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

**Date** 28 June 2018, 11–3:30pm  
**Venue** Meeting room 6A, Delta House, Glasgow G1 2NP

### Present

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
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<tbody>
<tr>
<td>Lorna McKee</td>
<td>Chair</td>
<td>Incident Reporting and Investigation Centre (IRIC)</td>
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<tr>
<td>Karima Et Taouil</td>
<td>IRIC Co-ordinator (deputy for Innes Connor)</td>
<td>Scottish Intercollegiate Guidelines Network</td>
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<tr>
<td>Sarah Florida-James</td>
<td>Programme Manager</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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<tr>
<td>Christine Jess</td>
<td>Public partner</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Sharon Mercado</td>
<td>Patient representative</td>
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<tr>
<td>Carol McCambley</td>
<td>Stakeholder engagement manager</td>
<td>NHS 24/NHS Inform</td>
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<td>Isobel Montgomery</td>
<td>Patient representative</td>
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<tr>
<td>Jackie Montgomery</td>
<td>Team Lead Physiotherapist</td>
<td>NHS Greater Glasgow and Clyde</td>
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<tr>
<td>Tim Norwood</td>
<td>Data Measurement Advisor</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Mahesh Perera</td>
<td>Consultant Gynaecologist</td>
<td>Royal College of Obstetricians and Gynaecologists</td>
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<tr>
<td>Nicola Steedman</td>
<td>Clinical and Public Health Lead for maternal and sexual health information</td>
<td>Information Services Division, NHS National Services Scotland</td>
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<tr>
<td>Sara Twaddle</td>
<td>Director of Evidence</td>
<td>Healthcare Improvement 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 Wilkins</td>
<td>Subspecialist in Urogynaecologist</td>
<td>NHS Lothian</td>
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### In attendance

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<tr>
<th>Name</th>
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<tr>
<td>Nikolina Angelova</td>
<td>Health Service Researcher (observer)</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Uzma Aslam</td>
<td>Programme Manager</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Hilda Emengo</td>
<td>Health Service Researcher</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>Sarah O’Shaughnessy</td>
<td>Administrative Officer</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Fiona Wardell (part-meeting)</td>
<td>Team Lead Standards and Indicators</td>
<td>Healthcare Improvement Scotland</td>
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### Apologies

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<th>Name</th>
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<tr>
<td>Innes Connor</td>
<td>IRIC manager</td>
<td>IRIC</td>
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<tr>
<td>Karen MacPherson</td>
<td>Lead Health Service 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>Iain Stewart</td>
<td>Health Information Scientist</td>
<td>Healthcare Improvement Scotland</td>
</tr>
<tr>
<td>Brenda Wilson</td>
<td>Deputy Director of Nursing and Care</td>
<td>NHS 24 and Scottish Executive Nurse Directors (SEND)</td>
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**Item no** | **Item** | **Action**
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1. | Opening business |  
1.1 | Welcome, introductions and apologies | The Chair welcomed everyone to the third meeting of the oversight group and apologies were noted as above. The Chair welcomed the new members of the group to the meeting.  
1.2 | Declaration of interest | The Chair noted that any changes to member’s declaration of interests should be brought to the attention of the project team.  
The group discussed the DOI forms and how they are more tailored towards professional representatives rather than public and patient representatives. A request was made that the DOI form be revisited by the project team.  
1.3 | Minutes and action points of meeting held on 12 April 2018 | The group received the previous minutes from the meeting held on 12 April 2018 (paper TVMO-16). The following comments were made:  
- Item 1.1 – the fourth bullet point under ‘Group expectations included’ should read ‘improving the reporting, processing and recording of adverse events’ instead of ‘promotion of adverse incidents’.  
- Item 2.2 – there is a typo in third bullet; it should read ‘faecal incontinence’ not ‘foetal incontinence’.  
- Item 2.2 – a query was raised about the wording of the second bullet point which stated that ‘fewer mesh procedures are being undertaken in Scotland’. It was agreed, however, that this should not be changed as it had been raised as a comment at the previous meeting.  
- Page 7 – third paragraph under ‘Evidence’ it should read ‘If the group requires quantitative data, the evidence team can review this but qualitative feedback would require a further literature search and clinical input’. The reference to ‘a few weeks’ has also been removed.  
- Under 5.1 – ‘Stephen Ferguson, Communications Manager’ should be replaced with “Healthcare Improvement Scotland communications team”.  
- The role of physiotherapy was not noted in minutes but had been raised in the previous meeting under ‘AOB’. This will be added to the minutes.  
- The HIS project group will circulate the contact details of communications team to the group following the meeting.  
HIS project team

Taking all comments on board the minutes of the meeting on 12 April 2018 were accepted as an accurate record. The project team will publish the final minutes on the HIS website and permanently erase the recording.  
HIS project team
The group received the action point register (paper TVMO-17) for review from the meeting held on 12 April 2018 and noted the status report against each action.

The following action points were highlighted to the group:
- NHSScotland boards are aware of the self-evaluation tool which they are due to receive in the autumn 2018.
- The quality of coding has been raised with the NHSScotland Medical Directors.
- Both patient information and NHS Inform will be considered in more depth later in the meeting.

The physiotherapy representative on the group provided an update on the progress made with finding referral figures for women receiving physiotherapy. After identifying the relevant NHS board physiotherapy leads she held several phone calls with them and collected the information. This work is ongoing and the team lead physiotherapist requested that group members contact her directly with any feedback or suggestions.

From her initial conversations:
- The physiotherapist leads have been updated on the work of the TVMO group. This will help get support and feedback information to the physiotherapists, which will encourage two-way communication
- Data on women who have received physiotherapy has been requested from team leads but the data available is not in a presentable condition, it was reported that mesh from non-mesh cases could not be separated.
- There has been an increase in referrals to physiotherapists for pelvic cases. Referrals have been compared between two different time frames and a 27% increase was noted, though they are unable to confirm if they are related directly to one condition.

Following the update the group had a full discussion around this and the following was noted:
- NHSScotland boards have been asked whether there is a way to break down incontinence and prolapse referrals.
- Many treatments are currently conducted within the community but the data identified is from acute sites, such as hospitals. The team lead physiotherapist agreed to contact community physiotherapists for further data.

### 1.4 Chair’s update

The Chair and the Director of Evidence met with the Chief Medical Officer (CMO) on 13 April 2018. The meeting was very positive with the CMO being pleased with the progress to date and with the group membership. The Chair advised that at the meeting the CMO gave a clear message that the TVMO group should be producing small targeted outputs (periodically) rather than a single final report.

There has been some recent media attention around the work of the TVMO group. The media coverage was largely negative and highlighted individual members. The Chair emphasised that the work being done is a team effort and support will be given to those who need it. It was reiterated that if any members of the group are...
contacted by the media, they should get in touch with the HIS communications team.

2. Standing Items

2.1 Review of Data

a) TVMO data subgroup

It was agreed at the TVMO data subgroup meeting on 20 June 2018 that the group had fulfilled its role in defining the data specification for the main TVMO Group and would therefore be paused.

b) Data on numbers of mesh and non-mesh procedures in Scotland (tabled paper)

The HIS data measurement advisor presented an overview of the most current HIS analysis of data provided by ISD to the group. The following points were raised:

- The ISD data presented were for primary procedures only, the numbers are therefore smaller than if all procedures were included.
- The data has been limited by excluding people who have had a primary procedure in the last 5 years.
- Both mesh and non-mesh procedures for SUI were included for comparison. Mesh procedures for POP were also included. It includes data for readmissions within 30 and 365 days.
- The team highlighted that the data are not directly comparable as many mesh and non-mesh procedures have different levels of invasiveness and therefore might present different risks of complications and readmissions.
- It was suggested that having the rate (as opposed to just the number) of women readmitted would be the most useful for examining the data. In addition, presenting the data differently would be useful to the group, as well as excluding the readmission within 365 days data as this was not judged as helpful. The HIS data measurement advisor will review the data and send it to the group.
- It was agreed that it would be useful to have the key points of what the data presented summarised for the group in addition to detailed tables. Therefore, in future, the data analysts will produce the report in the same format but include a narrative. In advance of the meetings, high level figures should be sent to the TVMO group, if approved by the ISD Caldicott Guardian, and the data measurement advisor can interrogate the data in more depth at the meeting if required.
- The group revisited the decision to look only at primary procedures. Whilst these might be more appropriate for any comparative purposes, there are other reasons why comparisons between mesh and non-mesh procedures are cautioned against, including the inappropriate comparison of procedures with different levels of invasiveness and risk, and also the fact that different patient populations may be selected for different procedures. It was felt, in the end, that the role of the TVMO Group was to have oversight of the overall numbers of mesh and non-mesh SUI and POP procedures in Scotland, therefore it was...
agreed to go back to reporting on total numbers of procedures and not just primary procedures.

- The group were keen to have data on the number of ‘non-mesh POP procedures’ which had not been provided to date due to the perceived complexity of the number of such procedures. ISD agreed to examine this again with clinical representatives on the TVMO group to see if a list of ‘non-mesh POP’ procedures with appropriate codes could be agreed and, if so, if data on these could also be provided within the current data analysis financial bundle.

Data Measurement Advisor

c) **Adverse event reporting (IRIC/MHRA)**

There was a general group discussion first which centred around three separate points:

1. A national database.
2. Reporting incidents and adverse reporting, and
3. Clinical governance.

A discussion followed about how the data is received, collated and followed. It was agreed that there is often difficulty with the continuity of the information that is sent to IRIC and MHRA.

The group discussed that there was a general lack of clarity regarding reporting and that there is a risk of an individual clinician with poor outcomes being unaware of it. The differences in managing personal audits versus overall reporting was highlighted.

The group discussed the lack of an audit trail regarding patient information due to several factors. These factors include: patient hospital records being destroyed after 10 years if there has been no recent activity, key information not being fed back to the patient's GP and details of the procedure, including the device manufacturer on the hospital records but not passed back to the patient or GP.

Figures for the numbers of mesh procedure patients who have reported an adverse event to the IRIC were presented to the group. The number of incidents reported to IRIC were compared with those reported to the Medicines and Healthcare products Regulatory Agency (MHRA).

The following was discussed by the TVMO group:

- A mixture of databases are used by MHRA, IRIC and the various health boards, meaning systems do not always communicate well with each other. Health boards can contact IRIC relating to an adverse event which IRIC can then pass on to MHRA. IRIC do not receive reports from patients, who use the yellow card system and communicate directly with MHRA. Clinicians can report both to IRIC and the MHRA.

- There was discussion around why patients may be reluctant to report an incident. It was felt that the yellow card system may not be advertised well enough for patients to know that they can use it. There should be information on this on NHS Inform which the representative from NHS Inform will check.
After the meeting it was highlighted that the current Patient Information Leaflet (issued November 2016) has a list of useful links, including to the MHRA and the ‘Yellow Card System’.

d) Evidence

The evidence team updated the TVMO group on their progress and presented paper TVMO-21 for discussion. The group discussed the proposed key questions presented by the evidence team:

- Questions 2 and 3: What is the evidence on the use, efficacy and safety of transvaginal mesh implants (TVMO) for women with stress urinary incontinence (SUI) and pelvic organ prolapse (POP) compared with appropriate comparators (for example, mesh vs non-mesh; mesh vs mesh, mesh vs standard care)?
- Question 4: What are the experiences and perceptions of women with SUI and POP of TVMO and what is the quality/usefulness of the information they received before and after the procedure compared with women who opted for non-TVMO procedures or standard care?

The following was discussed:

- Research questions 2 and 3 were agreed. It was agreed that it was best to keep the research questions broad as the information will become more focussed through the research process.
- It was suggested that question 4 would be broken into 3 sub-questions. It was highlighted that there are limits to the quality of the information that can be provided particularly in relation to the experience of the women who have had the procedure as the data may not provide this information.
- Amending question 4 to attempt to get the views of women who have had mesh in comparison to the perceptions of women who have not may be useful.
- A discussion took place about the information that is available to patients before and after operations. This research may be a separate piece of work to find out what is available to patients and also to consider what information may be useful to patients. It was agreed that it was important for the literature search to review what is available for both before and after procedures, information on patient aftercare and support was of particular interest to the group.
- The evidence team reiterated that early searches suggest that there is a limit to the amount of qualitative literature available.

The evidence team provided a list of resources, organised by topic which could also be given to the patient information subgroup for consideration.

Additional resources were identified that may be useful to consider:

- International Urogynaecology Association, a non-UK resource, very useful and available in a range of translations.
- International Continence Society is another high quality resource for patient information.
- It was suggested that the Scottish Government Patient Information Leaflet from 2014 has been surpassed by a 2016 version, it was agreed this would be checked.
The NHS Inform representative noted that although it may appear that there is some duplication with the NHS Choices and NHS Inform resources as they work together, NHS Inform has information relevant to Scotland so worth considering separately.

A member of the project team will email the list of patient resources provided by the evidence team to the group.

2.2 Patient information sub-group

The TVMO programme manager outlined the work that had been undertaken since the last meeting. The key points were as follows:

- A Twitter account has been set up to promote engagement.
- Swati Jha has been contacted regarding the shared decision tool that is being developed in Sheffield.
- The HIS project team are liaising with the Patient and Public Involvement team for them to contact members of the public to join the patient information subgroup.
- The Scottish Women's Convention (SWC) have responded to say they have been unable to secure volunteers to be involved in a focus group.

The TVMO programme manager presented a proposal for the TVMO group to consider. The following outputs were identified for the group to consider:

a) review the existing patient information
b) recommend information updates NHS Inform, and
c) Identify and recommend a leaflet for patients if appropriate.

The TVMO group discussed this proposal and the following was noted:

- The group discussed who would take ownership of the information available to the public after the TVMO group are disbanded. It is essential that information available is accurate, up-to-date and that key messages consistent throughout. At the moment there is information on the NHS Inform website, however they are unable to take ownership of the information as they are not subject matter experts and require clinical input. It was agreed that the TVMO group will take ownership of the information that is on NHS Inform website with ownership being passed to the MCN upon its creation.
- It was highlighted that different types of media may be better for different patients. One group member suggested that YouTube videos may be a useful tool that more patients would be able to access. A request was made for multimedia resources to be added to the evidence resource list. The question of who would be responsible for producing and maintaining multimedia was raised.
- The Patient Information Leaflet (issued November 2016) was discussed and highlighted as a valuable resource by some group members.
- It was agreed by the TVMO group that a patient information subgroup should be established to ensure patient intended outputs were up-to-date and based on patient needs.
2.3 Reporting

a) Scottish Government
A progress update had recently been shared with Scottish Government. See document TVMO-23 for more information.

2.4 Self-evaluation tool

Background information and an update to the development of the self-evaluation tool (SET) was provided. The HIS programme manager explained that:

- The Quality Assurance Directorate (within HIS) have been rolling out a ‘quality of care’ approach to ensure consistency and improved patient experience. The SET will be aligned with this approach.
- A letter has been issued to NHSScotland Medical Directors advising them of the development of the SET. Two health boards have been identified to pilot the SET (NHS Lothian and NHS Grampian). The pilot will begin shortly for a period of 8 weeks. It was noted that the two health boards chosen are of particular value due to the mix of city and remote and rural. The information returned from the pilot will be used for key learning and identify any gaps within the SET.
- The SET will be rolled out to the health boards with each board being assessed individually. It will highlight what is done well and what can be improved so that they can compare their own outcomes over time rather than with other health boards. It is not a benchmarking exercise.
- The ultimate aim of the SET is to review how health boards are working to gain consistency across NHSScotland. HIS will receive anonymised information from the SET, which can be aggregated.

It was confirmed that the TVMO group will get sight of the SET before it is distributed to the health boards.

The group confirmed that they were content for the SET to proceed.

3. Any Other Business

3.1 Offline Item
An update was provided on the responses received from Medical Directors on the pathways of care. From the responses received it could be noted that:

- The West of Scotland are progressing with developing a shared pathway of care.
- The North and East of Scotland are still at an early stage in work.

Overall the feedback received has been very positive and the health boards are appreciative of what the TVMO group are doing.

3.2 Communication strategy
Given the recent media interest in the group, the communications team had suggested that the group identify the key messages they would like to share with their audiences. To help with this Stephen
Ferguson, Communications Manager, will attend the September meeting to discuss this further.

3.3 Exit Strategy
The need for the TVMO group to develop an exit strategy was raised. At the end of the two year period, the TVMO group will hand over to a clinical network that is currently under development.

It was agreed that any concerns or risks identified by the TVMO group would be fed back to the Scottish Government by the Director of Evidence.

4. Date and time of next meeting
4.1 Tuesday 18 September 2018, 11–3pm, meeting room 6A, Delta House, Glasgow