# MINUTES

Transvaginal Mesh Implants Oversight group (TVMO)

**Date**  
18 September 2018, 11–3:30pm

**Venue**  
Meeting room 6A, Delta House, Glasgow G1 2NP

## Present

<table>
<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>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>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</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 (deputy for Carol McCambley)</td>
<td>NHS 24/NHS Inform</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>NHS Greater Glasgow and Clyde</td>
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<tr>
<td>Tim Norwood (part meeting)</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>Helen Storkey</td>
<td>Information Consultant (deputy for Nicola Steedman)</td>
<td>Information Services Division, NHS National Services Scotland</td>
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<tr>
<td>Sara Twaddle (part meeting)</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 Urogynaecology</td>
<td>NHS Lothian</td>
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## In attendance

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<tr>
<th>Name</th>
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<tbody>
<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>
</tr>
<tr>
<td>Hilda Emengo</td>
<td>Health Service Researcher</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Stephen Ferguson</td>
<td>Communications Manager</td>
<td>Healthcare Improvement Scotland</td>
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<tr>
<td>Billy Hislop</td>
<td>Category Manager</td>
<td>National Procurement</td>
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<tr>
<td>Paul Hornby</td>
<td>Head of Strategic Sourcing</td>
<td>National Procurement</td>
</tr>
<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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<tr>
<td>Fiona Wardell</td>
<td>Team Lead Standards and Indicators</td>
<td>Healthcare Improvement Scotland</td>
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## Apologies

- Lorna McKee
- Karima Et Taouil
- Sarah Florida-James
- Margaret Hogg
- Christine Jess
- Gail Lumsden
- Sharon Mercado
- Jackie Montgomery
- Mahesh Perera
- Helen Storkey
- Sara Twaddle
- Veenu Tyagi
- Julia Wilkens
1. Opening business

1.1 Welcome, introductions and apologies

The Chair welcomed everyone to the fourth meeting of the oversight group and apologies were noted as above. The Chair noted that Paul Hornby and Billy Hislop from National Procurement and Stephen Ferguson from the Healthcare Improvement Scotland (HIS) Communications Team would be attending later in the meeting.

1.2 Declaration of interest

No interests were declared in advance of or throughout the meeting. The Chair reiterated that if there are any changes relating to member's declaration of interests that they should inform the project team as soon as possible.

1.3 Minutes and action points of meeting held on 28 June 2018

As the minutes of the meeting were previously reviewed by group members (via email) the chair noted a change to the normal procedure. The minutes would not be reviewed page-by-page and instead members were asked to raise any amendments with the project officer after the meeting.

The Chair referred to the action point register, paper TVMO-28 and update was provided by the Team Lead Physiotherapist on her activities since the meeting on 28 June 2018.

Work is continuing with NHS boards and the physiotherapy leads as they begin to scope out and explore what is happening across Scotland. A database is being compiled of women's experience based on the information found. The database will include the received referrals for women with SUI and POP.

As an example it was noted that the numbers of referrals for physiotherapy within Greater Glasgow and Clyde have risen but that there is currently no data and it is unclear whether the numbers include women who have had mesh surgery. A discussion followed around using the self-evaluation tool (SET) to gather such information and how it could help identify referral patterns, such as primary or secondary care and volume. The project team agreed to consider how to frame the questions for the SET.

The Team Lead Physiotherapist added that the physiotherapy pathway and the point at which physiotherapy should take place must be clear. More reliable data will aid this process. It was agreed...
that waiting times would be a good indicator of variance in service and this should be included as a measure.

The group agreed that they were content for the Team Lead Physiotherapist to continue exploring the NHS boards and provide an update at the next meeting.

1.4 Chair’s update

The Chair advised that she and the Director of Evidence had meetings with the Scottish Government and the Chief Medical Officer on 6 September 2018. Both meetings were positive with a strong appreciation of the work being carried out by the TVMO group.

The Chair referred to the parliamentary debate on 12 September 2018 where the Cabinet Secretary for Health and Sport announced an immediate halt to the use of transvaginal mesh implants until a new restricted use protocol has been put in place.

The Chair provided reassurance that the work of TVMO group will continue and asked if group members had any questions regarding the announcement.

An open discussion followed with the group asking if there will be a change to the remit of the group. As the role of the group has not changed the TVMO group will continue to oversee the data relating to transvaginal mesh procedures and non-mesh procedures. The group deliberated over how important our role is in considering the conditions in which the halt can be lifted. The group noted that many of the restrictions on providing the procedure are already in place.

There was concern about how the halt might affect the Patient Information Subgroup. It was agreed that the work of the subgroup is important as it will help to establish what is required for patients to give them informed consent.

A member of the group asked about support for those who have been affected by mesh implants as this is another aspect that should be considered by the patient subgroup. The Director of Evidence advised that work is being carried out in three regions of Scotland to consider the pathways of care. However what is unclear is whether patients will be involved in this work. The project team agreed to explore this and report back.

It was noted that Greater Glasgow and Clyde have already developed a pathway of care, including those who have experienced an adverse effect due to transvaginal mesh. There is currently no link between primary and secondary care which should be considered in the SET to review how different regions are managing this. All members were in agreement that the SET will be extremely useful as it will reflect and highlight any changes that take place in the NHS boards.

One of the group’s Subspecialist in Urogynaecology advised that she has been working on developing a patient information leaflet within her own board (NHS Lothian) and could bring it along to the subgroup. This information and the literature from other NHS boards is to be added to the agenda for the meeting on 8 October 2018.
The Cabinet Secretary for Health and Sport mentioned the work of the group at the ministerial debate but the group was uncertain what was meant by “a high-level external review”. Clarification will be sought from the CMO.

HIS Project Team

At the meeting with the CMO the setting of national standards for surgical intervention was raised. The Team Lead for the Standards and Indicators team at HIS gave an overview of the Standards and Indicators Methodology. It was noted that the work to create National Standards would have significant overlaps with the work currently being carried out by the TVMO group. It was clarified that creation of National Standards of transvaginal mesh has not been commissioned. If National Standards were to be written, it would be a separate piece of work that would require further commitment.

The Chair highlighted that the Britton Report is to be published in November and clarified that this is the review of the Independent Review of Transvaginal Implant published in March 2017, and that the TVMO group has no involvement in this.

1.5 Cumberledge Review
The group discussed the publication of the Cumberlege Review in July 2018 which called for a pause in the use of Transvaginal mesh. The report has a definition for ‘high vigilance’ in a question and answer section. The project team will recirculate the review to the group.

A question was raised about whether there is a difference between a ‘halt’ and a ‘pause’. It seems that there are differences but it was agreed that a piece of work should be carried out and sent to the group for clarification.

HIS Project Team

2. Standing Items

2.1 Review of Data

a) ISD
A summary of key messages relating to mesh and non-mesh procedures for SUI and pop was tabled to the group. The summary is based on data from April 2009 up to March 2018. The group were given a few minutes to read the paper and were reminded that the contents of the summary is confidential.

Following reading time the group agreed that for the next meeting in December the group would review the charts as well as reviewing the summary paper. Discussions evolved around the figures and around the amount of work that will be required from NHS boards.

The Chair thanked the Data and Measurement advisor for creating the summary noting it was useful to have a user friendly version.

Data Measurement team

b) Adverse event reporting (IRIC/MHRA)
Paper TVMO-29 was tabled with IRIC Co-ordinator addressing the MHRA summary. The figures were discussed for all adverse incident reports received for SUI, POP and unknown indication for
urogynaecological surgical mesh from January 2013 to August 2018 inclusive. The reports were also split into Health Care Professional Reports and Member of the Public reports.

The IRIC Co-ordinator provided an update on the discrepancies found between IRIC and MHRA. IRIC are working with MHRA to ensure consistency with the data received. Reassurance was given at a recent meeting between IRIC and MHRA where they discussed the importance of the accuracy of their figure submission. MHRA will adopt a more robust system with a ‘mandatory fields’ being created to ensure that accurate information is received by IRIC.

The importance to report nationally was discussed and it was noted that the Chief Executive letter (CEL) is out of date. The Chair asked what role the TVMO group could take with this matter. The HIS Programme Manager advised that two questions regarding this are within the SET. The Director of Evidence agreed to raise with the Scottish Government about the out of date CEL.

A statement was made on how confident are we that clinicians are reporting incidents, as there is a loss of confidence (amongst patents) that clinicians are not reporting incidents. The group then discussed:

- the difference between adverse events, incidents and complications
- knowing when something should be escalated
- the Yellow card not being user friendly
- underreporting, and
- gaps in the system.

The chair summarised the group’s thoughts whilst adding that the SET will give us an insight into what needs to be addressed.

c) Evidence

An update was provided by the Health Services Researchers. They explained that the group previously agreed to look at 2 broad areas; clinical and safety aspects and qualitative data. Both are on the experiences and perceptions of women with SUI and POP of TVMO and the quality/usefulness of the information they received.

A literature search has been carried out for the clinical and safety aspects. The results from that will be circulated for the meeting in December 2018.

With regards to the qualitative aspect, the researchers found where they could source the literature from extremely challenging. The Health Services Researcher added that data from the studies identified were obtained using quantitative measures like questionnaires. They also noted challenges with synthesising the evidence including differences in the types of procedures investigated, questionnaire used and outcomes that were examined.

The group were asked if there was any information regarding the clinical relevance/significance of the some of the outcomes identified
like sexual function. A Subspecialist in Urogynaecology highlighted a paper that was published 7 years ago, which considered any results greater than half the standard deviation as being clinically important. She added that subsequent studies have used this measure for sexual function. She agreed to try and source the reference for this and send on to the group.

The chair asked if there were any qualitative data from clinical trials, the health service researchers were uncertain. The chair added that she thought Aberdeen University had trials identified and she agreed to look into this.

A patient representative noted how interesting this was and asked those working at board level if women have reported that they found feedback/information they gave to them as being helpful or unhelpful.

A Subspecialist in Urogynaecologist asked if the researchers found any information on shared decision making clinical tools with mesh or non-mesh. The researchers did not think so but agreed to have a second look.

The chair summarised discussions advising that the questions within the SET will help. She also proposed that the primary data can be used to support the summary of findings, which will be provided by the researchers. However, the evidence team added that should the group wish to analyse the primary data more time would need to be allocated for this.

2.2 Procurement update

Paul Hornby and Billy Hislop from National Procurement gave an overview on the procurement process to the group:

They explained that the procurement team follows a clear, transparent method as they are required to provide evidence when a supplier or product may not be successful. The process involves engaging with experts across the country on a ‘Commodity Advisory Panel’ (CAPs). This panel considers a range of factors, including whether a product is safe and who has decided it is safe. The panel also scrutinises evaluations of products and look for clinical evidence prior to procurement. The procurement process takes between 2-5 years and National Procurement will aggregate the spend of a product across NHS boards if more than one NHS board uses the product.

To date National Procurement have been reluctant to award a national supplier for mesh due to the limited evidence available.

The project team will circulate the report created by procurement.

2.3 Comms update

Stephen Ferguson, Communications manager was introduced and welcomed by the group. A discussion about the best way to communicate followed.
The Communication Manager highlighted the importance when considering our target audience for our communication. The TVMO group currently use a range of media to communicate their work:

- Twitter
- Flash reports
- HIS website
- press release, and the
- Self-evaluation tool.

All of these have aided our communication. In order to effectively engage with patients, the group needs to consider how to break the structure down into a more targeted group. Traditionally patient information leaflets have been used to engage with patients but there is concern about the effectiveness of these.

It was highlighted that if the halt on mesh procedures is lifted, it would be useful for the Patient Information Subgroup to have input from the team about how best to communicate information to patients. It was also suggested that a communication resource would be helpful. It was reiterated that the audience is the most important factor when considering communication, followed by the message that is to be communicated. The communication manager suggested that a communication resource may be of limited use.

It was noted that NHS24 is a resource that patients can use and that they are reviewing the ability to support video content.

The group discussed the need for openness and transparency whilst being conscious of the need for confidentiality. It was highlighted that there are ways to communicate information without compromising personal data.

It was agreed that while the work of the TVMO group has been progressing, it is not currently at the stage where it can be shared but that more information will become available as it is ready.

The Chair reiterated that the communications team should be contacted with any questions relating to communication or media enquiries.

2.4 Patient information subgroup
A verbal update was provided by the HIS Programme Manager.

The first Patient Information Subgroup will take place on 8 October 2018. Based on the system used by Scottish Intercollegiate Guidelines Network (SIGN) for their patient information leaflets the HIS programme manager has adopted a methodology using a tool called ‘Discern’. Discern is a structured questionnaire which provides users with a valid and reliable way of assessing the quality of written information on treatment choices. Using the discern tool will help when reviewing the current resources to get a better idea of how they were developed.

It is the intention that the Patient Information Subgroup will meet 2-3 times during 2018-2019. However it was noted that a lot of work will be conducted out with the meeting.
The membership of the group was confirmed and will be co-chaired by the Chair of TVMO and a patient representative. The Subspecialist Gynaecologist will be an associate of the subgroup. The paper that she has written will be discussed at the first meeting.

A question was raised if carers could perhaps join the group but for the purposes of the patient information subgroup it’s to be patients with lived experience.

The group further discussed the existing resources that are available. It was noted that none were against Greater Glasgow and Clyde but they are used but not available on the website. It was agreed to approach the Greater Glasgow and Clyde Medical Director to ask if leaflets could be uploaded to the website.

The group also raised and conferred over outdated patient information leaflets and the affect the announced ‘halt’ will have on NHS boards. The HIS Programme Manager advised that within the SET it asks the NHS boards what information do they provide to patients.

The chair thanked the HIS Programme Manager for her update.

### 2.6 Self-evaluation tool

The Quality Assurance (QA) Directorate Programme Manager updated the group and referred to paper TVMO-30. All comments were taken on board and the template was created. Two NHS boards are piloting the SET over the next 8 weeks. Meetings with the pilot NHS boards will take place as a teach-back session to discover what worked well, what could be improved upon and how labour intense it was in completing the SET.

The results from this will be shared with the group at the December meeting.

A request was made that the introduction should include the recent parliamentary statement. It was agreed that the content would be updated.

The chair thanked the QA programme manager for all her efforts especially as this piece of work is not part of her substantive post.

### 2.6 Reporting (off-line items)

a) Scottish Government

The HIS project officer referred to paper TVMO-31 advising that the update report was for information only as it was used at the Scottish Government for their meeting on 6 October 2018. Going forward a more detailed update report will be drafted.

b) TVMO Data Subgroup

The HIS project officer referred to paper TVMO-32 noting that the last meeting of the data subgroup was held on 20 June 2018. The final minutes were approved by the subgroup members and distributed to the TVMO group for information only.
3. Any Other Business

3.1 Chair thanked the group for their contributions.

No other business was raised.

4. Date and time of next meeting

4.1 Friday 14th December at 11am in Delta House, 50 West Nile Street, Glasgow.