involves sharing information with patients, allowing them time to process the information and make a decision. Within each NHS board, consent is obtained at a separate appointment scheduled after information is shared.

The region uses the MDT when considering all complex cases, mesh surgery as well as colpocleisis cases. The decision made at MDT is then shared with patients and a plan is developed with input from the patient.

**Good Practice:**
Using the MDT when considering all complex cases. The decision made by the MDT is then shared with the patient and a plan is developed with their input.

**QoL Questionnaires**

NHS boards within the North of Scotland, reported using a number of QoL questionnaires to obtain information from women on the quality of their experience.

- Within the North of Scotland, the use of QoL questionnaires was not consistent with three NHS boards reporting that they did not use QoL questionnaires.
- One NHS board provided three QoL questionnaires that they issue to patients although no information was given around the process used or the response rates.

**Patient Feedback**

As a region, the North of Scotland has a range of methods for obtaining patient feedback:

- Direct feedback from patients at their review appointment.
- Information leaflets are provided to patients that include information on how they can provide feedback on the service.
• One NHS board reported the use of an improvement tree, where patients could write down their concerns.
• Details of how a patient can provide feedback is outlined on the website within a number of the NHS boards within this region.

One NHS board was very pro-active in obtaining feedback from patients by offering a range of methods.

**Good Practice:**
Having a range of methods for obtaining patient feedback including improvement tree, notice board on the ward, website, feedback cards and real time feedback to staff members.

From the evidence provided, the TVMO group has seen that the region has clear methods for patients to provide their feedback.

**Patient Information**

NHS boards across the North of Scotland, has provided the TVMO group with examples of the patient information leaflets they provide. The TVMO group noted that most NHS boards within this region direct patients to the RCOG, BSUG and/or BAUS websites to obtain patient information. Other sources of information include:

• One NHS board have developed a number of patient information leaflets.
• Other national information online, for example, Scottish Government.
• Another NHS board has established a peer review process on the information provided to patients.

**Good Practice:**
Having a peer review process on the information provided to patients. If there is not enough information provided then another clinician could be contacted for more information.

The TVMO group noted the consistent approach within this region when issuing patient information.
C. Delivery of safe, effective, compassionate and person-centred

Please note that one NHS board within this region has provided a ‘not applicable (N/A)’ return to this aspect of the self-evaluation review.

Safe delivery of care (Quality Indicator 5.1)

During the self-evaluation process, evidence was shared on how NHS boards within the North of Scotland report adverse events:

- Three NHS boards within this region outlined the system they used as being Datix.
- One NHS board reported their adverse events are discussed at risk management meetings.
- One NHS board records the adverse events in a special pelvic floor register.
- One NHS board does not report adverse events as they do not carry out procedures.

Assessment and management of people experiencing care (Quality Indicator 5.2)

Throughout the self-evaluation process, the TVMO group were given evidence that boards within the North of Scotland are reporting adverse events to IRIC and/or MHRA.

Continuity of care (Quality Indicator 5.3)

The SET questions did not fully capture specific evidence on patient’s experiences of continuity of care.

Clinical excellence (Quality Indicator 5.4)

The North of Scotland region, provided the TVMO group with information on the implementation of the recently published NICE guidance. Where applicable NHS boards within this region are taking steps to implement these as fully as they can. At present there are no nationally agreed standards or indicators for NHS boards to adhere to. The TVMO group were satisfied with the efforts within this region.

Data for improvement and evidence based learning (Quality Indicator 5.5)

Throughout the self-evaluation process several NHS boards reported they are not recording data into a database. One NHS board reported recording data into the BSUG/IUGA database.

The TVMO group are aware of ongoing work involving Scottish Government to develop a UK registry to ensure consistent data collection.

Quality improvement processes, systems and programmes (Quality Indicator 5.6)

NHS boards across the North of Scotland provided evidence that they use a number of systems when collecting data:

- To collect data on adverse events three NHS boards use Datix.
- One NHS board reported using BSUG/IUGA databases.
D. Workforce management and support (Quality Framework Domain 7)

Staff recruitment, training and development (Quality Indicator 7.1)

During the self-evaluation review, NHS boards across the North of Scotland submitted evidence to demonstrate their approach to recruitment, training and staff development:

- NHS boards that carry out procedures, have reported having RCOG accredited clinicians who can perform a range of procedures.
- The North of Scotland region support and encourage staff to attend educational events such as conferences and have educational days to support their development. Clinicians are encouraged to attend conferences and update their CPD.
- One NHS board outlined the role of the MDT with regard to education and information sharing.
- The region use staff annual appraisals to discuss personal and professional development.
- One NHS board outlined peer support during surgery (buddy operating).

Workforce planning, monitoring and deployment (Quality Indicator 7.2)

NHS boards across the North of Scotland manage clinical performance in a number of ways including appraisal, complaints, buddy operating, and adverse events. The TVMO group were encouraged there were mechanisms in place to monitor this.

Communication and team working (Quality Indicator 7.3)

The North of Scotland region shared information that demonstrates that NHS boards are encouraged to work in a multidisciplinary way.

It was noted that one NHS board had excellent representation on their MDT group.

Good Practice:
Having an MDT with good multi-disciplinary representation that includes: - gynaecology, urogynaecology, incontinence nurse, community nurse, physiotherapist and colorectal surgeon.

The evidence provided outlined a wide range of ways that staff are encouraged to work together:

- Senior staff meetings
- Support and guidance from clinical leads, clinical director and associate medical director
- Job planning
- Regular team meetings
- Weekly M&M meetings
North of Scotland - Key areas for improvement

- There was no direct involvement of patients in the pathway development process. This could be addressed as pathways are implemented and reviewed.

- The region should consider developing and implementing pathways of care for SUI and POP. This would allow for a consistent approach.

- A consistent approach is required when taking account of NICE guidance\(^3\).

- There is a need for consistency within this region, when providing patients with information resources.

- It was noted that the use of QoL questionnaires was not consistent.
Reference List


# Appendix 1: TVMO Group Membership

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lorna McKee</td>
<td>Independent Chair</td>
<td></td>
</tr>
<tr>
<td>Nikolina Angelova</td>
<td>Health Services Researcher</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Hannah Coats</td>
<td>Digital Content Designer</td>
<td>NHS Inform</td>
</tr>
<tr>
<td>Marie Duffy</td>
<td>Patient representative</td>
<td></td>
</tr>
<tr>
<td>Sarah Florida-James</td>
<td>Programme Manager</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>(Until Summer 2019)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Christine Hemming</td>
<td>Consultant Gynaecologist</td>
<td>Scottish Association of Medical Directors (SAMD)</td>
</tr>
<tr>
<td>Margaret Hogg</td>
<td>Public Partner</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Christine Jess</td>
<td>Public Partner</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Sue Lloyd-MacGilp</td>
<td>IRIC Co-ordinator</td>
<td>Incident Reporting and Investigation Centre (IRIC)</td>
</tr>
<tr>
<td>Karen MacPherson</td>
<td>Lead Health Services Researcher</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Sharon Mercado</td>
<td>Patient representative &amp; co-chair of patient resource subgroup</td>
<td></td>
</tr>
<tr>
<td>Isobel Montgomery</td>
<td>Patient representative</td>
<td></td>
</tr>
<tr>
<td>(until Summer 2019)</td>
<td></td>
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</tr>
<tr>
<td>Jackie Montgomery</td>
<td>Team Lead Physiotherapist</td>
<td>NHS Greater Glasgow and Clyde</td>
</tr>
<tr>
<td>Tim Norwood</td>
<td>Data and Measurement Advisor</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Mahesh Perera</td>
<td>Consultant Gynaecologist</td>
<td>NHS Greater Glasgow and Clyde</td>
</tr>
<tr>
<td>(Until Spring 2019)</td>
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<tr>
<td>Name</td>
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</tr>
<tr>
<td>Alison Pettigrew</td>
<td>Nurse</td>
<td>NHS Lanarkshire</td>
</tr>
<tr>
<td>Safia Qureshi</td>
<td>Director of Evidence</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Alex Stirling</td>
<td>Clinical and public lead for maternal and sexual health</td>
<td>Information Services Division (ISD)</td>
</tr>
<tr>
<td>Sara Twaddle</td>
<td>Director of Evidence</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>(until Spring 2019)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venu Tyagi</td>
<td>Subspecialist in Urogynaecology</td>
<td>NHS Greater Glasgow and Clyde</td>
</tr>
<tr>
<td>Julia Wilkens</td>
<td>Urogynaecologist</td>
<td>NHS Lothian</td>
</tr>
<tr>
<td>Brenda Wilson</td>
<td>Deputy Director of Nursing and care</td>
<td>Scottish Executive Nurse Directors (SEND)</td>
</tr>
</tbody>
</table>

With support from:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Organisation</th>
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<tbody>
<tr>
<td>Uzma Aslam</td>
<td>Senior Project Officer</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Claire Henry</td>
<td>Administrative Officer</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Kelly Macdonald</td>
<td>Programme Manager</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Tracey Mitchell</td>
<td>Project Officer</td>
<td>Healthcare Improvement Scotland</td>
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## Appendix 2: Glossary of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tbody>
<tr>
<td>AHP</td>
<td>Allied Health Professional</td>
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<tr>
<td>BAUS</td>
<td>British Association of Urological Surgeons</td>
</tr>
<tr>
<td>BSUG</td>
<td>British Society of Urogynaecology</td>
</tr>
<tr>
<td>CMO</td>
<td>Chief Medical Officer</td>
</tr>
<tr>
<td>CPD</td>
<td>Continuing Professional Development</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>ICIQ</td>
<td>International Consultation on Incontinence Questionnaire</td>
</tr>
<tr>
<td>IGUA</td>
<td>International Urogynaecological Association</td>
</tr>
<tr>
<td>IRIC</td>
<td>Incident Reporting and Investigation Centre</td>
</tr>
<tr>
<td>M &amp; M</td>
<td>Mortality and Morbidity</td>
</tr>
<tr>
<td>MDT</td>
<td>Multi-disciplinary Team</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and Healthcare Products Regulatory Agency</td>
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<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
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<tr>
<td>POP</td>
<td>Pelvic Organ Prolapse</td>
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<tr>
<td>QoCA</td>
<td>Quality of Care Approach</td>
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<tr>
<td>QoL</td>
<td>Quality of Life</td>
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<tr>
<td>RCOG</td>
<td>Royal College of Obstetricians and Gynaecologists</td>
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<tr>
<td>SET</td>
<td>Self-Evaluation Tool</td>
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<tr>
<td>SUI</td>
<td>Stress Urinary Incontinence</td>
</tr>
<tr>
<td>TVMO</td>
<td>Transvaginal Mesh Implants Oversight Group</td>
</tr>
</tbody>
</table>
Appendix 3: Self-Evaluation Process

1. Draft Self-evaluation Tool *(Late 2018)*
2. Circulate Draft Self-evaluation Tool to pilot NHS boards *(8 weeks)*
3. Redraft Self-evaluation Tool based on key learning from Pilot
4. Communicate with NHS boards to:
   - identify key contacts
   - share expectations/process and timelines
5. Circulate Self-evaluation Tool to all 14 NHS boards *(6 weeks)*
6. Analyse results with stakeholder subgroup
7. Request additional information from NHS boards *(4 weeks)*
8. Analyse results with stakeholder subgroup
9. Circulate draft Self-evaluation report to TVMO Group for sign off *(December 2019)*
10. Circulate draft Self-evaluation report to Accountable Officers for comment *(2 weeks)*
11. Consider/Amend Draft self-evaluation report
12. Finalise self-evaluation report
13. Distribute Final self-evaluation report *(Early 2020)*
December 2020

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