MINUTES

Transvaginal Mesh Implants Oversight group (TVMO)

Date 14 December 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>
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<tr>
<td>Marie Duffy</td>
<td>Patient representative</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>Gail Lumsden</td>
<td>Stakeholder engagement manager</td>
<td>NHS 24/NHS Inform</td>
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<tr>
<td>Sharon Mercado</td>
<td>Patient representative</td>
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<tr>
<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>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 Wilkens</td>
<td>Subspecialist in Urogynaecologist</td>
<td>NHS Lothian</td>
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<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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In attendance

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<tr>
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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>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>Tracey Mitchell</td>
<td>Project Officer</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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Apologies

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<tr>
<th>Name</th>
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<tr>
<td>Karima Et Taouil</td>
<td>IRIC Manager</td>
<td>Incident Reporting and Investigation Centre (IRIC)</td>
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<tr>
<td>Sarah Florida-James</td>
<td>Programme Manager</td>
<td>Scottish Intercollegiate Guidelines Network (SIGN)</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>Tim Norwood</td>
<td>Data Measurement Advisor</td>
<td>Healthcare Improvement Scotland</td>
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Item no Item Action
1. Opening business
   1.1 Welcome, introductions and apologies
The Chair welcomed everyone to the fifth meeting of the oversight group and apologies were noted as above.

A warm welcome was extended to our new patient representative, Marie Duffy who has joined the TVMO group. It was noted for information that she has already attended and is a member of the Patient Resource Subgroup.

As well as the new arrival, the chair announced the departure of several members of the group:

- Karima Et Taouil, IRIC manager is leaving to take up a post with NSS. Her successor is to be announced.
- Sarah O’Shaughnessy, the project team’s administrative officer has been successful in obtaining a secondment opportunity as a Project Officer and starts her new job in the New Year.
- Sara Twaddle is taking early retirement and leaves her post April 2019.

The chair wished everyone well and thanked them for their valuable contributions.

1.2 Declaration of interests

The Chair asked for members to report any new declaration of interests, two members noted that they had attended a cadaver course since the previous meeting. The course was sponsored by Contura. It was clarified that Contura had no input regarding the contents of the teaching or demonstrations and that the cost of accommodation was paid for by the course. The details will be added to the relevant members’ DOI forms.

It was announced that new DOI forms would be distributed for group members to complete for the following year.

1.3 TVMO Remit

It was agreed at the last meeting that the remit of the group should be restated. The chair referred to the group’s 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 framework to NHS boards for completion and analyse the results, and
- discuss the potential for the development of quality performance indicators (QPIs).
The Chair reiterated that despite the halt on the use of transvaginal mesh implants in Scotland the work of the group could continue with the above remit.

Due to the importance of the group’s remit it was agreed that the remit of the group would be added to future agendas and highlighted at meetings in 2019.

1.3 Minutes and action points of meeting held on 18 September 2018

The minutes from the meeting in September were previously circulated by the project team and comments received were incorporated. The minutes were noted as being an off-line item. Group members were asked to email the HIS project team with any further 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:

- a request for a report on waiting times was sent to the Allied Health Professionals (AHP) Directors’ group and then cascaded appropriately
- a good response was received from Health Boards with the Team Lead Physiotherapist following up on the few non responders
- the Chair of the Pelvic, Obstetric and Gynaecological Physiotherapy (POGP) group in Scotland has taken interest in the work and asked for an update, and
- as a member of the patient resource subgroup the Team Lead Physiotherapist is developing a new resource for patients.

Following questions and a group discussion the Team Lead Physiotherapist clarified that waiting times are from both community settings and from hospitals. However there are some areas that have not provided full information as yet.

The Team Lead Physiotherapist requested the permission from the TVMO group to compile a report detailing the number of referrals, physiotherapy resources and average waiting times. The group agreed and it was suggested that the report would initially be shared with the AHP Directors’ group for feedback.

The Chair thanked the Team Lead Physiotherapist for all her efforts and the update.

**Item 1.4.**
The project team were asked to explore if patients are involved in the development of the pathways of care. The project team noted they had contacted Dr Iain Wallace, Medical Director with NHS Lanarkshire who is developing a shared pathway of care for the West of Scotland.

The Chair read out Dr Wallace’s response where he noted that patients were not represented on the group that he chaired but would be involved shaping services at board level.
A discussion evolved around patients being involved at all levels. The patient representatives felt it would be useful to have a better understanding of how patients are currently involved. The Director of Evidence suggested that this would be a useful criterion to include in the self-evaluation tool.

**Item 1.4**

Clarity was sought on the meaning of “high level external review”.

The current process for adverse event reporting is out-of-date and following contact with the Health and Sport Committee Healthcare Improvement Scotland will undertake a review of the process.

The Chair noted that she had no further information regarding the inclusion of qualitative date collection in various trials led by the University of Aberdeen. However the Chair will be speaking with some of the review team on Monday 17 December to get more information.

All other actions are complete or ongoing.

**1.4 Chair’s update**

The Chair noted the following:

- the Scottish Government have agreed additional funding for continuation of the TVMO group in 2019/20
- two meetings of the patient resource subgroup had occurred since the last meeting. A more detailed update is provided under item 3.3
- on 28 November 2018 both the TVMO Chair and the ISD Clinical and Public Health lead for Maternal and Sexual Health Information attended an HQIP-run Stakeholder Workshop meeting in London. The Chair briefed the group on the programme, which included reviewing the data requirements exploratory work organised by Healthcare Quality Improvement Partnership (HQIP). The long term goal on behalf of HQIP is to establish a data register for mesh and non-mesh surgery for POP and SUI which is planned to cover the whole of the UK.

Overall the Chair felt that the event was extremely worthwhile with useful contribution from all stakeholders, including patient representatives.

**1.5 Self-evaluation tool**

The HIS Programme Manager advised that the pilot self-evaluation tool (SET) had been written and issued to the pilot boards at the beginning of September 2018, NHS Grampian and NHS Lothian. The two NHS boards had 8 weeks to submit a response. One response has been received and a meeting will take place with the other NHS board to review the challenges and barriers they faced.

The HIS project team agreed to:
- use the pilot as a learning experience
- make any necessary changes to the SET
- arrange pre-work and/or meetings with NHS boards to raise awareness of what is involved when completing the SET, and
2. **Group Discussion**

2.1 **English ‘pause’ and Scottish ‘halt’**

The HIS Project Officer summarised in a detailed report the differences between the pause in England and the halt in Scotland. A group discussion then followed.

The group members discussed the limited differences between the two countries, whilst also noting that both countries included the need for a “high vigilance process”.

Some of the group suggested that there was a lack of transparency in Scotland and that the role of primary care requires clarification. It was agreed that the group will once more explore how to open up a means of communication with primary care.

3. **Standing Items**

3.1 **Review of Data**

a) **ISD**

In the absence of the HIS data and measurement adviser the ISD Clinical and Public Health Lead for Maternal and Sexual Health Information spoke to paper TVMO-36.

The data summary contained key messages relating to mesh and non-mesh procedures for stress urinary incontinence (SUI) and pelvic organ prolapse (POP). It was reported that the ISD Clinical and Public Health Lead for Maternal and Sexual Health Information was content that the data was accurate in terms of analysis and interpretation and laid out in an intuitive way. The dates covered within the summary were from April 2009 to September 2018, this is due to the fact that many mesh-related codes did not come into use until 2007.

The group were asked to note the following:

- procedures stated are reported when the procedure took place and against the Health Board where the procedure took place
- over-sewing and/or mesh removal is reported against the Health Board of Residence, as a proxy for the original Health Board of Treatment
- readmissions are reported for the health board where the index mesh treatment took place
- readmissions are non-specific, i.e. the data includes patients being readmitted to hospital for any reason, not necessarily those related to the POP or SUI procedure
- the data presented to the TVMO group in June 2018 selected only the first known procedure, whereas this data includes the total number of all mesh and non-mesh procedures.

The group then reviewed 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

The group approved of the new format of a data summary with access to the more granular data if needed. A query was raised regarding the non-mesh for SUI procedure and if it included urethral bulking by injection. It was confirmed that it is included. It was agreed that the data summary to be recirculated with the codes attached as this would be useful for the clinicians to know what is and what is not included.

A group discussion followed regarding the various procedures included and readmission data. A patient representative added that she feels patients are unsure which procedure to have and perhaps they step back from the more invasive procedures. Also discussed was how patients on the waiting list were contacted and their reaction towards invasive procedures.

The Chair summarised discussions and thanked the ISD Clinical and Public Health Lead for Maternal and Sexual Health Information for stepping in at the last minute.

b) Adverse event reporting (IRIC/MHRA)
In the absence of the IRIC representative the HIS Programme Manager spoke to paper TVMO-37 and TVMO-38.

The HIS Programme Manager advised that the IRIC representative had supplied a brief written summary. She added that at the IRIC report includes all the important points about the reporting process in Scotland.

Out of courtesy it was noted that MHRA let IRIC know, for awareness only, when they receive Scottish incident reports from patients. The group were asked to note that patient reports remain out with the IRIC remit.

c) Evidence
The group had been asked to review papers TVMO-39 and TVMO-40 prior to the meeting. Two health services researchers took the group through the individual papers. The first report was on women’s perceptions and experiences of transvaginal mesh implants (TVMO-40)

Points covered were as follows:
• Relevant evidence was gathered using the following research questions:
  ➢ What are the experiences and perceptions of women with stress urinary incontinence (SUI) and pelvic organ prolapse (POP) of transvaginal mesh (TVM) implants?
  ➢ What is the usefulness of the information women receive before and after the procedure?
• The majority of studies included in the report used subjective quantitative measures to evaluate women’s quality of life, satisfaction and sexual function after the transvaginal mesh implants for SUI and POP.

• Discussions followed around using quality of life questionnaires. The TVMO Chair advised that HQIP had a list of validated questionnaires, which was discussed at the stakeholder event in London on 28 November 2018. Following the discussion it was agreed that the project team could incorporate that into the SET questions.

• It was agreed that various quality of life questionnaires should be discussed at the next meeting of the patient resource subgroup. The HIS Project Team will add to the business planning schedule.

The second report was presented to the group (TVMO-39), which was a summary of evidence published since the April 2018 evidence report. Following discussions it was agreed that:

• discussions would take place outside the meeting to explore who the report could be shared with

• the report should be circulated to NHS board Medical Directors for the attention of their accountable officers

• the group should consider a shared decision making tool and areas of funding, and

• the report should be uploaded to the TVMO website.

The TVMO Chair thanked both the health services researchers for their valuable report and input.

3.2 End of year report

The HIS Programme Manager presented a proposed content list for the end of year report. The group were asked to consider what should be included what our key messages would be.

The group agreed that they were comfortable with the proposed content and timelines. The group discussed that a primary care representative would be an excellent addition to the group and consideration also be given to recruiting an incontinence nurse. The Deputy Director of Nursing and care agreed to forward contact details to the project team to establish contact.

The Chair summarised discussions and thanked the HIS Programme Manager.

3.3 Reporting

Scottish Government

The HIS Project Officer referred to paper TVMO-41 advising that the update report was for information only as it had already been submitted to the Scottish Government.

The co-Chair for the patient resource subgroup provided a verbal update to the group. The following points were covered:

- the subgroup has met twice since the last TVMO meeting (on 8 October 2018 and on the 16 November 2018)
- 61 written patient resources have been reviewed using the independent Discern Tool to evaluate content
- most group members are positive regarding the Discern Tool, although it was noted there was a lack of consideration of visuals and also the randomisation aspect was queried
- further analysis work on the Discern Tool findings is being carried out with the HIS project team and Evidence team.
- any identified gaps will be incorporated into the user-testing phase, which begins January 2019, and
- user-testing for selected resources will be carried out with interviews being transcribed and categorised using Peter Morville’s honeycomb model.

The discussion concluded with the co-Chair updating on the next steps in the process and advising that the TVMO group will be kept abreast of the work as it progresses.

4. Any Other Business

4.1 Professor Britton Report

The Chair and the Director of Evidence spoke to this item and summarised the context and some of the relevant findings and recommendations of the report. It was noted that the Britton report focussed on process and was not tasked with apportioning blame or questioning the actual conclusions of the review. It concluded that there were systematic process failures during the mesh review and the lead up to its publication.

Although primarily directed at guiding future Independent Review processes, a number of the insights and recommendations are of relevance to the conduct and processes of an oversight group. The following points were singled out:

- the Chair should have involvement in the title and the remit of the group
- all members are asked to contribute towards the remit
- there should be consultation on the remit
- the Chair should identify areas that may have the potential to compromise the independence of the investigation. This is part of their overall duty to ensure an effective inquiry process and public confidence in the outcomes and recommendations.
- a process should be in place to identify and measure potential conflicts of interest to ensure that a proportionate response can be made
- the selection and appointment of the Chair should be an open and transparent process
- the Chair should have no personal or perceived conflicts of interest
- the Chair should be involved in the appointment of group members
• group members should have equal access to information and contact
• it is important to remind the group of its remit, and each individual should feel heard
• there should be realism about expectations, and
• when referring to reporting methods and media handling, information should be transparent and evidence based.

With regard to TVMO group and the salience of these recommendations the following observations were made:

• the Director of Evidence explained that she had been involved in the early stages of naming the group and shaping the remit prior to the appointment of the Chair
• the specific recommendation for consultation on remit did not fit with the process by which HIS was commissioned to undertake this work
• the Chair was interviewed and appointed through a formal open selection process
• broad group membership was discussed with the Chair
• the issue of conflicts of interest are addressed at each meeting with all members including the Chair completing and updating their DOI on a regular basis
• there is strong emphasis in the conduct of meetings on ensuring that all voices are heard; and that group members are equally given access to information; and treated respectfully
• the group remit is revisited at each meeting to ensure expectations are managed and the focus retained, and

A point of clarification was made by one of the patient representatives regarding a statement made within Annex 2 of Professor Britton's report. The statement questioned authorship of the patient representative’s personal report to the Independent Review, March 2017. The statement implied that the patient representative may not have written the report herself but had help from experts, and on that basis went on to question the independence of the patient representative. The patient representative found that this challenged her professional integrity.

The patient representative clarified to TVMO group members that her personal report to the Independent Review was entirely her own work and that her independence was not jeopardised.
4.2 Health Board Accountable Officers Group Meeting and Exit Strategy
Scottish Government have established a Health Board Accountable Officer’s group to oversee surgery for SUI and POP. It was noted a meeting is arranged for February 2019. The links between TVMO and this group are to be clarified and a discussion to take place about how the remit and roles will play out over time.

An exit strategy for the TVMO group was also raised as a discussion point and should be a consideration for meetings in 2019. The HIS project team will add to the business planning schedule for future meeting agendas.

4.3 An opinion was sought by TVMO group members about patients receiving a hard A4 sheet of paper with all the relevant links to the various patient resources. A small discussion followed where opinions were shared. It is felt the best option would be give the patient the choice whether to receive such a list. The Team Lead Physiotherapist added that the majority of patients are using mobile devices to access the internet and leaflets and resources need to be accessible in this particular format.

4.4 Any other business
The Chair also suggested that it may be timely for group members to have a second audit of meeting processes to reflect if there are any areas for improvement. The project team agreed to circulate a survey to the group.

5. Date and time of next meeting

5.1 Thursday 27 June 2019, 11–4pm
Wednesday 11 December 2019, 11–4pm

Patient resource subgroup:
Tuesday 26 March 2019, 1pm