# MINUTES

**Transvaginal Mesh Implants Oversight group (TVMO)**

**Date:** Thursday 27 June 2019  
**Time:** 11:00 to 15:30  
**Location:** Meeting room 6.5, Delta House, Glasgow G1 2NP

### Present

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<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Representing</th>
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<tbody>
<tr>
<td>Lorna McKee</td>
<td>Chair</td>
<td>NHS24</td>
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<tr>
<td>Hannah Coats</td>
<td>Digital Content Designer</td>
<td>NHS24</td>
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<tr>
<td>Christine Hemming</td>
<td>Consultant Gynaecologist</td>
<td>Scottish Association of Medical Directors (SAMD)</td>
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<tr>
<td>Margaret Hogg</td>
<td>Public partner</td>
<td>Healthcare Improvement Scotland</td>
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<td>Christine Jess</td>
<td>Public partner</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Susan Lloyd MacGilp</td>
<td>IRIC Coordinator</td>
<td>Incident Reporting and Investigation Centre (IRIC)</td>
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<tr>
<td>Sharon Mercado</td>
<td>Patient representative</td>
<td>NHS Greater Glasgow and Clyde</td>
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<tr>
<td>Jackie Montgomery</td>
<td>Team Lead Physiotherapist</td>
<td>Healthcare Improvement Scotland</td>
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<td>Tim Norwood</td>
<td>Data and Measurement Advisor</td>
<td>Healthcare Improvement Scotland</td>
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<td>Allison Pettigrew</td>
<td>Nurse</td>
<td>Primary Care representative</td>
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<td>Safia Qureshi</td>
<td>Director of Evidence</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Alex Stirling</td>
<td>Clinical and Public Health Lead for maternal and sexual health information</td>
<td>National Services Scotland</td>
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<tr>
<td>Veenu Tyagi</td>
<td>Subspecialist in Urogynaecology</td>
<td>NHS Greater Glasgow and Clyde</td>
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<tr>
<td>Julia Wilkens</td>
<td>Subspecialist in Urogynaecologist</td>
<td>NHS Lothian</td>
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### In attendance

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<th>Name</th>
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<tr>
<td>Nikolina Angelova</td>
<td>Health Service Researcher</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Aoife Bradley</td>
<td>Health Services Researcher</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Ed Clifton</td>
<td>Team Lead, Scottish Health Technologies Group (Observing)</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Kelly Macdonald</td>
<td>Programme Manager</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Karen Macpherson</td>
<td>Lead Health Services Researcher</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Tracey Mitchell</td>
<td>Project Officer</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Louise Taylor</td>
<td>Research Analyst</td>
<td>Healthcare Improvement Scotland</td>
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<td>(part meeting)</td>
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<tr>
<td>Fiona Wardell</td>
<td>Standards and Indicators Lead</td>
<td>Healthcare Improvement Scotland</td>
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### Apologies

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<tr>
<td>Marie Duffy</td>
<td>Patient representative</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Sarah Florida James</td>
<td>Programme Manager (SIGN)</td>
<td>NHS 24 representing senior management and Scottish Executive Nurse Directors</td>
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<tr>
<td>Brenda Wilson</td>
<td>Deputy Director of Nursing and Care</td>
<td>NHS 24 representing senior management and Scottish Executive Nurse Directors</td>
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1. Opening business

1.1 Welcome, introductions and apologies

The Chair welcomed everyone to the sixth meeting of the oversight group and apologies were noted as above. The Chair asked the group members’ permission to record the meeting and there was reassurance that the meeting would be recorded in line with Healthcare Improvement Scotland’s (HIS) data protection and confidentiality policies.

New group members were welcomed as follows:

- Aiofe Bradley, Health Services Researcher
- Sue Lloyd-MacGilp, IRIC Coordinator
- Karen Macpherson, Lead Health Services Researcher, returning from a seconded post
- Alison Pettigrew, Primary Care representative
- Safia Quereshi, Director of Evidence
- Alex Stirling, Clinical and Public Lead for Maternal and Sexual Health

Observing the meeting was the Head of the Scottish Health Technologies Group, Ed Clifton.

The Chair confirmed that since the last meeting a patient representative and a Consultant Gynaecologist had left the TVMO group. Both members had stepped down due to ill health. Individual introductions were made and the Chair emphasised that the TVMO group is a team effort. Everyone’s contribution is welcomed, respected and valued. Any decisions that the group make will be transparent, open and ethical.

1.2 Declaration of interests (DOI)

No interests were declared in advance of or throughout the meeting. The Chair reiterated that any changes should be passed to the project team as soon as possible. Any member who has not completed a DOI form should contact a member of the HIS project team.

1.3 TVMO Remit

The Chair restated the group’s remit and terms of reference.

The TVMO group is a multidisciplinary with the remit of:

- reviewing data on the use of transvaginal mesh implants in NHSScotland
- reviewing adverse event reporting by NHS boards
- considering how significant new evidence can be incorporated into the agreed NHSScotland pathways of care, and
- ensuring that any patient information is up to date and appropriate.

In addition to these four main functions, the group will also:

- develop and issue a self-evaluation tool (SET) to NHS boards for completion and analyse the results, and
- discuss the potential for the development of quality performance indicators (QPIs).
A question was raised by a patient representative. She asked that given the recent media on mesh complications had we been asked to look into the evidence around this. The Chair replied that this was not asked of us and we would pass on any evidence that we had gathered.

With regards to the last bullet point on the development of QPIs, the project team will explore the feasibility of this further.

1.4 Minutes and action points from 14 December 2018

The minutes from the meeting on 14 December 2018, were previously circulated by the project team and comments received were incorporated. The minutes were noted as being an off-line item and would not be discussed further. Group members were asked to email the HIS project team with any comments.

The group reviewed the action point register with the following updates being provided:

- **Item 1.3**
  The Team Lead Physiotherapist provided an update regarding waiting times for physiotherapy within NHS boards. She noted that she attended the Allied Health Professional Directors Scotland Group (ADSG) meeting in June 2019, and the meeting was positive. They agreed to further discuss the Team Lead Physiotherapist's paper and the actions for physiotherapy. However, more work is still required and the Team Lead Physiotherapist felt confident that she would present the action plan at the next TVMO group in December 2019.

- **Qualitative data:** The Chair advised that following the review team meeting in Aberdeen on 17 December 2019, she had no further intelligence. The Chair referred to a recent qualitative study on the use of pelvic floor exercises, led by the University of Stirling and a systematic review paper on mesh, led by the University of Aberdeen, which is also noted within the evidence team review item.

- **Item 4.2**
  A shared decision making tool was discussed. It was advised that NICE had produced the following patient decision aids, and user guides for healthcare professionals, to help women and their healthcare professionals discuss the different types of surgery -
  - Surgery for stress urinary incontinence: [patient decision aid](#) and [user guide](#)
  - Surgery for uterine prolapse: [patient decision aid](#) and [user guide](#)
  - Surgery for vaginal vault prolapse: [patient decision aid](#) and [user guide](#).

  It was agreed that the NICE decision tool information is to be shared with the TVMO group members.

  The dissemination of paper number TVMO-39 will be discussed under 3.1c Evidence.

2. Chair's update
   
a) Accountable Officers (AO)
   
The Chair provided a brief overview of key mesh related developments since the December 2018 meeting of TVMO, including details of the...
establishment of the Accountable Officers (AO) group which followed the mesh, ‘Halt’, introduced in September 2018:

The following information highlights were covered:

- The AO group was convened following the mesh, ‘Halt’, as part of the high vigilance process. All Scottish health boards were asked by the Chief Medical Officer to identify an Accountable Officer. The group met for the first time in February 2019. The TVMO Chair, TVMO Programme Manager and HIS Evidence Director are members of the group as well as the Health and Social Care Alliance Scotland (the ALLIANCE).

- In April, a short life working group (SLWG) on mesh complications was formed as part of the AO group to explore the course of care for women experiencing mesh complications.

- Membership of SLWG presently includes:
  - AOs
  - TVMO Chair
  - TVMO Programme Manager
  - HIS Director of Evidence
  - ISD representative
  - Team Lead Physiotherapist (from TVMO group)
  - Nurse representative
  - Primary care representative, and
  - Colleagues from the ALLIANCE.
  - Also invited to contribute and attend is a nominated clinician acting as the Scottish Mesh Survivors (SMS) Representative.

- The remit of the SLWG is to consider aspects of the service and care available to women suffering from stress urinary incontinence (SUI), and pelvic organ prolapse (POP), who have experienced complications after mesh implants. Care pathways and good practice are discussed. Three meetings have taken place to date.

- Timelines for the SLWG are noted to be extremely tight with a report due autumn 2019.

- Health boards have been invited to submit their care pathways.

- Information from a survey completed by the SMS was presented to the SLWG at its June meeting by their representative.

- The ALLIANCE have been asked to liaise with the TVMO group and to investigate women’s experiences around mesh complications to complement the SMS piece. The main liaison will be with the patient resources subgroup of the TVMO. Discussions are ongoing.

A query was raised by a public partner if it had been defined where the pathway of care for the management of complications would begin. A discussion followed around how currently there is no standardisation for health boards. The group recognised that having a mutual understanding and a recognised pathway would ensure every patient gets the same quality of care. The importance of patient informed pathway development was raised.

b) The ALLIANCE
A meeting between the ALLIANCE and the TVMO patient resource subgroup (PRS) was held prior to the TVMO group on 27 June. However, further clarification is needed from the Scottish Government before the ALLIANCE confirm the scope of their patient engagement on mesh complications. Feedback from the ALLIANCE is awaited. A draft terms of reference for the PRS was tabled at the meeting. The ALLIANCE is to lead this independent work. The PRS will primarily act as a reference group; with two joint meetings proposed, and input at the outset to identify themes and content of the work; then provision of comments on any final output.

c) KHUB
The Chair asked the TVMO group how they found the new information sharing platform; KHUB. The TVMO group agreed that they were impressed and that it was liked. Some members have requested that they continue to receive hard copies of papers.

3. Standing Items

3.1 Review of Data
The Chair asked the Data Measurement Advisor to speak on this item and asked colleagues to refer to paper TVMO-44.

a) ISD

The Data and Measurement Advisor stated that the data summary contained key messages relating to mesh and non-mesh procedures for SUI and POP. The dates covered within the summary were from April 2009 to March 2019.

The data is based on records available at the time of producing the summary. It was noted the last three months records were estimated to be 78% complete for Scotland as a whole.

The group were asked to note that:

- procedures SUI and POP are reported against the health board where treatment took place
- mesh removals and over sewing procedures are reported against the health board of residency
- readmissions are reported for the health board where the treatment took place, however readmissions are for all causes, not just complications from procedures
- all procedures are included in the data, not just the first recorded procedure for each woman

The group proceeded to review the data in the following areas:

- Mesh for SUI
- Non-mesh for SUI
- Transvaginal mesh for POP
- Trans abdominal mesh for POP
- Non-mesh for POP
• Removals/over sewing mesh procedures

A query was raised by the Subspecialist Urogynaecologist regarding the data for transvaginal mesh for POP. Discussions followed around incorrect codes perhaps being used in error. It was agreed that the ISD Clinical and Public Health Lead for Maternal and Sexual Health Information, will follow up with health boards regarding the coding issue.

The Subspecialist Urogynaecologist, commented on the contrast in the data in terms of mesh versus non-mesh procedures. The primary care representative, added that more patients are opting for conservative management rather than surgery. It was noted that waiting times for physiotherapy are increasing and that this could make the patient care pathway even more difficult as the physiotherapist is often expected to be first line of care. Discussion evolved around how many women are not coming forward to speak to their GPs or seek treatment. It was felt that instead patients are trying to self-manage. The group felt this is reflected when reviewing the data.

The Chair asked for thought to be given on how the data can be best represented in order for it to have an impact and to whom it can be directed. The Data and Measurement Advisor advised that there are some parts of the data that could be shared, by agreement with ISD. He added that internal discussions are needed to establish how to publish the data, but in a way which would not identify individuals.

The representative of the Scottish Association of Medical Directors (SAMD) noted that it would be useful to find out if there is a rise in the use of pessaries since the halt of mesh procedures. The use of pessaries is not coded and a separate assessment would need to be done to try and capture this level of detail. It was also pointed out the complexity of gathering this data as they are inserted in both primary and secondary care.

The TVMO group reflected on how to capture this type of treatment intervention as well as identifying themes and data trends. The group acknowledged the importance of logging these points for any final reporting on gaps in knowledge and data.

The Data and Measurement Advisor explained that the number of procedures had not been presented as a rate per resident population, because the value of this was being questioned. He asked the TVMO group if this information was needed in order to be aware of the number of procedures in health boards. It was agreed that it would be helpful to have this information and especially useful to pass to the AO's. The Data and Measurement Advisor agreed to prepare an SBAR on the best way to look at the number of procedures for discussion with members of the TVMO Data Subgroup.

The Chair summarised discussions and thanked the Data and Measurement Advisor for the data summary and for his very clear presentation and analysis.

b) Adverse event reporting (IRIC/MHRA)
The Chair invited the IRIC Coordinator to speak to this item and asked colleagues to refer to papers TVMO-45 and 46.

The IRIC Coordinator referred to paper TVMO-45 and reported that:

- the figures are for all Scottish adverse incident reports that have been received for SUI and POP from 2008 to 2019
- incidents are mainly submitted by clinicians
- members of the public can report incidents using the yellow card system/MHRA but are not included in the TMVO report
- at least 25 per cent of recorded incidents have no named product manufacturer
- one manufacturer is stopping production rather than continuing to invest in clinical data to support additional EU requirements and have withdrawn their product completely from circulation
- not all health boards have reported incidents to IRIC
- information of the referring board to the tertiary centre is not available.

The IRIC coordinator provided an overall summary of the paper adding that incidents have been reported since 2014. For this year the number received is low and the next report would be due in December 2019.

**MHRA**

The IRIC coordinator referred to paper TVMO-46 MHRA. She reported that:

- adverse incident reports involving SUI and POP were greater in 2015
- a decrease in number of healthcare professionals reporting was noted
- a change in reporting for POP and SUI, which will become clearer at the end of the year.

The Chair summarised discussions and thanked the IRIC Coordinator for her helpful analysis and input.

c) **Evidence**

The Chair invited the evidence colleagues to speak to this item and asked the group to refer to paper TVMO-47

The Lead Health Services Researcher advised that a systematic search of the secondary literature was carried out from January 2019 to June 2019. The evidence report was a summary of evidence published since January 2019.

It was reported that:

- An updated NICE clinical guideline on the management of urinary incontinence and pelvic organ prolapse had been identified. A list of papers informing the relevant recommendations within the guideline has not been provided as the evidence base is extensive; instead a hyperlink is provided.
Two recommendations have been withdrawn since the publication of the guideline and instead a reference inserted to the relevant IP guidance. While the NICE clinical guideline has no status in NHSScotland, Scotland subscribes to the IP programme and therefore these recommendations should be followed in Scotland.

It was agreed that a couple of corrections to the referencing were required and that a new version of the paper with these changes would be provided.

The next literature update will cover material published up to the end of December 2019.

Going forward there is a need to decide on target audiences for the evidence syntheses and a dissemination strategy agreed. AOs, Medical Directors and other constituencies seem relevant. It was suggested that the current report be combined with the update for the next six months and then this circulated to interested parties.

To ensure the evidence material selected is clinically accurate and relevant, the Lead Health Services Researcher, advised that it would be helpful to have a, ‘clinicians’, input. It was agreed that the Lead Health Services Researcher liaise with the group's two Subspecialist Urogynaecologist's and the SAMD representative.

The Chair thanked the HSR team for their comprehensive and very welcome review.

3. Standing Items (continued after lunch)

3.2 Patient Resource Subgroup (Research Analyst joined the meeting)

The Chair provided an overview of the recent activities of TVMO patient resource subgroup. She advised that they had met three times since the TVMO meeting in September 2018, with their work focussing mainly on reviewing patient information leaflets. Two main methodologies were trialled for assessing patient resources: the, ‘discern tool and user testing’. The Chair asked the Health Services Researcher to speak to paper TVMO-48.

a) Discern

The Health Services Researcher provided background information around the Discern tool. The following key points were noted:

- A total of 61 patient information resources on treatment for SUI and POP were systematically identified (national and international) and quality assessed using the discern tool. 32 of the resources were treatment options for POP and 23 for SUI. Only three were explicitly about mesh implants, and the remaining three leaflets were covered other related topics.
- The resources providing information about treatment options for SUI scored the highest average score (4). The rest of the publications scored an average of three on the discern tool.
- The common strengths of information resources across the different topics were the clarity of their aims and how well they were achieved. Another was the description of different treatments and how each treatment works, as well as their benefits and risks.
The common weaknesses of publications were related to the lack of information about the references that were used to compile the publication, the date of publication or the consequences of undergoing NO treatment.

A full discussion followed with the following observations being noted:

- Scores were presented as an average score.
- Low scoring organisations were emailed advising of their score outcome.
- The discern tool, although effective, did not capture visuals well
- Resources were assessed by patients and one clinical member of the TVMO patient resource subgroup.

The group discussed the value of sharing the learning from this piece of work. A public partner advised that she had hoped to speak to this item and share the learning from this exercise via the Scottish Health Council’s public partner conference. Some limitations of the discern tool were noted. One board member also noted how interesting it would be to have medical consultants conduct this same evaluative exercise to compare scores. Again the issue of how best to disseminate insights from this exercise to boards and others was raised. The Health Services Researcher advised that with regards to next steps it was agreed she would work with the Research Analyst to combine the findings and the user testing piece into a joint publication.

The Chair thanked the Health Services Researcher for her hard work and input. She also thanked all the TVMO patient resource subgroup members who devoted time to assessing the leaflets.

b) User testing

The Chair invited the Research Analyst to speak to this item and asked the group to refer to papers TVMO-49 and TVMO-50.

The Research Analyst advised that:

- The user testing process consisted of a series of interviews reviewing two leaflets with patients that would then be transcribed (26 hours in total).
- Two resources were identified as being of good quality using the discern tool, one on mesh complications and the other on pelvic floor exercises. Both were used during interviews one after another.
- In total 13 patients took part in the user testing interviews, six patients with lived experiences, one carer and six staff members from Healthcare Improvement Scotland.
- Interviews were mostly carried out at Delta House, however one was held in Dumfriesshire and a video conference with a patient from Shetland.

The Research Analyst, continued to explain the findings and how they were coded against the analytical Honeycomb model. The following key points were discussed:
• Both resources were considered clear and helpful by participants. However, participants’ opinions varied greatly and neither resource was universally liked or disliked.

• For both resources, barriers to understanding included the use of technical terminology.

• The use of a diagram facilitated understanding in one resource (pelvic floor exercises resource) but was seen as a barrier in the other (complications resource).

• Usability of the resources was influenced by font size, page layout and the use of headings and bullet lists.

• In both resources the physical appearance of the resources was considered a barrier to desirability. Although in most cases, participants reported they would pick up the resources because they had a personal interest in the content.

• Participants reported they would use the advice in the resources. The use of NHS branding promoted credibility and participants reported the detail of the information and tone of the writing promoted transparency.

Following discussions the group agreed that the user testing write up paper should move forward and the team should aim to publish the findings. The Research Analyst advised she would be working with Health Services Researchers from the Knowledge and Information team.

The Chair summarised discussions and congratulated everyone involved with the patient resource subgroup for this impressive piece of work. She also thanked the TVMO Programme Manager who conceived of the framework and approach; the Project Officer who conducted all the fieldwork and the Research Analyst and the Health Service Researcher, who led the analysis and write up of the two pieces of work.

3.3 Self-evaluation tool (SET)

The Chair asked the TVMO Programme Manager to update the group on the progress to date with the SET. The group were asked to refer to paper TVMO-51.

The TVMO Programme Manager reported that:

• 11 out of 14 responded to the SET request with two being submitted after the closing date and one return was a no response.

• A stakeholder subgroup was formed to analyse the 11 SETs.

• During analysis the stakeholder subgroup concentrated on three specific areas, they were:
  
  Establishing out of date information
  Where more information was needed, and
  Identifying areas of good practice.

• The preliminary SET analysis and tailored feedback have been circulated to each health board and they have been given another six weeks to respond with comments, elaborations and clarifications.
• The stakeholder subgroup will meet again in September 2019
• Final output will be one report split into three regional sections.

Acknowledgement was given to the Senior Project Officer with the Scottish Health Technologies Group for their invaluable contribution throughout the SET process. The final report is due late Autumn 2019.

The chair thanked the TVMO Programme Manager adding that the hard work from the HIS Project Team was very much appreciated.

4. Any other business

4.1 Exit Strategy

The Chair opened up a full discussion with the group on how the next six to eight months are to be managed as we reach the end of the project. She asked the group to consider goals and targets and how we ensure what we have done achieves proper notice and impact.

The TVMO Programme Manager added that the group has achieved a lot and we will aim to showcase the deliverables as well as investigating who will take over the work. She added that a meeting will take place with Scottish Government colleagues to establish which group the work will become the successor to the TVMO, and incorporate the work.

The TVMO group discussed the following:
• succession planning was felt to be important. Questions were asked, such as, where should the work of the TVMO group properly sit? The SAMD representative advised that the AO group could be expected to fulfil this role
• a good deal of debate took place about the need for enhanced patient representation on both the AO group and on the SLWG going forward. There was a groundswell of views that the value of broad patient voices and direct patient involvement should be highlighted as this been essential to the success of TVMO activities. A public partner advised of how the SMS were being represented by a clinician at the SLWG. A clinician member suggested that additional mechanisms are also needed to increase patient voice for the longer term.
• the TVMO group want to ensure that the work they have carried out can be meaningfully incorporated into the Scottish Government's future work around mesh. This will be raised in deliberations with the Scottish Government in late summer/early autumn
• Consideration will be given as to how achieve quality performance indicators using the best quality of evidence. Scottish Government would need to commission this, although the final output would need to be clarified.
• A final report will be created to synthesise and show case the work and to enable handover of TVMO.

The chair summarised discussions and thanked everyone for their contribution to these important discussions. She stressed that we need to recognise and support the project team as there will be a high level of effort and complexity involved during the transition and handover period. She advised that it would be good to perhaps working backwards from the closing down deadline.

Project Team/TVMO Chair
The TVMO Programme Manager raised the issue of the NHS 24 Inform website content, following the recent media interest. She referred to a parliamentary question answered by Jeanne Freeman, Cabinet Secretary, MSP on 6 June 2019. The statement was read out by the TVMO Programme Manager:

“Advanced specialist services are currently provided in Scotland by two Mesh Complication Centres, one in NHS Lothian and in NHS Greater Glasgow and Clyde. These centres offer a range of treatments, including partial and full mesh removal, as well as non-surgical interventions. Patients should not hesitate to discuss with their GP”.

The statement was discussed and the following points made:

- the awareness of the Advanced Specialist centres is not universally shared at present by patients or all health professionals
- GPs retain a key role in patient referral
- self-referral for incontinence is available in some boards but variations in care pathways remain.

The group agreed that it might be best to retain the status quo and that the website could be subsequently changed once an agreed pathway from the AOs group is in place and communicated to all.

5. Date and time of next meeting

5.1 Stakeholder Subgroup, Tuesday, 24 September 2019, 2pm
TVMO Group, Wednesday, 11 December 2019, 11am.
All meetings at Delta House, 50 West Nile Street, Glasgow.

The Chair thanked everyone for an excellent meeting and wished everyone a pleasant summer and drew the meeting to a close.