Title:

A Review into the process of establishing, managing and supporting Independent Inquiries and Reviews in Scotland (with specific reference to The Scottish Independent Review of transvaginal mesh implants)

Remit and terms of reference[1]

The remit of the review is to:

Consider the evidence on how to improve the investigative review process. Specific reference will be made to the Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women: Final Report of March 2017[2]*. This will inform recommendations for process of establishing, managing and supporting Independent Inquiries and Reviews in Scotland.*

The Report will comprise two Parts

1. A review of the processes undertaken which resulted in the above-mentioned Report. A comparison will be made and consideration given to other examples and approaches adopted when conducting an investigation.
2. Recommendations for conducting future reviews.

Part 1 will review the areas listed below with reference to the Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women, 2017. This list may develop as the investigation progresses.

Selection and responsibility of Chair;
Selection and responsibility of review members;

[1] The wording of the remit may be refined as the work progresses but provides initial framework.

[2] But not limited to.

Expectations of Chair and review members;
Potential conflicts of interest;
Conduct of members;
Timeframe;
Management and presentation of evidence;
Management of external influences.

The investigative review will make practical recommendations for requesting, scoping, and conducting a review. It will formulate these recommendations in response to the set of questions below.

Is there a process in place to agree the terms of an independent review?

Who appoints the chair?

What is the selection process for appointment?

Who appoints the members of the review team?

What is the selection process for their appointment?

How is the remit for the review decided?

How is the budget set?

Is there a process in place to agree the timeframe?

Membership

Two other panel members have now been appointed. There are several reasons for this. First, it will expedite the process and ensure efficiency and timeliness as the tasks will be divided among us. Second, given some of the discussions/ meetings may be of a highly sensitive nature, what is drawn from the discussions needs to be gauged accurately so it will be very helpful to have at least two people in attendance to assist with recall and understanding. Each person has been appointed on the basis of their

expertise in relation to Part 1 or II. Panel members may not be required to attend all discussions or meetings with witnesses but there will always be two in attendance. The responsibility will remain that of the chair to coordinate and compile the report with the input and consensus of the other two panel members.

Each member of the review panel will sit in a personal capacity and will not represent the views of any organisation or body. All panel members will undertake this review without honorarium. Approval to proceed on this basis has been given from their respective employers. The panel members have agreed to this not only as part of their civic duty but in the interests of ensuring the independence of the report.

Panel Membership

Chair- Alison Britton- Professor of Healthcare & Medical law, Glasgow Caledonian University;

Panel member - Dr Ealasaid Munro- Postdoctoral research associate: The Major Minor Cinema project, University of Glasgow Department of Theatre, Film and TV;

Panel member - Gerard Sinclair- Chief Executive and Principal Solicitor of the Scottish Criminal Cases Review Commission.

Evidence Gathering/ Methodology

Part 1 of the review will take a descriptive–interpretive approach to investigating the conduct of *The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants,* and the production of the *Final Report* of March 2017.The research questions animating this review, and structuring its data collection and analysis, are exploratory in nature. Following Barker et al (2002: 149) we feel that an exploratory approach is best deployed under certain conditions, including where the social phenomena under investigation – in this case, the conduct of the above mentioned review and production of the Final Report – are complex and potentially contested. As it is important in our case to understand the conduct of the Independent

Review and the production of the Final Report, a primarily qualitative framework will be employed for the present study.

Methods:

Appropriate methods include, but will not necessarily be limited to: Document analysis, interviews and focus groups. Interviews and focus groups will be held at a location convenient to those involved. Conference call and emails will be used to facilitate discussions where circumstances may prevent meeting in person.

Sampling:

Due to the challenging conditions presented to the panel, the present study will adopt a strategy of purposeful sampling. We will attempt, to the best of our ability, to speak with key stakeholders within and out with the Scottish Government, the Chair of the panel, and individual panel members. [3] Part II sampling will adopt the same approach and will be carried out to address the questions posed above.

Triangulation and validity:

Triangulation via mixed methods – that is, document analysis, interviewing, and focus groups – has been built into the present study from its inception. We feel that incorporating triangulation in this case safeguards validity, and will strengthen the evidence base for the recommendations. The results of the present study will be subject to ongoing internal auditing procedures (within the team) and, at the conclusion of stage 1, auditing by the participants in order to obtain feedback/approval of their own contribution.

[3] There will be other stakeholders added to this list as our initial investigations proceed.

Data preparation and analysis:

All interviews and focus groups will be recorded, and transcribed verbatim. Transcripts will be checked by a panel member who was present at the interview/focus group, and will be sent to individuals for their approval before they are analysed. (See Discussion format and care of participants including ethical considerations below).

Premises

It is proposed that the panel meet on a monthly basis starting with the first meeting in September 2017. Meetings will be scheduled well in advance to meet the diary requirements of the panel. The meetings will last no more than 2 hours and will conclude in April 2018. Given that there will be only 3 people, these meetings will be held in my office at the university or at a venue agreed by the panel. Catering will be provided by the university. Monthly meetings will be arranged and minutes recorded by the administrator (see admin below) but it is anticipated that, in addition, there will be email exchange and *ad hoc* communications as and when required.

Discussion format and care of participants including ethical considerations

A short Plain Language Statement, which details the terms of reference of the present study and the remit of the panel will be prepared and distributed to all prospective participants (individuals and organisations). It will be made clear in the statement that participation is voluntary. Consent forms will be distributed to participants, detailing their rights as regards anonymity and the use of their data. The data collected will be stored securely, safely and in accordance with Data Collection Act (1998). Interviews will be transcribed by the researcher or by arrangement of the administrator. They will ensure confidentiality.

Contact details will be provided so that there will be an opportunity to ask any questions and participants will be made aware that they can withdraw from the research at any time. Interviews and focus groups will be recorded. A consent form will be available to

participants prior to the discussion taking place. A transcript will be written up and sent to all participants for their approval of their own individual contribution.

Security of data collected and stored

All work, including literature reviews, statements, and interview transcripts will be stored on an encrypted machine. Data sticks will also be used and they will be my responsibility for safe keeping. These will be kept locked in my office at the university.

Administration and Research

The Administrator would arrange the date and venue of the monthly panel meetings. They would also arrange meetings, with individuals and organizations and liaise with panel over venues. They would assist in arranging focus groups and any associated catering and transport. They would arrange transcription of the recordings from the focus groups.

The Researcher will work closely with and be directed by Dr Munro. They will be responsible for scoping the existing literature both in terms of comparable approach to the subject area, and matters of process and governance, including the experiences and approaches taken in other jurisdictions. A log will be kept of what is researched or recovered and where it was located. The researcher will also maintain a bibliography and provide the Chair and panel members with a brief summary of relevant materials. They will undertake work that may be required on an *ad hoc* basis from panel members. They may be required to sit in on the focus group discussions. It is envisaged that much of this element will be 'frontloaded' and will reduce as the review progresses. (Suggested 2 days a week for first 4 months, Sept- Dec)

Panel members, admin support and researcher should have the necessary skills, knowledge and independence. No conflict of interest and of course- sufficient time to

undertake the role. The need to understand the sensitivity of the issues under investigation and the duty to respect confidentiality will underpin all appointments.

Budget and Expenses

The panel would expect that all reasonable expenses will be covered which will allow them to undertake and successfully complete the review. There are already some IT related materials that we require and would like to have a system where these can be easily and promptly purchased. As noted several times, we are aware that our investigation will require a courteous and sensitive approach. We have addressed some of this in the 'care of participants' section above and it is a priority for the panel that the participants are put to the least inconvenience or stress. One element of this is to ensure that their expenses will be made readily available to them.

Timetable:

July/August: Arrange administrative support. Appoint researcher, and 2 panel members.

September: First meeting of panel (and thereafter monthly) Evidence gathering and identification of key stakeholders and relevant witnesses.

September- February: Discussions commence. Focus groups arranged and held. Visits arranged if required.

March/April- writing up report and any final or follow up meetings.

June: Production and publication of Review.

Communication of findings

A template will roughly follow and include the following- this will be adapted to suit the requirements of our findings.

Introduction

Executive summary

Terms of reference/remit

Methodology- including explanation and purpose of Parts 1 and II

Background and chronology of events

Findings

Conclusions

Recommendations.