MINUTES

Transvaginal Mesh Implants Oversight group (TVMO)

Date    19 January 2018, 11–3pm
Venue Room 4, 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>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>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>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>
<th>Name</th>
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<tr>
<td>Karen Grant</td>
<td>Project officer (secretariat)</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>Donna O'Rourke</td>
<td>Project Officer (secretariat)</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

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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>Carol McCambley</td>
<td>Stakeholder engagement manager</td>
<td>NHS 24, NHS Inform</td>
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<tr>
<td>Tracey Mitchell</td>
<td>Project officer</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 first 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 data protection and confidentiality policies.

Individual introductions were made and as an icebreaker the members were asked to say which group they represented as well as identify their expectations of the TVMO group.

In line with the remit, these expectations included:
- providing clarity of evidence to inform the decision making of clinicians and women
- ensuring patient information is accessible, understandable and evidence-based
- bringing multidisciplinary knowledge and expertise to the group

In terms of expectations of group process members also stressed the need to:
- be open and transparent
- ensure group consensus
- listen to positive and negative experiences
- minimise any future incidents, and
- support each other to achieve goals.

Following this discussion the chair emphasised the importance of providing a deputy for every meeting should members not be able to attend. Group members to email Tracey Mitchell confirming who would deputise in the event they are unable to attend future meetings. 

2. Governance

2.1 Code of conduct

The code of conduct was outlined to the group, including the need to be supportive and respectful. It was noted that the discussions of the group must have integrity and stand up to scrutiny.

The group discussed the sharing of information from meetings, especially those who will be engaged with members of the public with experiences to share.

It was highlighted that the HIS project team would be publishing information on the meetings on the HIS website. Flash reports will be published after each meeting but will not contain details, the minutes of each meeting will be published after the group has agreed them at the following meeting.

Due to the sensitive nature of the project, the HIS project team will be working closely with the HIS communications manager, Stephen Ferguson to ensure confidentiality and protection. Any press interest should also be directed to Stephen Ferguson in the first instance.
If members are unable to attend any future meetings, a deputy should be sent in their place. Confidentiality and data protection will be discussed with the deputy in advance of the meeting. It was agreed by the group that teleconference should only be used as a last resort.

The confidentiality agreement was reviewed and agreed by the group, with members to sign it by the end of the meeting.

It was agreed that any data reviewed or shared at the meeting should not be shared with anyone else and that members should not take away detailed notes on unpublished data for reasons of security and confidentiality.

The following actions were agreed:
- group members to sign confidentiality agreement before the end of the meeting, and
- group members to fill in, sign and return their declaration of interest forms

2.2 Reporting structure/ways of working

The HIS programme manager advised that reports from the TVMO group would be issued every 6 months and NHS boards would also receive a self-assessment framework to complete and return. The HIS project team would be producing a flash report after every meeting but this would be signed off by the group before publication on the HIS webpage. The group members agreed to participate and provide input to the reports for publication.

A discussion followed regarding the TVMO group’s life span. It was noted that the life span is expected to be 2 years after which a managed clinical network (MCN) group would take over the role. The Chief Medical Officer (CMO) is currently working to establish the MCN. The CMO will also consider the best way for the work of the two groups to be integrated.

The HIS team advised the group that any risks to the project would be recorded in the risk register and risks mitigated internally.

The following actions were agreed:
- follow up regarding the life span of the TVMO group and how it will engage with the MCN once it has been established, and
- a risk register to be produced.

2.3 Declarations of interests (DOI)

It was noted that members are expected to complete a DOI form and submit to the HIS project team. At each meeting members will be asked by the chair if there have been any changes to their interests.

3. Background

3.1 Presentation from HIS

A presentation was provided to the group by the HIS programme manager. The presentation outlined:
- progress to date
• data from ISD
• adverse event reporting
• evidence, and
• patient information

The chair encouraged the group to ask questions throughout the presentation.

The HIS project team were asked to include the following to the Terms of Reference (TOR):
• the development of the annual self-assessment framework, and
• potential development of Quality Performance Indicators (QPI).

The group discussed developing their own protocol in the event that they noticed any trends with regard to data; possibly a red flag system if anything concerning was identified.

The HIS team were also asked to change the word ‘scrutinising’ to ‘reviewing’ or ‘assessing’ in any of the meeting paperwork. The group discussed their own remit with regards to data. It was noted and agreed that the group has responsibility to produce reports on the use of mesh implant to the public and to the CMO. This should also be clarified in the TOR.

The group also had a discussion around expectations regarding the independent/private sector. It was noted that HIS do have a remit to inspect some independent hospitals but there would be an expectation that any reporting on independent hospitals with regards to the use of mesh implants would take a different route. There would be a need for HIS to investigate how complaints are reported in the private sector. The point that adverse reporting could come through the NHS, which may be picking up incidents from the independent sector and that the journey of care should be considered was raised. It was also noted that ISD do not hold data on the independent sector.

The group discussed prevention and the effectiveness of physiotherapy before and after child birth. It was emphasised that the group would not have a role to develop any care pathways, rather the group would report on significant data and make recommendations to those who are responsible for developing the care pathways. The project team will investigate who is leading on this work.

The group cannot make any decisions around whether or not mesh implants should be banned or discontinued.

A question was raised following the presentation with regards to any membership gaps. The following additional group membership was agreed:
• specialist physiotherapist (women’s health)
• second urogynaecologist
• primary care physician
• representative from Scottish Executive Nurse Directors (SEND)
• specialist continence nurse
• communications expert, and
• a representative from the Scottish Government (the director of evidence agreed to raise this with the CMO) who could attend the TVMO meetings as an observer

It was noted that the group was currently missing a consultant urogynaecologist and this input was essential. However the chair announced the appointment of Dr Christine Hemming who had accepted the role to represent the Scottish Association of Medical Directors but is a practicing gynaecologist with a special interest in post-reproductive gynaecology. It was therefore thought that a second urogynaecologist who could specifically represent that group of specialists should also be appointed to the TVMO Group.

The HIS project team asked the group to consider ways of engaging with people who have experiences to share. It was agreed that the group should have a patient representative to attend meetings. The Chair advised that 3 letters had been sent already to attempt to recruit a patient representative and this was currently ongoing.

The HIS project team asked that if any members of the group had suggestions for involvement, to contact the team. It was also noted that the group would also co-opt people to provide their expertise where necessary.

The HIS project team agreed to circulate future meeting dates to the group. It was agreed that meetings would initially be every 3 months.

The following actions were agreed:
• the annual self-assessment and QPIs to be added to the TOR
• change ‘scrutinising’ to ‘reviewing’ or ‘assessing’ in any of the meeting paperwork
• clarify that the TOR should include group remit to produce reports for the public and for the CMO
• investigate how complaints are registered in the independent sector
• raise the request for a representative from the Scottish Government in the group with the CMO
• fill remaining gaps in group membership
• circulate future meeting dates to the group
• consult with the Nursing and Midwifery and Allied Health Professional (NMAHP) regarding a specialist nursing representative from SEND, and
• contact CSP for specialist women’s health physiotherapist
• investigate who are responsible for developing the care pathways.

3.2 Terms of reference
Many of the points and actions were raised earlier in the meeting, (see 3.1 above)

4. Working methods
4.1 Sub groups
It was suggested that a patient sub-group should be set up to review patient information. Moving forward other sub-groups may be identified and created..
4.2 Minutes of future meetings and action point register

The programme manager advised that all future meetings would be recorded. The minutes of all future meetings would be agreed at the next meeting then uploaded to the website. A rolling action point register to be created to keep track of actions.

4.3 Review of data

The HIS data measurement advisor presented an overview of the most current HIS analysis of data provided by ISD to the group.

Highlights from proceeding discussion included:
- challenges around mesh being classified as a medical device
- publication restrictions on data due to confidentiality rules and small number suppression to protect patient identities
- difficulty in tracking trends due to limited data
- coding issues and margins of error which present as a consequence of the secondary interpretation of surgical notes.
- dialogue around the most appropriate member of staff to input this complex coding information
- questions around data collection for women who have had more than one procedure and coding dependent on type of procedure
- difficulties in comparative analysis of data over time due to modern process and procedure as well as updated coding conventions
- detail that is contained in individual operation notes are not necessarily in the national data, for example the specific manufacturer of mesh used during each procedure
- suggestion of a self-assessment tool to understand the types of mesh used by each health board area
- challenges relating to readmissions data as the data records readmission for any reason, whether or not it was mesh related
- data on removals is based on resident health board of the patient, not Board where removal procedure was carried out as only a limited number of centres offer removals so this would skew the ‘Board of treatment’ data for removals.

The HIS project team and HIS analysts will continue to work with ISD (and the wider group) to develop the best format to display the data moving forward.

The chair recommended the establishment of a sub-group to consolidate the data which has been collected to date and explore the priorities of the group to garner meaningful data collection and analysis. The sub-group should meet prior to the next group meeting on 12 April 2018 and bring suggestions to the group for approval. For example, the group has yet to decide whether to review numbers of women undergoing procedures or overall numbers of procedures.

HIS project team

Adverse event report

The group were offered figures of the numbers of mesh procedure patients who have reported an adverse event to the Incident Reporting and Investigation Centre (IRIC). The numbers of incidents reported to IRIC were compared with those reported to the Medicines and Healthcare products Regulatory Agency (MHRA).
It was highlighted that the data from IRIC is based on the date when a report is received and not when an incident may have taken place and that they are reliant on information being sent through to them. There is also a possibility of duplication as a report is sent in by the clinician responsible for dealing with the adverse event, but the patient, for example may also send in a report.

**Evidence**

A HIS Health Information Scientist was in attendance to present the evidence review on transvaginal mesh to the team. The chair suggested that it would be useful to have regular updates on the research that is being conducted in mesh. Due to the number of links included in the literature review, it was suggested that an electronic copy be sent to the group.

The HIS Director of Evidence suggested that the review would be very useful for those who would be involved in producing the patient pathways. The information from the review will also be highlighted in a flash report. It was noted that the evidence was not graded for quality so the Health Information Scientist and the SIGN programme manager will work together to produce a summary on evidence quality as it was agreed that it would be useful to have this information.

**The following actions were agreed:**

- link with colleagues (TN, NS, MP & LM) to develop a sub-group to identify the key data to be considered by the group
- send an electronic version of evidence review to the group
- share the literature review with patient pathways development group
- create flash report to contain highlights of the literature review, and
- create summary of evidence review to indicate quality of publications.

**5. Communication**

5.1 Comms update/plan

See note below*

**5.2 Public reporting and engagement**

See note below*

**6. Any other business**

6.1 Outline of today’s events

A letter regarding the mesh helpline was read to the group, it highlighted the clinical guidance on the content of webpages and frequently asking questions (FAQs). It is expected that NHS Inform would receive complete FAQs, to which to refer, by the time the helpline is closed. Further investigation into this matter is required, especially with clinical members.

It was reiterated that group members should send any member recommendations to the HIS project team.
*Due to adverse weather conditions the meeting was adjourned following this item. Remaining agenda items will be sent to the group by the HIS project team.*

The following actions were agreed:
- investigate the process of transferring web content and FAQs from mesh helpline website to NHS Inform
- send remaining agenda items to group.

6.2 Next steps
See note above*.

7. Date and time of next meeting

7.1 Thursday 12 April 2018, 11–3pm, meeting room 4, Delta House, Glasgow G1 2NP.

TVMO HIS project team email address:
hcis.standardsandindicators@nhs.net