DOCUMENT 1

From: Bishop D (David)
Sent: 02 February 2017 14:49
To: Cabinet Secretary for Health and Sport
Cc: [redacted]
Subject: Independent Review of Transvaginal Mesh

Hi Lynn

The Cabinet Secretary is aware that the Independent Review of Transvaginal Mesh is presently preparing its final report, and we wanted to give you a brief update should the Cabinet Secretary ask about progress.

The Review group met on 23 January in order to consider a draft of the final report. Due to the complex nature of the report, the group was not in a position to agree a final version of it at that meeting, and some further drafting is therefore being undertaken at the present time. A further meeting is being scheduled for early March, so that the final report can be agreed and published during the spring.

Many thanks

David

David Bishop
Scottish Government | Directorate for Health Finance and Infrastructure

Basement Rear, St Andrew's House, Regent Road, Edinburgh, EH1 3DG
Tel: 0131 244 1816

DOCUMENT 2

From: Davies S (Sara) Dr
Sent: 15 May 2017 13:21
To: Cabinet Secretary for Health and Sport
Cc: [redacted]
Subject: FW: Independent review of vaginal mesh

Dear [redacted]

As we chatted just now, attached is the independent expert's declarations of interest. There was a proposal that the Cabinet Secretary would discuss the role with the expert tomorrow. The briefing role and background is also attached. Could you let us know if this is going ahead and whether we should liaise with the expert ? If needed a draft letter to send to the PPC Convenor on Thursday can also be sent up today. Best wishes, Sara

From: Britton, Alison
Sent: 15 May 2017 13:10
To: Davies S (Sara) Dr; [redacted]
Cc: Bishop D (David)
Subject: RE: Independent review of vaginal mesh

Dear Dr Davies

Thank you for your email. I am in the university until around 3pm this afternoon and direct dial as below but it may also be helpful to have my mobile- [redacted – personal information].

Please find re-attached the completed declaration of Interest. Tuesday(tomorrow) around midday is fine.

Best regards

Alison.

Alison Britton
Professor of Healthcare and Medical Law
Dept of Law , Economics, Accountancy and Risk
Glasgow School for Business and Society
Glasgow Caledonian University
Tel : [redacted – personal information]
Email: [redacted – personal information]

From: [redacted]
Sent: 11 May 2017 12:21
To: [redacted] Britton, Alison
Cc: David.Bishop@gov.scot
Subject: RE: Independent review of vaginal mesh

Dear Professor Britton

Many thanks for your helpful response and it will be lovely to speak next week. I'm one of Terry's colleagues and part of the secretariat for the Independent Review. I just wanted to flag now that if possible, the Cabinet Secretary would be keen to speak by phone on Tuesday around 12 noon, or a bit before or after. Can you keep these times in mind? We'll be in touch next week re telephone numbers etc. We will also need to ask you to share your declarations of interest so for simplicity just now I attach our standard template.

Best wishes, [redacted]

Dr Sara Davies
Consultant in Public Health Medicine
Planning and Quality
Directorate of Healthcare Quality & Improvement
Health & Social Care
The Scottish Government
Room GE06
St Andrew's House
Regent Road, Edinburgh
EH1 3DG
Tel: 0131 244 2287

From: [redacted]
Sent: 11 May 2017 08:27
To: Britton, Alison
Cc: Davies S (Sara) Dr; Bishop D (David)
Subject: Re: Independent review of vaginal mesh

Alison,

Many thanks and very helpful. I have cc'd this to Sara and David (can we discuss) and we will liaise with Cab Sec Office.

Will be in touch.

[redacted]

From: Britton, Alison
Sent: 11 May 2017 07:38
To: [redacted]
Subject: Re: Independent review of vaginal mesh

Dear [redacted]

Thank you for your email. That looks to be a helpful overview and the initial suggestions look the direction that I would hope to take.

I [redacted – out of scope of request] shall be back at the university on Monday and will be pleased to speak with the Cabinet Secretary then by phone or Tuesday in person if that's preferable.

Very best wishes

Alison

Sent from my Samsung device

-------- Original message --------
From: '[redacted]
Date: 10/05/2017 14:09 (GMT+00:00)
To: "Britton, Alison"
Cc: '[redacted]
David.Bishop@scotland.gsi.gov.uk
Subject: Fw: Independent review of vaginal mesh

Dear Alison,

[redacted – out of scope of request]

As you will appreciate your agreement in principle to look at the Independent Review of vaginal mesh has been discussed and there is an eagerness to move forward with this, as illustrated by the e-mail below. I think this is self-explanatory and although I am away next week, I am sure Sara Davies and David Bishop will provide any assistance you need.

Last week we did discuss some areas that might be relevant for your review and I think these could form the basis of the ToR. However, they are only suggestions and you will have your own views:

- Terms of reference
- Selection of review committee members
- Conflicts of interest
- Conduct of members and how this was managed
- Management and presentation of evidence
- Management of external influences

We did not think there is an appetite to re-review scientific evidence and I think we agreed the emphasis should be on learning with a view to improve processes in the future.

Finally, the Cabinet Secretary is appearing before the Parliamentart Petitions Committee next Thursday (18th May) and is keen to be able to announce your involvement as well as an outline ToR. She is also keen to speak with you early next week if this possible. I appreciate the timescale is "tight" and will value your thoughts. We will of course provide any assistance we can.

With best wishes,

[redacted]

From: David.Bishop@scotland.gsi.gov.uk <David.Bishop@scotland.gsi.gov.uk>
Sent: 09 May 2017 09:08
To: [redacted]
Cc: Davies Sara (NATIONAL SERVICES SCOTLAND)
Subject: Professor Britton

Morning [redacted]

Sara and I met with [redacted] yesterday, and briefly mentioned Alison Britton and the proposal that she take on the task of reviewing the Independent Review. We know from previous conversations with you that Professor Britton would be looking for someone to provide secretariat support to her. This would most likely have to come from someone within the Scottish Government, albeit someone that has not previously been involved in the Review.

To help us identify someone, we thought it would be helpful if Professor Britton was able to give us a proposal in writing that sets out what support she would be looking for. We need to understand – amongst other things – what she would be looking to them to do (e.g. set up meetings, help to draft her report, etc.) and how much time she envisages them spending on it.

In addition, it would be useful if – aside from secretariat issues – Professor Britton's proposal could also set out what additional funding she might require from us.

Having something written will allow us to clearly identify to senior managers, e.g. [redacted] what is needed, and to seek their approval.

Would it be possible that you could ask Professor Britton to consider this and commission something along these lines from her? I don't know how quickly she would be able to put this together, but I know that you're on holiday the next couple of weeks and if Professor Britton wanted to send us something while you are off, I'm happy that you give her my email address so that she can send it directly to me.

Many thanks

David

David Bishop

Scottish Government | Directorate for Health Finance and Infrastructure

Basement Rear, St Andrew's House, Regent Road, Edinburgh, EH1 3DG

Tel: 0131 244 1816

Attachment 1:

Declaration of Interests

NAME (block capitals) Alison Britton .....

1. Personal interests over the last 12 months

This involves payments[1] (or other support) from any one company to an individual member or their spouse/partner/cohabittee or close relative. The main examples are consultancies, fee-paid work, travel grants or company shares. (The amount of money involved does not have to be declared).

Company	Nature or purpose of support from the company	Period of support From	To
Lundbeck Limited St Albans, AL1 2PS, United Kingdom	2 Presentations on the role of the Expert witness.	March 2017	April 2017
Law Society of Scotland.	Research Consultant	May 2016	April 2017

1 for practical purposes, payments and/or support to a value in excess of £100 annually should be declared. (Threshold of £100 chosen locally to exclude amounts for trivial items such as pens, post-its, books etc.)

2. Non-Personal interests over the last 12 months

This implies support[2] from any one company for your unit or place of work. It may be financial or in kind e.g. funding of a nurse, colleague, building or piece of equipment. (The amount of money involved does not have to be declared).

Company	Nature or purpose of support from the company	Period of support From	To

2 for practical purposes, payments and/or support to a value in excess of £1000 annually should be declared. (Threshold of £1000 chosen to concord with Scottish Medicines Consortium guidance.)

Signature Date 15 may 2017 .....

.....

Aide-Memoire to Declaration of Interests at Meetings and Participation by Members

Working Group members are required to declare relevant interests and to state whether they are personal or non-personal interests and whether they are specific to the product under consideration or non-specific.

A member must declare a personal specific interest if he or she has at any time worked on the product under consideration and has personally received payment for that work, in any form, from any relevant body, including companies, charities etc. The member shall take no part in the proceedings if they relate to that product. If the interest is no longer current, the member may declare it as a lapsed personal specific interest.

A member must declare a personal non-specific interest if he or she has a current personal interest in any relevant body concerned which does not relate specifically to the product under discussion. The member shall take no part in the proceedings as they relate to the product, except at the Chairman's discretion.

A member must declare a non-personal specific interest if he or she is aware that the department for which he or she works has at any time worked on the product but the member has not personally received payment in any form from the body for the work done. The member may take part in the proceedings unless he or she has personal knowledge of the product through his or her own work or through direct supervision of other people's work, in which case he or she should declare this and not take part in the proceedings.

A member must declare a non-personal, non-specific interest if he or she is aware that the department for which he or she works is currently receiving payment from any relevant body concerned which does not relate specifically to the product under discussion. The member may take part in the proceedings unless the Chairman rules otherwise.

Attachment 2:

An independent expert to will be appointed to:

- consider how the process was undertaken and see what lessons can be learned in the future:
  - terms of reference of the Independent Review;
  - selection of review committee members;
  - conflicts of interest;
  - conduct of members and how this was managed;
  - management and presentation of evidence; and
  - management of external influences.

- draft guidance for the Chairs and members of all independent inquiries to ensure full understanding of the roles and terms of references, good governance and support for those who give their time and expertise.

Discussions have been held with Professor Alison Britton of Glasgow Caledonian University, who has agreed to take on this role. The aim will be for Professor Britton to speak to the Cabinet Secretary on Tuesday 16 May, and to subsequently announce her name at the Committee. A declaration of interests signed by the Professor will be attached to the letter to the Convenor, setting out draft terms of reference for the review.

Professor Britton is a specialist in public healthcare, clinical negligence, mental health law and professional ethics. In recent years, her interests have focused upon the practical application and the role of law in matters of public health. Professor Britton is currently working with the GMC on their review of consent.

She has been involved in consultancy work for the World Health Organisation, the Department of Health (England and Wales) and the organisation, Childlessness Overcome through Surrogacy (C.O.T.S). She has sat on two BMA ethics' committees, contributing to their Codes of Practice on Advance Statements. She has delivered presentations nationally, and internationally, provided training for health care organisations, and taken part in radio and television broadcasts – she was also consultant on a medico-legal story line in Merseyside Television's Brookside series. She has recently completed three year tenure as Subject Lead for Law.

Alison was appointed legal adviser to the Health Committee of the Scottish Parliament for the Adult Support and Protection (Sc) Act 2007 and Health and Sport Committee on the End of Life Assistance (Scotland) Bill in 2010.

She is the Convenor of the Health and Medical Law Sub Committee for the Law Society of Scotland.

Alison is an honorary tutor in Cardiff School of Medicine for collaborative work with Cardiff University and the British Pain Society on palliative care and resolution of law and damages for patients in chronic pain. She is a regular visitor to the Grameen College of Nursing, Dhaka, Bangladesh, advising on Academic Quality Enhancement, Audit and Design in learning and teaching. She delivered their inaugural Professorial Lecture in May 2014.

DOCUMENT 3

From: [redacted]
Sent: 14 July 2017 09:51
To: [redacted]
Cc: Davies S (Sara) Dr; Bishop D (David)
Subject: Mesh issues: update
Importance: High

Dear [redacted]

[redacted – out of scope of request]

We thought it would be helpful to bring you up to date with progress on mesh issues, particularly work with HIS in establishing an oversight group and Alison Britton's independent review.

i. [redacted – out of scope of request]

ii. Alison Britton's Independent Review
Prof. Britton (AB) recently provided a draft ToR for her review (attached). This has been discussed within SG and is being progressed. All necessary support is being provide for AB to allow her to complete her work. As above, finance will be discussed with Alan Morrison next week.

I trust this update is useful. It will be helpful to discuss the proposals for the oversight group and mcn at an early opportunity. Perhaps this could be a focus for the next MD/ Clinical Leads meeting when board progress against recommendations in the IR is reviewed.

Best wishes,

[redacted]

Attachment 1:

[redacted – out of scope of request]

IE

	WTE	
Researcher	0.5	23,000 (if not SG secondee)
Administrator	0.2	0 if SG secondee
Travel expenses		2,000
Total cost per annum		25,000

[redacted – out of scope of request]

Attachment 2:

Remit and terms of reference[1]

The remit of the review is to: ***Consider the evidence on how to improve the investigative review process. The focus will be drawn from the 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 the conduct of future investigations.***

The Report will comprise two Parts

[1] The wording of the remit may be refined as the work progresses but provides initial framework.
[2] But not limited to.

1. A review of the processes undertaken which resulted in the abovementioned 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. This list may develop as the investigation progresses.

Selection and responsibility of Chair
Selection of review committee members;
Potential conflicts of interest;
Conduct of members and how this is managed;
Management and presentation of evidence;
Management of external influences.

Part ll, based on the conclusion of Part 1, will make practical recommendations for consideration when requesting, scoping, and conducting a review.

Membership

I would like to have two other members 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 will be appointed on the basis of their expertise in relation to Part 1 or ll. I have not approached anyone but do have a couple of names if this was agreed. The responsibility will remain mine to coordinate and compile the report. (More will be said in relation to this below under 'administration'.)

Each member of the review panel will sit in a personal capacity and will not represent the views of any organisation or body.

Evidence Gathering/ Methodology

A mixed approach will be taken. A literature review will be used to scope out previous relevant work and findings will inform and provide a framework for the initial investigation in part 1. Meetings will be arranged to enable discussions with individuals and groups. The discussions will initially focus, but will not be limited to, the areas identified in Part 1 . They will, in turn, help shape Part ll, but it is anticipated that there will be an overlap. Conference call and emails will be used to facilitate discussions where circumstances may prevent meeting in person.

Previous published reports will be considered if it was felt that they were relevant to the remit and their contents will be reflected in our deliberations. They will not be limited to the subject matter of the Independent Review but instead will focus on process and governance.

Premises

It is proposed that the panel meet on a monthly basis starting with the first meeting in August 2017. Given that there will be only 3 people, plus an administrator, these meetings can be held in my office at the university. This will incur no charge. Catering- tea , coffee water 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

Every reasonable effort will be made to ensure that discussions are held at a location convenient to those involved. Will there be expenses available to meet any reasonable costs that participants may incur? All individuals and organisations with whom discussion / meetings are held will be sent information, including terms of reference/remit of panel in advance of the discussion. Contact details will be provided so that there will be an opportunity to ask any questions. The discussions will be recorded and 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.

Security of data collected and stored

I would like to have access to a laptop for my personal use for the duration of the review. All work, including literature reviews, statements, interview transcripts will be stored on this machine. It will be secured by a password. Data sticks will also be used and my responsibility for safe keeping. These will be kept locked in my office at the university. The laptop will be cleaned and returned on conclusion of the review.

Administration and Research

I would like the review to have an administrator. This person would arrange the monthly panel meetings, take minutes, transcribe recording of discussions etc. They would also arrange meetings, with individuals and organisations and liaise with panel over venue. They would assist in arranging focus groups and any associated catering and transport.

We have also spoken about recruiting someone to undertake research. The researcher would ideally have experience in legal/health or governance since a mixture of these disciplines will contribute to the review. 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 with a brief summary of relevant materials. They would undertake work that may be required on an *ad hoc* basis from panel members. They would have good analytical skills and work alongside the panel. They will be required to sit in on the discussions. It is envisaged that much of this element will be ‘frontloaded’ and will reduce as the review progresses. (suggested 2-3 days a week for first 3 months)

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.

Timetable:

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

August: First meeting of panel and thereafter monthly - and exploration of issues and who we wish to speak to.

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/July: 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 ll

Background can chronology of events

Findings

Conclusions

Recommendations.

DOCUMENT 4

From: Davies S (Sara) Dr
Sent: 10 August 2017 09:40
To: [redacted]
Cc: [redacted]
Subject: RE: MESH Correspondence

Dear [redacted] and [redacted – personal information]

Thanks for the copy and our view was it was part of the Independent Review's work and therefore a decision for the group and I'm happy with the outcome. Best wishes, Sara

-----Original Message-----
From: [redacted]
Sent: 09 August 2017 19:27
To: [redacted – personal information]
Cc: [redacted] Davies S (Sara) Dr
Subject: Re: MESH Correspondence

Of course, [redacted] will send you a copy if Sara is happy that it's not a breach of protocol

On 9 Aug 2017, at 11:00, [redacted – personal information] wrote:

Hello [redacted]

I work as a researcher in the Parliament's information centre and I was wondering if you might be able to help me with something I am working on for an MSP. I have been asked a number of questions about MESH, including the allegations that things were omitted from the final report. I met with Sara Davies and David Bishop last week to try to understand in more detail what was being claimed and they were both very helpful. One of the things I asked was whether I could get a copy of the letter you wrote to the Cabinet Secretary which is referenced in the preface. Sara and David thought it best that I ask you for this. Would it be okay to get a copy? I figure it might be helpful to send them something more official and thorough rather than just my ramblings!

Happy to discuss on the number below.

Best wishes
[redacted – personal information]

DOCUMENT 5

From: [redacted]
Sent: 29 August 2017 09:03
To: [redacted]
Cc: Davies S (Sara) Dr; Bishop D (David); [redacted]
Subject: Letter for Alison Britton
Importance: High

Dear [redacted]

Further to my e-mail yesterday, I attach a letter for Alison Britton confirming her appointment. The text contains reference to the terms of reference (also attached) which have now been accepted. If you are "content" then I will ask Anne to format appropriately and dispatch. I trust this is satisfactory.

With best wishes,

[redacted]

Attachment 1:

Chief Medical Officer Directorate
Chief Medical Officer and Deputy Chief Medical Officer

Scottish Government
Riaghaltas na h-Alba
gov.scot

E: CMO@gov.scot

Alison Britton
Professor of Healthcare and Medical Law
Dept of Law , Economics, Accountancy and Risk
Glasgow School for Business and Society
Glasgow Caledonian University
[redacted – personal information]

x August 2017

Dear Professor Britton

THE SCOTTISH INDEPENDENT REVIEW OF THE USE, SAFETY AND EFFICACY OF TRANSVAGINAL MESH IMPLANTS

Thank you for agreeing to undertake an independent expert's review of the above named process. The Cabinet Secretary was pleased to inform the Public Petitions Committee of your appointment on the 17 May 2017.

This is important work that will be of value to the conduct of any necessary reviews in the future. I note the scoping document (attached) and I look forward to seeing your report in 2018.

I understand there will be certain costs associated with the work, and I would therefore ask that you liaise with my Officers, [redacted] in relation to funding arrangements.

Yours faithfully

CATHERINE CALDERWOOD
Chief Medical Officer
cc Alan Morrison
Richard McCallum
David Bishop
Terry O'Kelly
Sara Davies

Attachment 2:

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[3]

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[4]. 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;
Expectations of Chair and review members;
Potential conflicts of interest;
Conduct of members;
Timeframe;

[3] The wording of the remit may be refined as the work progresses but provides initial framework.
[4] But not limited to.

Management and presentation of evidence;

Management of external influences.

Part ll, of the review, based on the conclusions of Part 1, 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 ll. 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, Part l- Dr Ealasaid Munro- Postdoctoral research associate: The Major Minor Cinema project, University of Glasgow Department of Theatre, Film and TV;

Panel member Part ll- 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. [5] Part ll 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 presented in Part ll. 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.

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).

The data will then be imported into NVivo[6], where it will be coded and analysed. It is expected that this will be done by the appointed researcher, under the supervision of Dr Munro.

---

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

[6] NVivo is a qualitative data analysis (QDA) computer software package produced by QSR International. It has been designed for qualitative researchers working with very rich text-based and/or multimedia information, where deep levels of analysis on small or large volumes of data are required. NVivo is used predominantly by academic, government, health and commercial researchers across a diverse range of fields.

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

I would like the review to have an administrator. This person 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.

Yousaf Kanan has been interviewed and selected to be the project researcher. He 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. He will undertake work that may be required on an *ad hoc* basis from panel members. He 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. We would welcome guidance from you as to how this will operate. For example, subject to the production of receipts, could a working budget be made available to the panel so that it can be drawn upon, to purchase sundries and manage both the panel`s and participants` expenses?

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. We are looking to achieve this before the parliamentary recess commences for summer 2018.

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 ll

Background and chronology of events

Findings

Conclusions

Recommendations.

DOCUMENT 6

From: Bishop D (David)
Sent: 28 September 2017 13:58
To: [redacted] Davies S (Sara) Dr; [redacted]
Subject: Quick summary of mesh discussion at PPC

All

You are aware that [redacted] and [redacted] appeared at the Public Petitions Committee this morning. I was able to watch most of it, so a short summary of what I picked up from it:

[redacted]

- Thinks the way Chapter 6 was presented in the Interim Report was better because a lay-person could understand it. It included patient views and came to conclusions based on those as well as the evidence.

- Thinks conclusions 7 and 8 could be safer: 7 should have the word 'routinely' removed, and 8 should recommend that transobturator procedures should only be used exceptionally.

- Thinks because of the change of format between Interim and Final Reports, doctors performing the operations are confused. Some think the procedures must be safe, others don't.

- Considers Nature to be a better source of evidence than what was actually considered, as the randomised control trials relied on do not follow patients for long enough.

- Doesn't really know why his preferred approach for Chapter 6 was not accepted by the other clinicians.

- Does not think there were external influences that led to the change of approach. He said he was 'not a politician' when asked whether he thought the review was independent.

- Thinks that the outcomes of the Independent Review need to be reviewed, as well as the process of it, as being examined by Alison Britton. He also thinks that the findings should be put to public consultation.

- Thinks all clinicians completed Declarations of Interest properly, but thought they should go further back and also pointed out that the form did not ask whether the clinician represented a Health Board that was still carrying out mesh operations.

[redacted]

- Agree with Dr Agur's thoughts.

- Think the Review lost focus after [redacted] was replaced as Health Secretary and after the resignation of the first chair.

- Their views were not listened to and were not invited to certain meetings. There was a considerable amount of pressure placed on them by the new Chair and other members.

- At establishment of the group, they had to push to have 'Safety' included in its title as they were told that was out of remit. They also tried to suggest surgeons that were not pro-mesh that could participate in the group, but got nowhere with it.

- Think the evidence should have strengthened the findings of the Interim Report.

- Leaflets available on NHS and SG websites out of date.

- Their contributions to the Report were not removed despite requesting this of the Cabinet Secretary. They asked present Cabinet Secretary to delay publication of the Report so that their considerations could be further considered, but this did not happen. Instead it was rushed out.

The attached letter has come in about the leaflets available on websites. I will look at this with [redacted] when she's back from leave next week.

David

David Bishop
Scottish Government | Directorate for Health Finance and Infrastructure

Basement Rear, St Andrew's House, Regent Road, Edinburgh, EH1 3DG
Tel: 0131 244 1816

Attachment:

PUBLIC PETITIONS COMMITTEE

Shona Robison MSP
Cabinet Secretary for Health and Sport

CabSecHS@gov.scot
DGHSC@gov.scot

Public Petitions Committee
Room T3.40
The Scottish Parliament
Edinburgh
EH99 1SP
Tel: 0131 348 5254
Type Talk 18001 0131 348 5982
petitions@parliament.scot

28 September 2017

Dear Shona,

PETITION PE1517: POLYPROPYLENE MESH MEDICAL DEVICES

As you may know, the Public Petitions Committee took evidence this morning on PE1517 on polypropylene mesh medical devices.
One of the issues that came up was a question about the availability of the updated patient information leaflet and the presence of outdated information on Scottish Government and NHS Scotland websites. Understandably this is an issue which is of significant concern to the members.
The Committee therefore asks that you work with the Chief Medical Officer and Chief Executive of NHS Scotland as a matter of priority to ensure that any outdated information is removed from websites at the earliest opportunity and to provide an update to the Committee to confirm that the appropriate action has been taken.

Yours sincerely

Johann Lamont MSP
Convener
Public Petitions Committee