

# Transvaginal Mesh Case Record Review

June 2023



This report is about the planning, processes and execution of the Transvaginal Mesh Case Record Review. I was commissioned to undertake a case record review and produce a template that would accommodate a larger number of people who wished to have their case records reviewed. Starting with a blank canvas, I am grateful to the Directorate for the Chief Medical Officer and Deputy Chief Medical Officer who have been steadfast in their support of this Review. To my colleague Rachel Bond for her creative insights, good advice and IT skills - thank you!

It is often said the engagement between law and medicine is not an easy one. This was the opposite of my experience when working with my clinical colleagues on the Panel. Their patience and generosity in explaining the nuances of the history, care and treatment of this area has done much to enrich my understanding. Each brought a unique perspective to our discussions and to our recommendations. Mr Ian Currie, Dr Carey Lunan, Professor Anthony Smith and I express our warm thanks to our administrator, Irene Brown. Irene's common sense, kindness and patience is the backbone that has supported every stage of the Review. Irene, may I wish you a long and happy retirement.

Finally, I express my gratitude to the 18 women who came forward to have their case records reviewed. Their personal experience and insight have informed much of the structure and content of this Report. Despite personal and emotional cost, the majority of these women engaged in the Review, not only or even for themselves, but to make a difference to the quality of life for other women. I hope that this Report reflects their experiences and that we learn from them.

Alison Britton, Professor of Healthcare and Medical Law, Glasgow Caledonian University. 20 June 2023

## Contents

Moderator’s Introduction and Overview .....	3
Contents of the Report .....	15
Recommendations .....	18
Chapter 1 - Background and Process .....	22
Chapter 2 - Advance Planning.....	29
Chapter 3 - Preparation of Documentation and Templates .....	40
Chapter 4 - The Case Record Retrieval Process.....	46
Chapter 5 - Review of the Case Records and feedback to the Participants .....	53
Chapter 6 - Alternative approaches: International experiences and perspectives*..	59
PART II .....	71
Chapter 7 - The Lived Experience of the Women.....	72
Chapter 8 - Communication, Clarity of Language, and the Process of Information Disclosure and Consent.....	81
Chapter 9 - Acknowledging the Past and Looking to the Future.....	99
ANNEX 1 – DOCUMENT TEMPLATES .....	120

## Moderator's Introduction and Overview

Polypropylene pelvic mesh implants are medical devices used in a number of operations to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP). Historically, synthetic materials were employed in surgery for stress incontinence in the second half of the last century but largely abandoned because of problems with erosion and infection. More recently, the use of polypropylene mesh in the form of a tension free vaginal tape/sling for the treatment of stress incontinence of urine in women was popularised in the 1990s. Extensive publications demonstrated that it was as effective as all other procedures previously described.

The success of the stress incontinence surgery led to the development of procedures for the treatment of pelvic organ prolapse with polypropylene mesh augmentation of the repair. This involved much larger pieces of mesh and has been associated with significantly more reports of mesh related complications.

Following the first approval by the American Food and Drug Administration in 1996 there were a 'cascade'<sup>1</sup> of devices similarly approved based on the fact that they were of 'substantial equivalence'.<sup>2</sup> Although the majority of these operations have delivered good outcomes,<sup>3</sup> details began to emerge that a number of women were

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<sup>1</sup> Motamedi, M., Carter, S.M. & Degeling, C. (2022) Women's Experiences of and Perspectives on Transvaginal Mesh Surgery for Stress Urine Incontinency and Pelvic Organ Prolapse: A Qualitative Systematic Review. *Patient* **15**, 157–169. Available from: <https://doi.org/10.1007/s40271-021-00547-7> [Accessed January 13 2022]

<sup>2</sup> Karmakar D, Hayward L. (2019) What can we learn from the vaginal mesh story? *Climacteric*. 22(3):277–82, in Motamedi, M., Carter, S.M. & Degeling, C. Women's Experiences of and Perspectives on Transvaginal Mesh Surgery for Stress Urine Incontinency and Pelvic Organ Prolapse: A Qualitative Systematic Review. *Patient* **15**, 157–169 (2022). Available from: <https://doi.org/10.1007/s40271-021-00547-7> [Accessed January 13 2022]

<sup>3</sup> Angelova, N et al (2021) User testing a patient information resource about potential complications of inserted synthetic mesh, *BMC Womens Health*. 2021; 21: 35. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7831188/#CR3> [Accessed February 5 2023]

experiencing post-surgical adverse events including pain (especially vaginal and groin pain), specific pain during intercourse (dyspareunia), worsening of urge incontinence and mesh exposure.<sup>4 5</sup> These experiences have been the subject of intense scrutiny and debate not only in Scotland,<sup>6</sup> but across the world.<sup>7</sup> In April 2014, medical mesh devices were the subject of a petition to the Scottish Parliament's Public Petitions Committee.<sup>8</sup> The Petition was lodged to draw attention to a number of women who had experienced serious complications following procedures to treat pelvic organ prolapse and stress urinary incontinence. The Petition received over 1700 signatures and 212 comments.<sup>9</sup> In June 2014, Alex Neil – then the Cabinet Secretary for Health and Wellbeing – informed the Committee that he intended to commission an Independent Review. The Review would not only explore the evidence that the petitioners had provided, but also consider complication rates and under-reporting of adverse events as well as reviewing the overall evidence base for mesh devices.

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<sup>4</sup> Muller P, Gurol-Urganci I, Thakar R, Ehrenstein MR, Van Der Meulen J, Jha S. (2022) Impact of a mid-urethral synthetic mesh sling on long-term risk of systemic conditions in women with stress urinary incontinence: a national cohort study. *BJOG An Int J Obstet Gynaecol.* 129(4):664–670.

<sup>5</sup> Keltie K, Elneil S, Monga A, et al. (2017) Complications following vaginal mesh procedures for stress urinary incontinence: an 8-year study of 92,246 women. *Sci Rep.* 7(1):12015. 10

<sup>6</sup> Morling JR, McAllister DA, Agur W, et al. (2017) Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997-2016: a population-based cohort study. *Lancet* (London, England).389(10069):629–640.

<sup>7</sup> Thompson C, Faunce TA. (2018) Australian senate committee report on transvaginal mesh devices. Thompson C Faunce TA Aust Senate Comm Rep Transvaginal Mesh Implants *J Law Med.* 8;25(4):934–943.

<sup>8</sup> PE1517.

<sup>9</sup> PE1517 was lodged on 30<sup>th</sup> April 2014 and closed on Sept 9<sup>th</sup> 2021. For a full chronology, see <https://archive2021.parliament.scot/GettingInvolved/Petitions/scottishmeshsurvivors>

On 27 March 2017, the Scottish Government published the Mesh Review's Final Report.<sup>10</sup> It received widespread criticism over a range of concerns including the evaluation and inclusion of certain evidence, the nature and quality of the independence of the review process, and the inclusion of the two petitioners' input despite their resignation and request for their contribution to be removed.

In May 2017, I was commissioned by Shona Robison, then the Cabinet Secretary for Health and Sport, to investigate the process by which the review came to its conclusions. The findings of our Investigative Review were published in October 2018.<sup>11</sup> The report highlighted a number of failings and made recommendations on how independent reviews should be conducted in future. Despite being well received,<sup>12</sup> to date, none of the 46 recommendations made have been implemented by the Scottish Government.

In November 2019, the First Minister met a number of women who had experienced complications after having had surgery for mesh implants. In addition, some of these women expressed concerns about their clinical care, how it was documented in their case records and how it was reported to them. Following those meetings, the First

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<sup>10</sup> Scottish Government Publications (2017) *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*. Available from: <http://www.gov.scot/Resource/0051/00515856.pdf>.

<sup>11</sup> Britton A. (2018) *An Investigative Review into the process of establishing, managing and supporting Independent Reviews in Scotland, with particular reference to the Independent Review of Transvaginal Mesh* Available from: <https://www.gov.scot/publications/investigative-review-process-establishing-managing-supporting-independent-reviews-scotland/>

<sup>12</sup> Scottish Parliament Official Report 18 December 2018, at columns 29-36, The Justice Secretary (now Cabinet Secretary for Health) noted that ; *'I absolutely accept the vast majority of the recommendations, but I am giving further consideration to a few others'...Many of the review recommendations, certainly the central ones, make a lot of sense to me, especially those on impartiality of members and there being more transparency about remits and terms of reference....'* At column 35. Available from: <https://www.parliament.scot/api/sitecore/CustomMedia/OfficialReport?meetingId=11854> [Accessed January 23 2023]

Minster confirmed that these women would be given an opportunity to raise their concerns and offered them a review of their case records.<sup>13</sup>

On the 12th February 2021, the then Cabinet Secretary for Health and Sport, Jeane Freeman, introduced the Transvaginal Mesh Case Record Review.<sup>14</sup>

This Report presents the findings of the Review. Our Terms of Reference required us to undertake an assessment of our Review processes including their value and their impact on any similar, future work. This work would be regarded as a '*pilot*' which would include recommendations for requesting, scoping and conducting a future case review for a larger number of women.

Our Report comprises nine chapters and is divided into two parts. Part I takes a reflective and chronological approach, starting with the rationale for the commissioning of the Case Record Review, and then goes on to describe the advance planning, process and methods that were adopted.

The nature of the Review required us to engage with a number of parties and our report considers their role and their contribution. Central to our work was the review of participants' case records and this Report reflects on how we initially engaged with the participants and describes the process of requesting, retrieving and collating their case records. The final part of that process was to evaluate their medical records and to provide an individual report to each participant, detailing the Panel's findings. In every case, the Panel was unanimous in its findings and feedback for every set of

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<sup>13</sup> Scottish Government, 'Support for mesh victims.' (23/2/2020) Available from: <https://www.gov.scot/news/support-for-mesh-victims/> [Accessed September 29 2021]

<sup>14</sup> The case Record Review and its membership was announced by the Cabinet Secretary in the Scottish Parliament February 12 2021. Available from: <https://www.parliament.scot/chamber-and-committees/questions-and-answers/question?ref=s5w-35181> [Accessed April 28 2023]

records that we reviewed. The final chapter of Part I explores alternative approaches and considers how other countries have reached out to women who have raised concerns following transvaginal mesh surgery. Unsurprisingly there is a common theme to these concerns and it is interesting to see how other countries have responded to these challenges and whether their approach may have value in shaping some of the future thinking in Scotland.

It is never an easy task to start any project, particularly when you are starting with an almost blank sheet. We had to design a process which would facilitate a new, innovative approach concerning the review of medical case records. We were given the names of 47 women who would be invited to participate in the review, all of whom had met with the First Minister or Cabinet Secretary for Health in November 2019. Out of the 47 selected, 19 women chose to meet with us, with 18 requesting a review of their records. All 18 remained engaged with the process – some for nearly two years – until the conclusion of their case record review and the receipt of their report.

The different rates of complications between stress incontinence surgery and prolapse surgery employing polypropylene mesh is often not highlighted in the debate about use of polypropylene mesh in gynaecological reconstructive surgery. All 18 participants in this Review underwent surgery using polypropylene mesh specifically for stress incontinence. Of the 18 women, 15 had a transvaginal tape-obturator (TVT-O) and 3 had a transvaginal tape(TVT) device. All had given birth to at least one child. Some of these women had additional surgeries at the time, for separate urogynaecological issues, such as prolapse. It is not known whether this was a chance occurrence or if this represents a trend in surgical complications associated with mesh surgery in gynaecology in Scotland.



The volume and extent of what we would request in terms of records for our Review was left for the Panel to decide. We were very aware from the outset, that the breadth and depth of any request would have an impact not only on us as a Panel in terms of our time but also upon those tasked within the relevant Scottish Health Boards with retrieving the case records on our behalf. Our initial requests to the Health Boards were made only a month or so after Scotland was emerging from its second Covid-19 lockdown in 2021. Whilst the timing was not ideal, the Accountable Officers, whom the Scottish Government had agreed would be the named contact for each Health Board to assist us, seemed largely unaware of the existence of the Review and their role within it. A lot of time was spent, up to several months in some cases, in trying to identify the name of the person from the Health Boards who would work with us. In several instances, this was not resolved without the intervention of the Scottish Government. This delay impacted upon the Panel's work and was frustrating especially given the pilot involved only a total of 18 sets of case records.

In terms of the volume and extent of our requests, whatever we decided was unlikely to satisfy all parties who would have a different understanding of what would be sufficient to meet the aims of our Terms of Reference and Remit. We are grateful to the Boards who provided us with what we requested. The Panel recognise that, in the majority of cases, our requests were extensive.

This can be explained by the fact that we were initially advised that all 47 women on the list that we were given had undergone either full or partial mesh revision surgery. This was not the case, and applied initially to only two of the 18 participants with a further four receiving mesh revision surgery over the next two years.<sup>15</sup> This meant

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<sup>15</sup> All six participants received their surgery out with Scotland.

that the majority of those who participated in the Case Record Review had not undergone any revision surgery, and their concerns focused instead upon a broader range of matters regarding their treatment and experiences of their healthcare. This required the Panel to revise its thinking not only in terms of what needed to be requested from the Health Boards but significantly extended the focus and duration of our work. Ultimately, we agreed that because of the diversity of issues that the participants raised, we would need to understand the chronology of what had led them to where they were currently, in terms of their outcomes. We would need to be prepared to request records that started with their initial consultation, moving on to any conservative treatments, consent processes, surgery (including any revision surgery) and other relevant treatments up to the time when we first met with the participant.

The practical consequence of this meant that we requested more than 40,000 pages of records. From our initial meeting with each participant, the subsequent request of case records to the completion of each report, it is estimated that some 45-50 hours was spent on each participant's case. We wrote 18 bespoke participant reports. It was a significant and resource intensive undertaking. We recognise that this was especially so when the participant numbers were not large.

We believe it was time well spent. Collaborating with the participants for nearly two years, brought valuable insights and understanding as a Panel and participants told us that they appreciated not being rushed and being able to define their journey in their own way and in their own time. Although we undertook a brief qualitative feedback process at the end of the Review, we believe that further work is required to ascertain a more in-depth picture of the participants' views on their experience of the Review and its outcomes. Importantly, since this was a pilot, we were constantly

reflecting upon, learning from, and adapting the review process as we went along, and we came to recognise that our initial approach would not be sustainable for a larger number of women who may wish to have their case records reviewed. We have suggested ways in which this process may be streamlined to accommodate a larger number of participants in the concluding chapter of Part I.

The second part of our Report considers some recurring themes that arose during our conversations with the participants. We encouraged all the women who were part of the Review to describe their lived experience. Many alluded to feeling that aspects of their lives had diminished or been lost altogether, whether this was engagement with family, intimacy with a partner, loss of job, financial independence, or the side-effects of medication. Often spoken about were feelings of anxiety and the practical consequences of the enforced isolation of lockdown during Covid-19 including the impact this has had on receiving treatment. Whilst much of this aspect may have been unavoidable, it continues to leave some women in a vacuum of uncertainty regarding next steps in the management of their care.

The importance of clear and informative dialogue between the women and their healthcare practitioners is considered in the light of the legal and clinical evolution of information disclosure and consent and good clinical case record keeping. By current legal and professional standards, this means not only recording a choice of treatment or option, but also documenting how that decision was reached. Informed decision making is central to the vitality and trust within a health professional's relationship with their patients; consent is not a 'one off' or a tick-box process, it is an integral and perpetual part of good clinical practice.

A significant theme in Part II of this Report concludes that if clear and commonly understood language had been used to explain to women potential treatments and outcomes (even if these were uncertain prior to surgery), this may have alleviated many of the issues that subsequently arose over the course of their clinical journey.

Every patient is entitled to expect and receive accurate information both before any treatment is chosen and to be advised on the effectiveness and consequences of any intervention. Most of the cases that we reviewed did not meet these standards.

We recognise that a generic consent form was used in most of the cases, certainly for the initial mesh surgery, and that this was in keeping with consent practices at that time. In some of the more recent cases that we reviewed, there was documented evidence of what appeared to be informed discussion, but the participant had no recollection that this had occurred. This highlights the need to create opportunities and time for patients to reflect, revisit and ask questions regarding potential treatments and alternatives. Discussion should be accompanied by accurate and comprehensive documentation to include information leaflets and procedure specific consent forms.

If a patient makes a request to be accompanied to a consultation or record a consultation, reflecting current professional guidelines, such requests should be encouraged and supported. The law and professional guidelines have changed progressively over the last 20 years, and significantly so post the case of *Montgomery*,<sup>16</sup> which brought to the fore the legal requirement to explain the specific risks and benefits of treatment options tailored to each individual patient. This is a

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<sup>16</sup> *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 is a Scottish case that outlines the rule on the disclosure of risks to satisfy the criteria of an informed consent. Chapter 8 considers the implications of this case.

foundation on which all good medical practice should be based and is not confined to this particular discipline of healthcare.

The final observations of Part II look to the future and consider the role of the complex mesh surgical services in Scotland.<sup>17</sup> It is vital to first understand the impact of the legacy of treatment that many of the women carry with them. Some of these legacies are not new and have been well documented elsewhere, but their significance means that they bear repeating and re-evaluating so that they may be kept to the forefront of decision making around the treatment and care of those who have experienced harm following a transvaginal mesh implant.

When mapping the process set out in Part I against the emergent themes set out in Part II of this Report, we asked ourselves whether a Case Record Review is the correct mechanism to address such themes. The answer is yes, partly, but not completely. Whilst a Review of this nature was requested by a number of women, was it really the most effective way to provide answers to all the questions that the women had raised?

We recognise that women had concerns about the accuracy and content of their case records and that this required to be explored. If they were to move forward with their lives, some women needed to have it acknowledged that they were not imagining the circumstances in which they find themselves. The review of case records highlighted, in many instances, a lack of clarity regarding the necessity of surgery, the outcome of conservative treatments, if any had been undertaken, or an explanation of the risk and benefits of potentially undergoing mesh surgery. Of note,

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<sup>17</sup> The Scottish Government announced its establishment in June 2020 and it opened in August 2020. Available from: <https://www.gov.scot/news/national-mesh-removal-service/> [Accessed January 24 2023]

in a number of the cases, we observed a lack of clarity in the case records documenting the nature and potential outcome of mesh revision surgery.<sup>18</sup> Some notes were misleading, but other cases, did not bear any reflection to the surgery that had occurred, nor its outcomes. These matters may have not come to light, without the commissioning of the Review.

Two points have stayed with me. First, by its very nature, the Panel could only review what was documented in the case notes; we could make no comments on conversations that had occurred verbally because there was no means or evidence on which to do so. Second, the Review focussed entirely on retrospective events. This gave rise to a number of questions including what could be gleaned from this Review to effect women's present and future care? The Panel agreed that it was impossible to extrapolate from a review of case records how these women felt. Matters of respect, dignity, and being listened to, cannot be evidenced solely by a case record review, nor can they be enhanced as a natural consequence of one. Having to exclude the lived experiences of the women from the practicalities of what could be evidenced in the case records, has made the Panel realise that the mechanics of a case record review cannot address the more nuanced parts of a lived experience, and the Remit of the Review did not include speaking to any of the clinicians involved in a participant's care. Something more inclusive is required and this Report makes some proposals on how to address this.

Is there a better way to manage care and meet the needs of these women's care in the future? Mesh revision surgery may not be the only solution; it may not even be

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<sup>18</sup> Surgery to remove all, or part of, the mesh (subsequently referred to in the report as 'mesh revision surgery').

the best solution. However, where it is clinically indicated and it is the woman's choice, it will have a role for a finite number of women.

In terms of the chronology of care, we have reached a crossroads where future management of care should include the involvement of multidisciplinary healthcare teams. We recognise that this is already happening through the combination of the Complex Mesh Surgical Services in Scotland who are integrated with healthcare teams at a local level. Where the responsibility of care lies, along with the referral processes have to be clear and we do not believe that this is yet the case.

The definition of healthcare in these contexts are broad. Recognising that their circumstances may require participants to require care and support for the rest of their lives, women are seeking support on matters which will enhance their quality of life; management of pain, diet and exercise, financial advice, companionship and they want to be part of shaping what these provisions may look like in Scotland. It is imperative that they are.

As a Panel, we completed what we were asked to do, and drawing on our experience from conducting this pilot Review, we suggest ways that a workable process for all parties could be made available to a larger group of patients.

Importantly, we believe that a case record review should form an important but only a part of this process.

## Contents of the Report

Each chapter discusses key areas integral to a Review of this nature. As befits a pilot study, we have been critical, analytical, and reflective. We have provided recommendations for the establishment, management and support of potential, larger scale future Case Record Review.

**Chapter 1** introduces key information about the composition of the Transvaginal Case Record Review Group and our methodology. It outlines the remit and terms of reference of the Review and our shared understanding of them. Finally, it describes the principles and essential characteristics that we agreed would form the work of our Review.

**Chapter 2** considers the advance planning that we undertook prior to the Review's launch by the Cabinet Secretary for Health & Sport in February 2021. Once the Panel had been appointed, there was an expected 4-6 months before the Cabinet secretary formally launched the Review. We used this time to undertake advance planning and preparations. The starting point was how we were going to design a workable process which was both understandable and effective for women who chose to engage with the Review. We knew that we would be working with a number of women where trust, or more accurately, a lack of trust, about their healthcare and the relationships within it, was a significant issue. It was vital to understand this and what was important to them. Where possible, it was hoped that we may be able to restore some elements of that breakdown in trust within patient and healthcare relationships.



**Chapter 3** describes the documentation and templates that were designed to assist both the Panel and the participants to navigate their way through the process. We recognised the need for these to be clear, concise and informative. We started to examine how we were going to store and transfer substantial amounts of sensitive information. **Chapter 4** considers the engagement with Health Boards, GP surgeries and other agencies in case record retrieval, while **Chapter 5 examines** how the Panel went about reviewing the case records and how we relayed our findings back to the participants. Part I of the report concludes with **Chapter 6** reflecting on some international perspectives; the experiences and work undertaken in other countries, namely Australia and New Zealand.

Part II starts with **Chapter 7**, and describes the characteristics of the women who shared their - often described as - lived experiences with us. This chapter considers how the women themselves perceive the challenges they have encountered in their daily lives, both with regard to their health and their well-being. An important aspect of this is to consider not only their lived experience to date, but their perceptions on where they are currently and what the future may hold for them.

**Chapter 8** provides that the use of clearly understood language and meaningful dialogue should be at the heart of any decision-making and consent processes. It reflects on the current legal and clinical frameworks for decision-making and their practical application throughout all aspects of a patient's engagement with their healthcare professionals, whilst **Chapter 9** looks to the future and reflects on ways to manage women's care, recognising the legacy of treatment and the impact that this has had on women's faith and trust in their healthcare. The future role of the complex mesh surgical service in Scotland and how it integrates with local services will also be addressed. The importance of data capture is recognised. Not only is this an

essential requirement to inform the allocation and provision of resources but to ensure that aftercare and follow up is available for those who have received treatment, both within and out with Scotland. Pathways for treatment and referral need to be clearly articulated and publicly available.

Whilst the responsibility for the contents and writing of this report is mine, the reflection contained in the following chapters is the result of the collaborative work and unanimous views of the Panel.

## Recommendations

- 1. We recommend that if deemed necessary by the Scottish Government, any bespoke Data Sharing Agreements should be put in place with the remaining Boards prior to the commencement of any larger case review.**
- 2. We recommend that it is critical to have a process whereby what is requested is what the individual wishes to see, and provides relevance and context to what they would like to know. We therefore recommend, that, in conjunction with other initiatives, the short form retrieval method is adopted.**
- 3. We recommend additional support mechanisms being put in place for GPs and practice teams to aid understanding and address concerns women may raise with them following a transvaginal mesh surgery.**
- 4. We recommend that Scotland maintains a Mesh Register which records surgery in Scotland, as well as surgery which has occurred in other parts of the UK and overseas.**
- 5. We were supportive of the practical and integrated response proposed by the New Zealand review and suggest that Scotland should reflect with a view to adopting similar initiatives.**
- 6. We recommend that there needs to be a clear understanding and precision regarding the language used to describe the procedure being proposed. If there is discussion regarding a potential procedure to remove mesh, it has to be made explicit what type of surgery is to be undertaken and the proposed extent of what is going to be removed.**

- 7. We recommend that, if requested by the patient, the organisation provides an explanation to the patient (or person authorised by the patient to request it on their behalf), why certain information has been redacted.**
  
- 8. We recommend keeping a detailed set of medical notes of the dialogue, including what leaflets were given (and including a copy of these in the records), what counselling and advice was given about the procedure, and which risks and potential complications were discussed that led to an informed decision being made. This should then be replicated in a letter to the patient and copied to the patient's GP.**
  
- 9. We recommend that surgical units should keep a version control of their patient information Leaflets and that this should be noted in the case records so that when looking back, it can be seen precisely what information was given to a patient at any point in time.**
  
- 10. We recommend that the use of patient decision-aids, checklists and information leaflets should be provided in advance of the consultation, so that the time available in the consultation can be optimised. This helps to ensure that patients are empowered with the information they need to decide and have shared responsibility for their care.**
  
- 11. We recommend the creation of a national specific consent form, for use across the country, to reduce variation, and improve consistency of information covered during the counselling process.**

- 12. We recommend to create the conditions in the NHS to enable an informed consent process, namely adequate training, and adequate time, supported by high quality decision aids and consent forms.**
- 13. We recommend that all information should be drawn together into a single website. This website should be clear about where the responsibility lies for patient care at each stage through the referral pathway.**
- 14. We recommend that dedicated funding should be made available so that work may be undertaken to make this website accessible, connected and regularly updated and maintained with up-to-date information.**
- 15. We recommend that information around referral and treatment pathways is clarified and published on the website. This needs to be specific to the processes of the Complex Mesh Surgical Service, Scotland and designed from the patient perspective. Where responsibility lies at each stage should be identified and signposted effectively. This should be regularly updated and maintained.**
- 16. We recommend the process of training and credentialing of surgeons in Scotland is a critical element and its process has to be clearly articulated, and made available, not only for clinicians, but also for women using the service.**
- 17. We believe that patients should be clearly informed of the options available during their appointment prior to attending the Complex Mesh Surgical Service Scotland, for example, to be accompanied by a trusted person and to record discussions that take place during the appointment. Such options will help to enable the patient to retain and reflect on the information and**

**treatment options discussed. It is recommended that this information is included on the single website.**

**18. We believe that it is crucial that there is an agreed system of NHS follow-up and ongoing support in place for patients who are returning from a mesh revision surgery which has taken place outside Scotland and that this data is captured, collated and forms part of a comprehensive evaluation mechanism.**

**19. We recommend the implementation of the Health Improvement Scotland Guidelines on data capture to also include national learning from significant adverse events.**

**20. We recommend the requirement for all Complex Mesh Surgical Services' across the UK to collaborate on agreed consistent data gathering, including on longer term outcomes from treatment**

**21. We recommend that agreement be reached on how 'success' should be defined and measured, from both a clinician and patient perspective.**

## Chapter 1 - Background and Process

- 1.1 In April 2014, Medical mesh devices were the subject of a petition to the Scottish Parliament's Public Petitions Committee.<sup>19</sup> The Petition was lodged to draw attention to a number of women who had experienced serious complications following procedures to treat pelvic organ prolapse and stress urinary incontinence. The Petition received over 1700 signatures and 212 comments.<sup>20</sup> In June 2014, Alex Neil – then the Cabinet Secretary for Health and Wellbeing – informed the Committee that he intended to commission an Independent Review. The Review would not only explore the evidence that the petitioners had provided, but also consider complication rates and under-reporting of adverse events as well as looking at the overall evidence base for mesh devices.
- 1.2 On 27 March 2017, the Scottish Government published the Mesh Review's Final Report.<sup>21</sup> It received widespread criticism over a range of concerns including the evaluation and inclusion of certain evidence, the nature and quality of the independence of the review process, and the inclusion of the two petitioners' input despite their resignation and subsequent request for their contribution to be removed.
- 1.3 In May 2017, Shona Robison, the then Cabinet Secretary for Health and Sport, commissioned me to investigate the process by which the Review came to its conclusions. The findings of the Investigative Review were published in October 2018.<sup>22</sup> It highlighted a number of failings and made recommendations on how such reviews should be conducted in future. Despite being well received, to date,<sup>23</sup> none of the 46 recommendations have been implemented by the Scottish Government.

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<sup>19</sup> PE1517.

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<sup>21</sup> Scottish Government Publications (2017) 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. Available from: <http://www.gov.scot/Resource/0051/00515856.pdf>

<sup>22</sup> Britton A. (2018) An Investigative Review into the process of establishing, managing and supporting Independent Reviews in Scotland, with particular reference to the Independent Review of Transvaginal Mesh. Available from: <https://www.gov.scot/publications/investigative-review-process-establishing-managing-supporting-independent-reviews-scotland/>

<sup>23</sup> Scottish Parliament Official Report 18 December 2018, at columns 29-36, The Justice Secretary (now Cabinet Secretary for Health) noted that; '*I absolutely accept the vast majority of the recommendations, but I am giving further consideration to a few others'...Many of the review recommendations, certainly the central ones, make a lot of sense to me, especially those on*

## Membership of the Transvaginal Mesh Case Record Review

- 1.4 In November 2019, the First Minister met a number of women who had experienced complications after having had surgery for mesh implants. Some expressed concerns about their clinical care, how it was documented in their case records and how it was reported to them. Following those meetings and to address such concerns, the First Minister confirmed that these women would be given an opportunity to set out their concerns about treatment and offered an independent review of their medical notes.<sup>24</sup>
- 1.5 On the 12th February 2021, the then Cabinet Secretary for Health and Sport, Jeane Freeman, announced the start of the Transvaginal Mesh Case Record Review.<sup>25</sup>
- 1.6 The Membership of our Panel was:
  - Alison Britton – Moderator of the Case Record Review. Professor of Healthcare & Medical Law, Glasgow School for Business and Society, Glasgow Caledonian University;
  - Mr Ian Currie – Consultant Obstetrician and Gynaecologist, Buckinghamshire Hospitals NHS Trust: 1997- Present;
  - Dr Carey Lunan, GP principal, NHS Lothian. Immediate past-Chair of Royal College of General Practitioners in, Scotland )2017-2020;
  - Professor Anthony Smith, Professor of Urogynaecology (Manchester Academic Health Services Centre) & Consultant Gynaecologist, Manchester (retired);
  - Administration – Irene Brown, Directorate of School Professional Services, Glasgow Caledonian University (retired);
  - Transcription - Irene Brown, Directorate of School Professional Services, Glasgow Caledonian University (retired); and

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*impartiality of members and there being more transparency about remits and terms of reference....'* At column 35. Available from: <https://www.parliament.scot/api/sitecore/CustomMedia/OfficialReport?meetingId=11854> [Accessed January 23 2023]

<sup>24</sup> Scottish Government, 'Support for mesh victims' (23/2/2020). Available from: <https://www.gov.scot/news/support-for-mesh-victims/> [Accessed September 29 2021]

<sup>25</sup> Scottish Government (2020), 'Support for mesh victims: Case Note Review to take place in Spring' (23/2/2020). Available from: <https://www.gov.scot/news/support-for-mesh-victims/> [Accessed September 29 2021]



- Transcription - Alison Lockhart, Directorate of School Professional Services, Glasgow Caledonian University.
- 1.7 Each member sat in a personal capacity and did not represent the views of any particular organisation or body.

## The Purpose of the Review - Remit & Terms of Reference

- 1.8 The Scottish Government commissioned and funded this Review. Its design, purpose and Terms of Reference are the product of a consultation process with interested parties, including, amongst others, the Short Life Working Group on Mesh Complications,<sup>26</sup> the Health and Social Care Alliance Scotland<sup>27</sup> and women's representatives, the General Medical Council,<sup>28</sup> the Scottish Public Services Ombudsman,<sup>29</sup> Central Legal Office,<sup>30</sup> Royal College of Obstetricians and Gynaecologists,<sup>31</sup> and the Panel members of the Review.
- 1.9 Much of the engagement with these parties had been conducted prior to the appointment of the Panel but once appointed, we were given the opportunity to adapt and revise any of the provisions.
- 1.10 Following the initial publication<sup>32</sup> of the Terms of Reference, a number of requests for clarity were received regarding some of its sections. As moderator, I attended a meeting with representatives from the Scottish Mesh Survivors

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<sup>26</sup> The remit of this Scottish Government Group established in March 2019, '*considers the care provided for women who experience complications following vaginal mesh surgery in Scotland.*' Available from: <https://www.gov.scot/groups/transvaginal-mesh-short-life-working-group/#:~:text=Overview,complications%20following%20vaginal%20mesh%20surgery> [Accessed January 8 2023]

<sup>27</sup> Available from: <https://www.alliance-scotland.org.uk/> [Accessed January 8 2023]

<sup>28</sup> Available from: <https://www.gmc-uk.org/> [Accessed January 8 2023]

<sup>29</sup> Available from: <https://www.spsso.org.uk/> [Accessed January 8 2023]

<sup>30</sup> Available from: <https://clo.scot.nhs.uk/> [Accessed January 8 2023]

<sup>31</sup> Available from: <https://www.rcog.org.uk/> [Accessed January 8 2023]

<sup>32</sup> Which was published on the Transvaginal Case Record Review website. Available from: <https://tmcr.scot/> [Accessed January 8 2023]

Group,<sup>33</sup> Jackson Carlaw MSP, Alex Neil,<sup>34</sup> Neil Findlay<sup>35</sup> and Dr Wael Agur<sup>36</sup> following which, a revised version was agreed and published.<sup>37</sup>

1.11 The purpose of the Review is set out in its Remit and Terms of Reference.

1.12 The remit of the Review was to:

‘Consider the serious concerns raised by some women at the meetings with the First Minister in November 2019. Specifically, if their case records accurately reflect whether they have undergone full or partial removal of transvaginal mesh. The Review aims to provide clarity on individual case records and the mesh removal procedure performed by providing an opportunity for women to set out their concerns and have their records reviewed by clinicians to allow for discussion, explanation and mutual understanding.’<sup>38</sup>

1.13 As a Panel, we unanimously agreed that the remit supported the rationale for the Review.

1.14 The remit was met by following the provisions contained in the Terms of Reference.

## Terms of Reference

*This Review is intended for the women in Scotland who have had transvaginal mesh implants and who attended the meetings with the First Minister in November 2019. The purpose is to address the concerns they expressed about their clinical care and how this is documented in their case records and/or how this care has been communicated to them. In particular, the Review will address concerns about the clarity of documentation regarding full and partial removal of mesh.*<sup>39</sup>

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<sup>33</sup> Scottish mesh Survivors Group website can be accessed on: <http://scottishmeshsurvivors.com/> [Accessed June 15 2022]

<sup>34</sup> MSP 1999-2021

<sup>35</sup> MSP 2011-2021

<sup>36</sup> Dr. Wael Agur is a lead urogynaecologist with NHS Ayrshire and Arran. He is also an honorary senior clinical lecturer at the University of Glasgow.

<sup>37</sup> Transvaginal Case Record Review website. Available from <https://tmcrr.scot/terms-of-reference/> [Accessed June 15 2022]

<sup>38</sup> Transvaginal Mesh Case Record Review website available from: <https://tmcrr.scot/terms-of-reference/> [Accessed June 15 2022]

<sup>39</sup> Transvaginal Mesh Case Record Review website available from: <https://tmcrr.scot/terms-of-reference/> [Accessed June 15 2022]

- 1.15 The Review was not intended to provide an examination of a participant's entire case history, nor was it to include any specific recommendations about further treatment. Instead, it was intended to examine case records relevant to the mesh care and treatment. Defining what constituted 'relevant' case notes was not as straightforward as was initially thought. This will be discussed further in this and the following chapter.
- 1.16 A bespoke report has been provided to each participant, summarising the findings of the Panel. This was accompanied by an invitation to meet to discuss our findings regarding the participant's case records. These meetings were optional but if they were requested, they were attended by the participant, moderator, administrator and one of the clinical panel members. All participants were invited to have someone attend these and all meetings with them if that was their preference.<sup>40</sup> There was a subsequent opportunity, after a period of reflection, for any follow-up comment and questions. Participants were encouraged to make their General Practitioner aware of their engagement in the Review. The Health Boards will add a note to a participant's case record to advise that they have participated in this Review. The terms of reference note that consideration will be given to offering a Review of this nature to other women who have had transvaginal mesh implants and who may have similar or other concerns.

### Structure of this Report

- 1.17 This Report presents our findings and comprises two parts. Part I provides a critical and reflective assessment of the review process that we adopted; its strengths, weaknesses and whether it achieved its aims. The terms of reference required that the Review was to be undertaken as a 'pilot' and that this Report should include a description and analysis, and make recommendations for some possible models that could be used to enable a larger number of women to engage in any future Case Record Review.
- 1.18 As such the concluding chapter of Part I contains practical recommendations for requesting, scoping and conducting any future larger review.
- 1.19 The second part of our Report considers some of the recurring themes which emerged as part of our discussions with the women who agreed to participate in the Review and also through our own engagement as a Panel with the case records.
- 1.20 The balance of this chapter outlines some of the challenges in relation to conducting a pilot review and what we did to address them. It concludes with key information about who this report was written for (our intended audience)

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<sup>40</sup> Participants were invited to have someone accompany them for any meetings that were held.

and acknowledges our thanks to those who chose to participate in the Case Record Review.

### What is a 'pilot' review?

- 1.21 A pilot process, or in this case, pilot review, will often bring with it a degree of uncertainty because it will be introducing untried or unique approaches. The purpose of the pilot is to ascertain the viability of the approaches taken using a smaller scale before committing resources for use on a larger scale.
- 1.22 This was true in this context, since a Review of this nature had not been undertaken before.<sup>41</sup> Part of the purpose of our Review was to prove the viability of the approach(es) that we adopted. The smaller scale elements were satisfied by confining eligibility to a group of 47 women who had attended meetings, in November 2019 with the First Minister and Cabinet Secretary for Health and Sport.
- 1.23 A first task for us was to design and create processes which would underpin the Review. Once these were in place we continued to test and reflect upon them throughout the Review's duration.<sup>42</sup> In particular this included the use of various documents. These comprised not only the final Report but included explanatory materials, consent forms, forms to ingather information and a clinical *proforma* which detailed what aspects of their case records the participants would want the panel to review. These documents are considered in more detail in chapters 3, 4 and 5.
- 1.24 This Report also documents our perceptions and experiences throughout the duration of the Review. As befits a pilot, it includes consideration of whether the Panel believes that the Review was viable and beneficial – not only as a concept in itself, but also whether the underpinning processes that were used achieved the aims and outcomes of the Review and, if so, what may be done to enhance the viability of a larger future review. Whether a review of case records should stand in isolation or form part of a multi-faceted approach to

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<sup>41</sup> Although there has been a number of studies into what was noted in case records. The primary purpose was not with a view to feeding back this information to the patients themselves. One such example was a study of case records of documentation of older people's end-of-life care in the context of specialised palliative care. What problems, wishes, aspects of wellbeing, assessment tools, and interventions are documented in patient records and to what extent? Sjöberg *et al.* (2021) Documentation of older people's end-of-life care in the context of specialised palliative care: a retrospective review of patient records *BMC Palliative Care* (2021) Available from: <https://link.springer.com/content/pdf/10.1186/s12904-021-00771-w.pdf?pdf=button> [Accessed January 8 2023]

<sup>42</sup> There are plenty models which helped us refine this task. Of particular note was information from the Association of Project Management, *What is the difference between a Pilot and a Trial?* Available from: [What is the difference between a trial and a pilot? | APM](#) [Accessed July 27 2022]

address the participants' needs and concerns, is a question that the Panel revisited a number of times throughout the review process, and is reflected in this Report.

### Intended audience

- 1.25 Although the office of the Cabinet Secretary for Health and Sport commissioned this Report, we anticipate that it will have a wide and diverse reading audience. It has therefore been written with that diversity of interests in mind. Where technical terms have been used, an explanation or links to further explanation can be found in the footnotes. If we have referred to other literature, a reference to this can also be found in the footnotes. All the templates that we designed and used during the Review process are included in Appendix 1 of the Report.
- 1.26 We also wanted all participants to feel involved in the review process; that we would seek to work with them in whatever way they felt comfortable engaging with us. When speaking with the women who participated in this Review, it was not unusual that their own words conveyed their experiences much more succinctly and powerfully than we could in the retelling. As a result, we believed that their words should be actively included in the composition of our Report. Their own words are quoted throughout Part I and Part II of the Report.
- 1.27 We would like to thank everyone who took the time to contribute to this work. A Case Record Review of this type has not been undertaken in Scotland before. Starting with a blank canvas, we drew upon a significant and diverse range of knowledge and expertise to design and effect a review of this nature. We are grateful to everyone who contributed.

## Chapter 2 - Advance Planning

2.1 Once the Panel had been appointed, there was an expected 4-6 months before the Cabinet Secretary was to formally launch the Review. We regarded this as a good opportunity to undertake advance planning and preparations. This chapter outlines what these were. Our starting point was to consider how we were going to make the process workable, understandable and effective for those women who chose to engage with the Review, the tone that we wanted to set, and the framework within which we would work.

### Trust and communication

- 2.2 These are central themes running through this Report. It is generally recognised that trust is an essential component<sup>43</sup> for a positive and engaged relationship between a patient and their clinician. Conceptualisations of trust within a clinical setting tend to bear the hallmarks of competence and welfare.<sup>44</sup> As such, they presume a level of professional, technical competence and that they will act in the best interests of their patient. This is also underpinned in ethics and the law. If the patient has trust in their clinician, this has been shown to have a positive effect on adherence to treatment and the continuity of care.<sup>45</sup>
- 2.3 Conversely, an erosion or absence of trust can give rise to a spectrum of poor consequences including a reluctance to accept advice about treatment or therapies whose outcomes may be uncertain or high risk. More generally, low levels of trust within therapeutic relationships can also result in overall dissatisfaction with therapeutic options and clinical care.<sup>46</sup>

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<sup>43</sup> Brennan, N., Barnes, R., Calnan M., et al (20) Trust in the health-care provider–patient relationship: a systematic mapping review of the evidence base *International Journal for Quality in Health Care* vol. 25 no. 6 pp682-688 at. p 682. Available from: [untitled \(silverchair.com\)](#) [Accessed August 1 2022]

<sup>44</sup> Rolfe A, Cash-Gibson L, Car J, Sheikh A, McKinstry B (2014) Interventions for improving patients' trust in doctors and groups of doctors (Review). Available from: <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004134.pub3/pdf/full> [Accessed January 13 2022]

<sup>45</sup> Rolfe A, Cash-Gibson L, Car J, Sheikh A, McKinstry B (2014) Interventions for improving patients' trust in doctors and groups of doctors (Review). Available from: <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004134.pub3/pdf/full> [Accessed January 13 2022]

<sup>46</sup> Brennan, N., Barnes, R., Calnan M., et al (20) Trust in the health-care provider–patient relationship: a systematic mapping review of the evidence base *International Journal for Quality in Health Care* vol. 25 no. 6 pp682-688 at. p 682. Available from: [untitled \(silverchair.com\)](#) [Accessed August 1 2022]

- 2.4 Like most relationships, those between a patient and their healthcare provider have changed and evolved over time.<sup>47</sup> Such changes are influenced by a number of factors including changing societal behaviours,<sup>48</sup> legal outcomes<sup>49</sup> and clinical practices in themselves. Trying to understand how to promote trust and its clinical attributes has become an especially important part of modern and often complex healthcare.<sup>50</sup> Studies have shown that a patient's experience of illness, clinical care, management of possible outcomes and, importantly for this Review, the amount of knowledge that patients and their peer groups have acquired about their condition, can all affect their willingness to trust.<sup>51</sup>
- 2.5 The Panel agreed that a significant reason for the commission of this Review had been the consequence of a breakdown of trust. We recognised that this could take several forms depending on the experience that each woman had. For example, a breakdown in the relationship between the individual and her healthcare provider(s) or, a breakdown in trust over her care more generally. Particularly important for us to understand was the evident lack of trust in what had been written in the women's case records.<sup>52</sup> Several participants referred to initially being unaware of, but subsequently acquiring more or conflicting information about, the adverse outcomes which may potentially arise following mesh surgery. Not only did this diminish their belief that the clinician was acting in their best interests, but also had an impact in lessening their belief and faith in their healthcare provision more generally.

*'I've lost a lot of trust in the NHS and that doesn't just apply to mesh. It applies to everything'.*

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<sup>47</sup> Coulter, A., (1999) Paternalism or Partnership *BMJ* 319:719. Available from: <https://www.bmj.com/content/319/7212/719/article-info> [Accessed August 1st 2022]

<sup>48</sup> Kraetschmer N, Sharpe N, Urowitz S, Deber RB. (2004) How does trust affect patient preferences for participation in decision-making? *Health Expect.* 7(4):317–26

<sup>49</sup> The Scottish landmark case of *Montgomery v Lanarkshire Health Board* in 2015 changed the legal landscape in terms of what a patient would expect in terms of the quality and quantity information disclosure prior to them making any decision about whether they would consent to a proposed treatment or therapy.

<sup>50</sup> Hall MA, Dugan E, Zheng B, et al, (2001) Trust in physicians and medical institutions: what is it, can it be measured, and does it matter? *Milbank Q.* 2001;79(4):613–39 at p.613. Available from: [BL047-05.txt \(nih.gov\)](#) [Accessed August 2 2022]

<sup>51</sup> Pokhilenko I, van Esch TEM, Brabers AEM, de Jong JD (2021) Relationship between trust and patient involvement in medical decisionmaking: A cross-sectional study. *PLoS ONE* 16(8) pp1-14 at p.2 Available from: [Relationship between trust and patient involvement in medical decision-making: A cross-sectional study \(nih.gov\)](#) [Accessed August 2 2022]

<sup>52</sup> This aspect had been made clear by the women who attended meetings with the First Minister in November 2020.



- 2.6 The Panel considered that, for the Review process to be as meaningful and effective as possible, it would be fundamental to find a way to establish, build and maintain trust: both in the individuals carrying out the Review, but also in the Review process itself. It was only the administrator and I who were going to be involved in all the initial and early-stage conversations with the participants. Since we had not met any of them before, this brought some advantage in that we were starting with a clean slate. Both the administrator and I have previous experience in meeting with people who shared a wide range of emotions, and we believed that we could draw upon this to help prepare us for the initial meetings. Being able to establish a relationship from the outset, free from legacy or previous encounter, was important.
- 2.7 Whilst we were able to put some level of preparation in place, every new project exposes those involved to new experiences and new learning, and we were unprepared for the enduring effect that some of our conversations with the participants have had, and continue to have, upon us. Themes arising from these conversations will be considered in Part II of this Report.

### Women and their healthcare

- 2.8 Our participants were going to be women who largely had concerns regarding trust, and who had also felt excluded more generally from decision-making regarding their healthcare.

*'Wherever you turn you just don't feel heard. You really don't. It's like here's another survey or here's another whatever, you know? The wee bit of energy you've got you are trying to fight to help'.*

- 2.9 There is a growing body of literature which attests to this, and it is not confined to experiences with mesh.<sup>53</sup> Many of the women eligible to be part of this

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<sup>53</sup> Cleghorn, E., (2021) *Unwell Women*. London: Weidenfeld & Nicolson



Review had also been interviewed for the Cumberlege Review<sup>54</sup> where they had stated they were disbelieved,<sup>55</sup> ignored,<sup>56</sup> and/or not listened to.<sup>57</sup>

*'When we've asked questions, I felt that they closed the doors and the patient has become the person who is at fault when all I did was I wet myself when I coughed and sneezed'.*

- 2.10 It was necessary not only to try to understand what impact these experiences may have had, but also to recognise the doubts and scepticism that some of the women would have had when considering whether or not to engage in this Review.
- 2.11 In general terms, autonomy refers to a person's ability to act in their own interests and on their own values. The principles of autonomy and self-determination<sup>58</sup> within a clinical setting have been extensively written about, but that does not mean that they are necessarily any easier to understand. In an attempt to bring about clarity and context, in healthcare settings, autonomy is often contained or quantified within a notion of what is referred to as 'informed

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<sup>54</sup> The Independent Medicines and Medical Devices Safety Review was announced in February 2018. It was asked to focus on how the health system responds when patients and their families raise concerns about the safety of treatments. Baroness Cumberlege was asked to chair the review and to look at the cases of vaginal mesh, sodium valproate, hormone pregnancy tests (HPTs), in this case Primodos. The Review published its report on 8 July 2020 and made 9 recommendations. Gov.uk (2020) First do no harm: Independent Medicines and Medical Devices Safety Review Report. Available from: <https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report> [Accessed January 13 2023]

<sup>55</sup> Gov.uk (2020) First do no harm: Independent Medicines and Medical Devices Safety Review Report. Available from: <https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report> [Accessed January 13 2023] at p. 153

<sup>56</sup> Gov.uk (2020) First do no harm: Independent Medicines and Medical Devices Safety Review Report. Available from: <https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report> [Accessed January 13 2023] at p. 151

<sup>57</sup> Gov.uk (2020) First do no harm: Independent Medicines and Medical Devices Safety Review Report. Available from: <https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report> [Accessed January 13 2023] at p. 140

<sup>58</sup> Schwab, A,P (2006) Formal and effective autonomy in healthcare. *J Med Ethics*. 2006 Oct; **32**(10): 575–579. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2563308/> [Accessed January 13 2023]

consent' which will be considered in greater detail in chapter 8.<sup>59</sup> In reality, autonomy should mean much more. It is also not a solitary principle. One person's autonomy is dependent on relationships with others and the nature, equality, and experience of the parties within any encounter influences and impacts upon each person's own autonomy.<sup>60</sup>

- 2.12 As part of the Review process, we wanted the participants to feel they could discuss issues as fully and freely as they wished; matters that were important to them, and what they wanted to get from the Review process. This was not an exercise in ticking boxes but a continuum of dialogue and engagement. We wanted the women who participated to feel that we were listening to them and hearing what they were saying to us.
- 2.13 As discussed in Chapter 1, this was the first time that a review of this nature had been conducted in Scotland and as such, were finding our way.

### Ideology behind the Review Process - Restoring Trust

- 2.14 We considered literature which touched upon issues of relevance to our remit, and we have been able to draw upon their content throughout our deliberations. Some literature was familiar to us, some less so. One recurring suggestion was to consider adopting an approach around the ideology of what has become generically known as 'restorative practice', we have refined the term a little to one of restoring trust.
- 2.15 The principles behind this ideology refer to the restoration of harmony, or repair of something or someone who has been harmed. Evolving throughout the 1990s, its application was originally seen more frequently within the criminal law and concepts of 'justice'<sup>61</sup> but it has also been used effectively as a means to rebuild relationships.<sup>62</sup> It is this latter element that is pivotal to the Review process.
- 2.16 Whilst its origins may lie within the criminal law, its application has been diverse and used within healthcare as a means to share experiences. This has

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<sup>59</sup> A full discussion on this point can be found in, Dodds, S., (2000) Choice and control in feminist bioethics. In: Mackenzie, C *et al*, eds, *Relational Autonomy: Feminist Perspective on Autonomy, Agency and the Social Self*. New York:Oxford University Press at pp 213-220)35

<sup>60</sup> D'Agincourt-Canning, Ells, C., Women's healthcare through a feminist ethics lens in: D'Agincourt-Canning, Ells, C., (2019) *Ethical Issues in Women's Healthcare* at p.3

<sup>61</sup> Meier, B. (1998). Restorative Justice - A New Paradigm in Criminal Law?, *European Journal of Crime, Criminal Law and Criminal Justice*, 6(2), 125-139. Available from: <https://doi.org/10.1163/157181798X00148> [Accessed January 13 2023]

<sup>62</sup> Boyes-Watson, C. (2014). Suffolk University, College of Arts & Sciences, Center for Restorative Justice

included the development of mental health services in England,<sup>63</sup> but of particular interest in designing our Review, was a study from New Zealand in 2019, which focussed on hearing and responding to the lived experiences of those who had described adverse events following their mesh surgery.<sup>64</sup> This study will be considered in more detail in Chapter 6 of this Report, but some analysis was undertaken following its completion which concluded that:

*[The] restorative approach supported substantive, psychological and procedural needs to be met during the Listening and Understanding phase of the project. The preservation of dignity, validation of experience, and respectful communication was experienced by most people.... Inclusion of multiple methods for storytelling ensured that a safe and supportive environment was experienced by the majority.*<sup>65</sup>

- 2.17 Given the report of such positive outcomes, the Panel could see potential merit in applying the principles of restorative practice within our Review process albeit on a smaller scale. The Panel recognised the importance of providing an environment where our participants would feel as physically and emotionally comfortable as circumstances allowed to describe their experiences: a chance for them to talk, and for us to listen. This included having adequate time available to share their experiences, and to raise matters of concern to them.

## Impact of Covid-19

- 2.18 Other aspects of advance planning were more challenging to oversee and the changing nature of the impact of Covid-19 was one of them. Whilst we had been planning for this Review, we had been in lockdown since March 2020. As we drew towards the end of 2020, there was, what turned out to be, some misplaced optimism that we would still be able to meet with the participants and as a Panel face to face. By January 2021, we had to accept that this was not going to be the case.

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<sup>63</sup> Restorative Justice Council, 'Restorative Practice in Mental Health' (2021) Available from: <https://restorativejustice.org.uk/restorative-practice-mental-health> [Accessed 16 June 2022]

<sup>64</sup> Wailling J, Marshall C, Wilkinson, J., (2019) 'Hearing and Responding to the Stories of Survivors of Surgical Mesh'. Available from: [Hearing and Responding to the Stories of Survivors of Surgical Mesh \(health.govt.nz\)](https://www.health.govt.nz/publication/hearing-and-responding-to-the-stories-of-survivors-of-surgical-mesh) [Accessed June 16 2022]

<sup>65</sup> Wailing j, Marshall,C, Wilkinson J, (2020) 'Healing after harm: An evaluation of a restorative approach for addressing harm from surgical mesh. Kia ora te tangata: He arotakenga i te whakahaumanu,' (2020), *The Diana Unwin Chair in Restorative Justice, Victoria University of Wellington*, Available at: <<https://www.wgtn.ac.nz/restorative-justice/our-work/research-evaluation/restorative-practice-and-surgical-mesh/healing-after-harm-evaluation-report-moh-pdf>> [accessed - 16 December 2022] at p.5

*Use of online communications*

- 2.19 Face to face interviews have long been the preferred technique for qualitative research such as this.<sup>66</sup> We had originally planned to arrange generic locations with suitable private access and facilities, and invite participants to meet with us. Where these were held would depend on where the participants lived. Recognising that there may have been some participants whose current circumstances prevented this, we would have arranged to conduct the meeting in either a different venue (including a home visit if they wished) or by telephone. The most immediate consequence of the Covid-19 pandemic and the restriction on face-to-face meeting, was the need to find an alternative solution.
- 2.20 We agreed that meetings would be held via the Microsoft conferencing platform 'Teams.'<sup>67</sup> The use of Teams facilitated not only all meetings with the participants but also for meetings of the Panel, whose members were based in different locations across the UK. Communicating in this way is known to bring both advantages and disadvantages.<sup>68</sup>
- 2.21 For the work of the Review, the main advantage was the flexibility it allowed in arranging and conducting meetings. There was no need for participants or for us as a Panel to travel to a particular venue and, since they and we could remain in our own homes, there was no risk of Covid-19 transmission. Being in familiar surroundings, without the need to configure rooms, it was also easier to address any needs that the participant may have had to keep them as comfortable as possible for the duration of the meetings. If the participant wished to have an advocate or supporter who was not residing in the same household, then this could also be safely accommodated.

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<sup>66</sup> Opdenakker, R (2006) Advantages and Disadvantages of Four Interview Techniques in Qualitative Research. *Qualitative Research Forum*. Available from: <https://www.qualitative-research.net/index.php/fqs/article/view/175/392> [Accessed January 13 2023]

<sup>67</sup> Microsoft Teams is a proprietary business communication platform developed by Microsoft, as part of the Microsoft 365 family of products. What is Microsoft teams? Available from: <https://support.microsoft.com/en-us/topic/what-is-microsoft-teams-3de4d369-0167-8def-b93b-0eb5286d7a29>

<sup>68</sup> Chouffani, R., (2021) 12 advantages and disadvantages of video conferencing. Available from: <https://www.techtarget.com/searchcontentmanagement/tip/8-business-benefits-and-challenges-of-video-conferencing> [Accessed 25 August2022]

- 2.22 It brought advantages for Panel meetings too. The five of us were in various locations across the UK,<sup>69</sup> so it made it easier for us to conduct our meetings with the logistics of travel removed.
- 2.23 The main disadvantages were due to the limitations that arise through engagement via any online communications platforms.
- 2.24 Any face to face interaction relies not only on verbal signals but also vital non-verbal signals, including, for example, gesture, posture and facial expression. There are many ways to pick up nuances of communication and conversation perhaps through the proximity of a reassuring nod or the reciprocity of a smile.<sup>70</sup> The benefits of such interaction are well documented.<sup>71 72</sup> In contrast, using online platforms can result in a lack of spontaneity and reduces such interaction to one dimensional; whether it is through a laptop, personal computer or mobile telephone.
- 2.25 During these initial meetings, the biggest disadvantage that the administrator and I found was the lack of personal physical interaction between ourselves and the participants. Unsurprisingly, the ability to read body language, physical expression was significantly reduced or even lost altogether. During the initial meetings I was aware that I tended to exaggerate gestures of reassurance in an attempt to make a participant more at ease, due to the sensitivity and personal nature of the subject being discussed. We also attempted to supplement this online discussion by offering other means of communication. For example, we made it clear that participants were welcome to contact us either by email or by telephone. Many participants availed themselves of this invitation and we were able to maintain an ongoing communication with the majority of participants and about one third of these for two years. We continued to provide updates for those who chose not to avail themselves of this option.
- 2.26 Disadvantages of a more technical nature also had to be addressed, particularly that of online connectivity issues or lack of confidence in the use of the technology. Conducting a meeting which already had the potential to be

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<sup>69</sup> The administrator and myself are based in Glasgow, Dr Lunan, our GP, in Edinburgh and our consultant Panel members, Mr Ian Currie and Prof Anthony Smith were based in England.

<sup>70</sup> Gagnon, M, Chérif, L, Roy-Charland, A (2022) Contextual cues about reciprocity impact ratings of smile sincerity, *Cognition and Emotion*. Available from: [Contextual cues about reciprocity impact ratings of smile sincerity \(tandfonline.com\)](https://doi.org/10.1080/02643758.2022.2100000) [Accessed August 25 2022]

<sup>71</sup> See for example, SCHMID MAST, M. (2007) On the importance of nonverbal communication in the physician–patient interaction. *Patient Education and Counseling*, 2007, vol. 67, no. 3, pp. 315-318

<sup>72</sup> Saarijärvi, M, Bratt E., (2021), When face-to-face interviews are not possible: tips and tricks for video, telephone, online chat, and email interviews in qualitative research, *European Journal of Cardiovascular Nursing*, Volume 20, Issue 4, April 2021, Pages 392–396. Available from: <https://doi.org/10.1093/eurjcn/zvab038> [Accessed January 13 2023]

stressful and emotionally challenging for participants was not helped by the enforced remoteness of our meetings and our engagement. There was an inevitability of network connectivity and issues relating to poor audio or video, or worse, being susceptible to being 'dropped' altogether. Whilst this was out with our control, it was not conducive to building rapport or confidence.

- 2.27 By the time we convened, as a Panel, all members had become quite familiar with forms of remote working in their professional lives, with some Panel members more adept than others. This mirrored our experiences in engaging with the participants; some of them were very confident in their use of technology and others a little more hesitant. In the latter cases, it was far from ideal to conduct an initial meeting when someone was struggling to hear or see us due to issues with their camera or microphones. In some cases, participants did not have access to a laptop or PC, so we conducted these meetings via their mobile devices.
- 2.28 Privacy and confidentiality of online meetings with the participants brought both an advantage and a disadvantage. Management of participants' privacy and their data remained of paramount importance throughout this review. Given that we had chosen to record all interviews and then transcribe them, we considered carefully how we would record them and store that recording securely. We chose not to use the 'record' function available via Teams. Instead, we used a simple dictation machine so that there was no data stored in any virtual environment outwith our oversight or control. Prior to switching on the recording device, we introduced ourselves to the participant, and explained the purpose of the meetings and the reasons for recording and transcribing them. The participants could then ask any question prior to deciding whether or not to agree to proceed. It was only if, or when, the participants gave their consent, that we switched on the recording device. At the participant's request it could also be paused at any time and restarted without disrupting the flow of our conversations. The recording device remained with the administrator at all times and once the meeting had been transcribed and confirmed as accurate by the participant, the recording was deleted.

## The participants & decisions regarding the requesting and collating of their case records

- 2.29 Our remit was to speak with those who had decided that they would like to work with the Panel to have their case records reviewed. The Panel received a list of the names of 47 women who had previously met with the First Minister<sup>73</sup> in November 2019, and had supposedly all undergone either a partial or full removal of their mesh. This was not in fact the case. This list correctly included women who attended the meetings, but the majority of those women did not have concerns about full or partial removal of mesh since they had not undergone either of these surgeries; their concerns lay elsewhere, and in the majority of cases, were much more broadly about the content of their case records. Given our original remit and terms of reference, we were not expecting to have to address this.
- 2.30 Given the importance of establishing trust and confidence as discussed earlier, one of our immediate tasks was to contact these women to reassure them that they were all welcome to participate in the Review, whether or not they had received surgery to remove either all or part of their mesh. The Terms of Reference subsequently had to be revised to accommodate this more complex remit.
- 2.31 This also meant that the case records that we were to review would no longer be focussed on just one aspect of the case records - namely the full or partial removal of mesh. For many women, their focus and concerns would be considerably broader, covering the spectrum of their care from their initial consultations and investigations, treatment options (including any conservative treatments), and initial mesh implant surgery, to any subsequent mesh-revision surgery and care.
- 2.32 This had significant implications for the scope and duration of our work. We were going to have to decide how we were going to request, retrieve and collate the potentially much larger volume of records required, to address the more complex concerns that some of the participants would be likely to raise.
- 2.33 The process which is generally referred to as a collation of medical case records draws together an 'indexed bundle' or bundles relating to some or all aspects of a patient's health care. This usually involves filtering large volumes of information which can amount to hundreds and sometimes thousands of pages. Given that for some of the participants, their care spanned more than a decade, or across different Health Boards, or countries, in terms of volume, we knew that their case records were likely to be more towards the latter.

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<sup>73</sup> We understand that some women also met with the then Cabinet Secretary for Health & Sport, Jeane Freeman.



- 2.34 Case records usually comprise a mixture of handwritten or typed notes, images, and diagrams. To draw together large volumes of documentation like this requires an expert who can undertake this task with meticulous precision.<sup>74</sup> It is also an extraordinarily time-consuming process. Whilst the Panel had originally believed that we could undertake this task when it was anticipated that there would be a relatively small and focussed amount of case records to review, this was no longer the case. We did not have the capacity, or the expertise. At the conclusion of the Review, I remain unconvinced whether we would ever have had the capacity and required expertise to collate and index even the smaller and more focussed case records that were first anticipated.
- 2.35 The Panel agreed that we needed expert assistance and that we would require to engage a clinical collation records service. This would allow us to have professional expertise not only to assist in the retrieval of records, but importantly, given the volume of records that we would be required to review, to also collate and index those case records, making them more accessible, accurate and readable for the Review Panel.
- 2.36 We chose *Clinco*.<sup>75</sup> Based in England, this removed them from the proximity of Scotland and any prior knowledge of the cases that would form part of our Review. They had not previously met nor worked with any members of the Panel. They also met the data protection standards within which we were to conduct the Review.<sup>76</sup> Clinco's Legal Director, Sarah Wallace and I met a number of times to discuss our remit and to create a bespoke provision which aligned to the terms of reference of the Review. Having discussed the nature, extent and scope of the work, it was agreed that that Clinco would retrieve, collate, index, paginate and provide chronologies for each individual participant. Their contribution exceeded our expectations and our initial brief and Sarah and her colleagues were a constant source of support and advice for the duration of this Review, not only for the Panel, but also in working in a collegiate, transparent and reassuring manner with the participants.<sup>77</sup>

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<sup>74</sup> For a good discussion on the challenges of this task please see Torrisi, A, Bevan, R, Atkinson, K et al., Combining Textual and Visual Information for Typed and Handwritten Text Separation in Legal Documents, (2019) in *Legal Knowledge & Information Systems*. Araszkieviev, M & Rodrigues-Doncel V (eds at p. 223. Available from:

[https://books.google.co.uk/books?hl=en&lr=&id=4GTIDwAAQBAJ&oi=fnd&pg=PA223&dq=collation+f+medical+records,+pagination+indexing&ots=LHrncQb9R-&sig=PblK8mIR\\_3uSu8jJakeJHMJoY4w#v=onepage&q&f=false](https://books.google.co.uk/books?hl=en&lr=&id=4GTIDwAAQBAJ&oi=fnd&pg=PA223&dq=collation+f+medical+records,+pagination+indexing&ots=LHrncQb9R-&sig=PblK8mIR_3uSu8jJakeJHMJoY4w#v=onepage&q&f=false) [Accessed 22 September 2022]

<sup>75</sup> Available from: <https://clinco.co.uk/> [Accessed February 28 2021]

<sup>76</sup> They are UK certified to the stringent international data protection standards of ISO27001. Clinco's information security management system (ISMS) which meets the requirements of [ISO 27001:2013](#) and their approach to management and storage of data can be found here: [data protection security confidentiality of medical records \(clinco.co.uk\)](#) [Accessed 22 September 2022]

<sup>77</sup> I remain personally indebted to Sarah Wallace and her team at Clinco for going above and beyond in their assistance with this Review.



## Chapter 3 - Preparation of Documentation and Templates

### Introduction

- 3.1 The Panel recognised that any initial communication would be highly influential as to whether a woman would decide to participate in the Review. We designed initial correspondence which took the form of a Letter of Invitation<sup>78</sup> from the Moderator to participate in the Review which explained why the Review had been commissioned<sup>79</sup> and what it would consider. The Letter of Invitation was accompanied by a consent form which, if returned to us, would confirm agreement to an initial engagement in the Review process. A short, Plain Language Statement, containing our terms of reference and remit was made available. These documents were approved by the Plain English campaign and received a 'crystal mark'.<sup>80</sup>
- 3.2 The Scottish Government launched a website<sup>81</sup> to accompany the Review on the 21<sup>st</sup> February 2021. This coincided with the Cabinet Secretary announcing the start of the Case Record Review. The website contained information regarding names and designations of the Panel members, Terms of Reference and contact details. It also included a Declaration of Interests for each member of the Panel. I asked at the beginning of each meeting whether members had any new Declaration of Interests to declare which were then updated as required, throughout the work of the Review.

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<sup>78</sup> This can be found in Appendix 1.

<sup>79</sup> This was emailed on the 22 February 2021, to all 47 names on the list we received from the Scottish Government.

<sup>80</sup> An explanation of what the Plain English Campaign do can be found here. Available from: <http://plainenglish.co.uk/about-us.html> [Accessed July 25 2022]

<sup>81</sup> Scottish Government (2021) Transvaginal Case Record Review website. Available from: <https://tmcrr.scot/> [Accessed June 15 2022]

### *The First meeting*

- 3.3 On receiving a participant's agreement to be part of the Review, the administrator invited her to meet with us. As well as introducing ourselves, the purpose of these initial meetings was to provide a verbal overview of the purpose of the Review and encourage the participants to ask any questions. We then checked with all participants that they were still willing to continue to engage with the Review. These meetings allowed the administrator and I to get to know and begin to understand each participant's lived experience and to identify where their concerns lay regarding their case records.
- 3.4 We found that some participants were wary of engaging in the process. Their initial questions often were around the independence of the Panel, our relationship with the Scottish Government and whether we had any potential association with the NHS or other government agencies.<sup>82</sup> Out of the 47 women on our list who had previously met with the First Minister in 2020, 19 women contacted us, 18 of whom ultimately agreed to have their records reviewed. The 19<sup>th</sup> participant wanted to meet with us to share some of her experiences but did not want a review of her case records. All 18 participants remained engaged with the review process until the culmination of our review of their records and the production and receipt of their individual report.
- 3.5 We encouraged all participants to have someone accompany them to these meetings. Seven participants were accompanied. Two had spouses present, one had one of their children with them and four chose to be accompanied by other women who were also participants in the Review. Prior to the start of our conversation, we asked each participant if they were comfortable having their supporters with them for the entirety of the meeting or if they would want some private time with us. All declined private time, and the supporter remained with the participant throughout the duration of our meetings. We could see the benefits for the participant, it appeared to give them confidence, assist them with recalling parts of their story and generally making them appear to be more comfortable engaging with us. The Panel considered if there might be any unintended consequences of being accompanied, in terms of independence, for example, or the ability to speak freely. We subsequently designed a form<sup>83</sup> containing information and questions for the participant to consider so that they could decide whether this was best option for them.

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<sup>82</sup> We have discussed this more fully in Chapter 2.

<sup>83</sup> This can be found in Appendix 1 of this Report.

**We view this as a valuable part of the process and recommend the incorporation of appropriate support/ advocacy for any future case record review.**

- 3.6 We wanted each participant to feel unhurried so the suggested duration of the initial meeting was two hours. We also wanted to make each participant feel that we were really listening, not least because we needed to understand where their concerns lay but we anticipated that, for some women, they would have to draw upon their emotional resources to tell us their stories. We did not want them having to retell a story because we were unable to recall some aspect of it, so we decided to record these meetings, transcribe them and return them to the participant for their agreement and any comment.
- 3.7 Some women had excellent recall and/ or had noted some details down in advance of the meeting. One participant had written exactly what she wanted to say to us and read it out. Others were a little more hesitant in their recall and the chronology of their treatment experiences were a little more fractured. This was another benefit of having recorded the conversation as we could then make sure that the transcript captured our conversations into a logical order which would make it easier for the participants to review. Some of the transcripts were 35 pages in length and our administrator transcribed each of them. Whilst a time-consuming task, many participants appreciated the cathartic nature of seeing their stories written down in such detail. The administrator and I found it invaluable in getting to know the participants and having a better understanding of what was important to them.
- 3.8 Finally, we wanted to provide reassurance that our engagement with the participants did not need to be confined to a 'one off' meeting but that we were able to engage with them in an ongoing capacity in whatever form suited them. We would work with them at their own pace, using their own words.
- 3.9 Once ready, the transcripts were shared only between the participant, the administrator and myself. Occasionally, having had time to reflect, participants provided additional information which had not been part of the original discussion. We included this in their file. Once a final version was agreed, we moved onto the next stage.

#### *Information gathering*

- 3.10 The next stage was to in-gather the issues that the participant wanted the Panel to review. Given that Clinco has the expertise in which information was essential to the retrieval of records, we agreed that they took the lead in drafting what we called the 'information gathering' form. Along with the transcripts from the meetings with the participants, and to present as full a

picture as possible regarding any concerns, we agreed that we should be guided by the participants as to which areas of their mesh care and treatment that they wanted us to review.

- 3.11 We designed a template which contained first, boxes for essential details required for the retrieval of records. These included name, date of birth, community health index (CHI) number,<sup>84</sup> name of GP/ surgery and location(s) where treatments took place. The following boxes then provided for areas that the participants wished the Panel to review. The template set these out in a chronological manner starting with '**before treatment**' which included matters pertaining to information disclosure and consent. The next section considered '**the treatment**' followed by a section '**remedial treatments and aftercare**'. Finally, there were template boxes for the participant to summarise where their concerns lay. These were subdivided into '**completeness of your case records**', '**accuracy of your case records**' and '**any other aspect of your case records**'.
- 3.12 We took the view that asking the participant to complete this form in their own words allowed a personal expression of their specific concerns. However, some preferred that I completed the form on their behalf, extracting the information from our first meeting and the resulting transcript. If this was the case, it was completed and then returned to the participant for approval. Once approved, the administrator asked the participants for confirmation that the form could be forwarded to Clinco.
- 3.13 This part of the process was facilitated solely by me and the administrator. Clinco had no engagement with the participants until the form was completed and sent to them.
- 3.14 This form was also approved by the Plain English campaign and received a 'crystal mark'.<sup>85</sup> Despite our best endeavours to keep the form clear and uncomplicated, we are of the view that some participants did find its completion an onerous and challenging task. Sometimes this was the practical consequence of not having access to a computer. Additionally, it did not view clearly on a mobile device. For others, it was simply the task of having to complete the form. We reflected on whether this could be streamlined in some way for any future work, but recognise it is a question of finding the right balance between providing the necessary level of detail to correctly identify and

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<sup>84</sup> More commonly abbreviated to CHI number. This is a unique 10-character numeric identifier, allocated to each patient on first registration with the system.

<sup>85</sup> An explanation of what the Plain English Campaign do can be found here. Available from: <http://plainenglish.co.uk/about-us.html> [Accessed July 25 2022]

retrieve the relevant case records, whilst not placing an undue burden on the participants.

*Consent form and questions and answer sheet for retrieval of case records*

- 3.15 We wanted the participants to be absolutely clear which information was going to be retrieved on their behalf. It was agreed that, once Clinco had received their information gathering form, there would be a second consent form sent to the participants from Clinco that explained which case records would be retrieved on their behalf. It also served to introduce the participant to Clinco and to highlight the next stage of the review process where Clinco would have a more prominent role. The consent form was accompanied by an information sheet which explained how the records were to be obtained, and why. The participant was advised that they could withdraw their consent at any time and that their records would then be deleted. To avoid an over reliance on technology, this was sent by post to the participant with a stamped addressed envelope provided. We believed that this additional request for consent provided a further opportunity for the participants to ask any questions and to reflect on their continued engagement with the Review.

*Digital transfer of sensitive information*

- 3.16 Once Clinco was engaged with the participants, they adopted the same referencing format that the administrator had designed and used from the outset of the Review. To avoid identifying a participant by name, they were each given a corresponding participant number. This was allocated in terms of the chronological order of when they first engaged with us. The first participant we met became participant one and so forth. For all communications during the Review, we continued to use this identifier and reference format. All emails and communications between the Panel that contained sensitive information were sent as password-protected via a secure file transfer system. Throughout the Review, only Clinco, the administrator and I knew the names of our participants, as only the CHI number and the participant number were shared with the clinical members of the Panel.

*Anticipated size of the case record files*

- 3.17 To allow us to prepare and allocate time to review each set of records, the Panel had to have some understanding of the format and volume of case records that we were likely to receive. Based on Clinco's experience, they advised us that case records would be indexed into volumes, of around 375

pages per volume. This was traditionally the number of pages which fit into a standard lever arch file, although it is now more common practice to create digital sets. The clinicians were familiar with reviewing records in a digital format, so we agreed that we would receive all records in this way.

- 3.18 File sizes depended on the extent of the medical history, which varied between participants. We anticipated that the files would be a minimum of 375 pages, and up to 2000 pages in some cases. This turned out to be a reasonable estimate as we requested in excess of 40,000 pages of records throughout the Review. We also recognised that case records are not purely text, as they can include handwriting, diagrams etc, and the size of a digital volume can vary between 10,000-40,000 KB. Any radiology files are much larger as something like a CT scan is very intensive with regard to digital storage space. These have tended, until very recently, to be kept on disc, but the pandemic has moved most users on to a secure portal link, which we also used.<sup>86</sup>

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<sup>86</sup> This will be discussed further in Chapter 5.

## Chapter 4 - The Case Record Retrieval Process

### Introduction

4.1 Once the documents were drafted and meetings had started to take place as described in Chapters 2 and 3, we were ready to progress to the next stage and to start requesting and retrieving case records. This chapter describes to whom these requests were made, the challenges that we encountered, and the steps we took in an effort to resolve and overcome them. Unsurprisingly, the most significant requests for records in terms of volume went to the Health Boards in Scotland followed by Scottish general practices. We were also required, for a small number of cases, to request records from English Trusts and from overseas. Some retrieval requests involved us asking the participants themselves for copies of their case records. We shall consider each of these groups in turn.

#### *Engagement with Scottish Regional Health Boards*

4.2 There are fourteen regional National Health Service (NHS) Boards that report to the Scottish Government and who have the responsibility for the delivery of frontline healthcare services in Scotland.<sup>87</sup> Where we directed our requests was based on a combination of where the participants resided (or had previously resided) and location(s) of where the treatments occurred. These factors required us to approach nine regional Health Boards.<sup>88</sup> These were:

- NHS Ayrshire and Arran;
- NHS Borders;
- NHS Fife;
- NHS Forth Valley;
- NHS Greater Glasgow and Clyde;
- NHS Highland;
- NHS Lothian;

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<sup>87</sup> Current boundaries of NHS Health Boards in Scotland are defined by National Health Service (Variation of Areas of Health Boards) (Scotland) Order 2013 (SSI 2013/347), which came into force on April 1st 2014, and replaces the previous definition based upon the former Regions and Districts of the Local Government (Scotland) Act 1973. For further information, see Scottish Government (2021) NHS Health Boards – Scotland. Available from: <https://www.data.gov.uk/dataset/27d0fe5f-79bb-4116-aec9-a8e565ff756a/nhs-health-boards-scotland> [Accessed October 26 2022]

<sup>88</sup> Some participants required us to retrieve records from more than one Health Board.

- NHS Lanarkshire;
- NHS Tayside.

*Data sharing agreements-*

- 4.3 Four months after the launch of the Review, in late June 2021, we were advised by the Scottish Government that Clinco would be unable to request any records from Health Boards until a separate ‘Data Sharing Agreement’ was put in place between the Scottish Government and each of the nine Health Boards involved. From the Panel’s perspective this was unexpected and unnecessary.
- 4.4 The Scottish Government agreed that whilst such Data Sharing Agreements were not legally required, it was felt that they served to document the transfer of information between two data controllers (in this case, the Scottish Government and the Health Boards). The suggestion was that the Agreement allowed the parties involved to have a shared understanding and expectation of the use of the data by the other, as well as helping both parties comply with accountability principles detailed in the UK General Data Protection Regulations (UKGDPR). Since the Scottish Government was the data controller and regarded the implementation of data sharing agreements as best practice, they required these to be put in place.
- 4.5 The Panel remain unconvinced for the need of such an additional agreement between the Scottish Government and Health Boards. Patients are legally entitled to request their health care records and they are not required to provide a reason for their request.<sup>89</sup> It is their choice whether they choose to share any such information and with whom. This can be for any purpose without any validation from any official body. To enable the participants’ choice, we had already designed rigorous consent mechanisms and both the Panel and Clinco remain of the view that that these sufficed to satisfy the necessary legal and ethical requirements to request and obtain records on the participants behalf.<sup>90</sup>
- 4.6 It was the middle of August 2021<sup>91</sup> before Clinco had the necessary consent processes established with the first two participants, so up until that point, waiting for the additional Data Sharing Agreements to be signed off had no detrimental impact on our timescales. However, as the months progressed, this

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<sup>89</sup> NHS inform sets this process out clearly. Available from: <https://www.nhsinform.scot/care-support-and-rights/health-rights/confidentiality-and-data-protection/health-records#accessing-your-health-records> [Accessed June 8 2023]

<sup>90</sup> The two-stage consent process is described in Chapter 3.

<sup>91</sup> The first participant’s consent form was received by Clinco on 18 August 2021.



was no longer the case as the numbers of participants ready to move to the retrieval stage, grew.<sup>92</sup>

- 4.7 It took nearly five months - from July 7 2021 until October 27 2021- to have the Data Sharing Agreements signed by all nine Health Boards. The signs-offs occurred on an incremental basis,<sup>93</sup> so to expedite matters, as soon as we had intimation from the Scottish Government<sup>94</sup> that each sign-off was complete, we proceeded to request case records.
- 4.8 Whilst this may have been something that was unforeseen, the Panel were frustrated at the delay in obtaining additional sign off from the nine Health Boards. In hindsight, this could have all been put in place with all 14 Health Boards, as soon as Clinco was engaged in March 2021 so that once it became apparent which Health Boards we needed to approach to request retrieval of case records, the agreements would have already been in place. We are of the view that such if such agreements are to be put in place in any future work, that this should be done with all Health Boards, prior to the commencement of any larger case review.

**4.9 We recommend that if deemed necessary by the Scottish Government, any bespoke Data Sharing Agreements should be put in place with the remaining Boards prior to the commencement of any larger case review.**

- 4.10 The Panel agreed that our main concern was to expedite and progress the Review. To enable this, once Clinco had received the consent forms from the participants, they then requested case records from all agencies other than the Scottish regional Health Boards<sup>95</sup> since no similar agreements were required for them. This included general practices in Scotland, Trusts in England, and overseas healthcare providers.

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<sup>92</sup> ...with a further two ready by the end of the following week.

<sup>93</sup> We were advised by the Scottish Government that Fife and Greater Glasgow and Clyde Health Board signed September 10 2021, Highland Health Board 14<sup>th</sup> September 2021, Lothian Health Board, 17 September 2021, NHS Borders 21 September 2021, Forth Valley NHS 6 October 2021, Tayside NHS Board 14 October 2021, Lanarkshire NHS 25 October 2021. Ayrshire and Arran HB 27 October 2021.

<sup>94</sup> I kept in regular contact with the Scottish Government at this time who understood that the delays were impacting on our timescales and I acknowledge the work that they undertook to expedite this process.

<sup>95</sup> First requests for the records of 3 participants from Clinco to GP surgeries and overseas treatment centres were made on September 8<sup>th</sup> 2021. First records received back from a GP on 29 September 2021.

### *Accountable Officers*

- 4.11 The Panel were advised prior to the commencement of the Review, that our primary contact from each Health Board would be the relevant Accountable Officer. They would be the named person that we would approach to assist with the retrieval of case records.
- 4.12 Prior to its launch in February 2021, the commissioning of the Review, and its purpose, appears to have been shared with those identified as Accountable Officers. This can be evidenced by the minutes of the meetings of the Scottish Government Transvaginal Mesh Short Life Working Group.<sup>96 97</sup> On December 4 2020, and February 26 2021(5 days after the Review was launched), an extract from their minutes confirmed that:

*“there will be an expectation that Accountable Officers assist with finding evidence and they will be contacted regarding this.”<sup>98</sup>*

*“The Case Record Review has been discussed regularly at these meetings [and], there is an expectation that the Accountable Officers will assist in locating and providing the records for review. In discussion, it was noted that the provision of the medical records (as long as there is a signed mandate) should not be an issue for Boards.”<sup>99</sup>*

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<sup>96</sup> The Scottish Government notes that: ‘*This group, established in March 2019, considers the care provided for women who experience complications following vaginal mesh surgery in Scotland.*’ Available from: <https://www.gov.scot/groups/transvaginal-mesh-short-life-working-group/#:~:text=This%20group%2C%20established%20in%20March,complications%20following%20v%20aginal%20mesh%20surgery> [Accessed January 14 2023]

<sup>97</sup> There is also a sub Group of the above for Accountable Officers whose membership is confined to only Accountable Officers but chaired by the same person as the short life working Group. Established in September 2018 by the Chief medical Officer, - *The accountable officer’s group has been convened to consider aspects of the service and care available to women suffering from stress urinary incontinence and pelvic organ prolapse.* The membership of this appears to be the same as above but without patient representatives. Available from: <https://www.gov.scot/groups/transvaginal-mesh-accountable-officers-group/> [Accessed January 14 2023]. At this date, there is only one set of minutes on the website from this group published in February 2019.

<sup>98</sup> Scottish Government (2020) Transvaginal mesh short-life working group minutes: December 4 2020(published October 2021). Available from <https://www.gov.scot/publications/transvaginal-mesh-short-life-working-group-minutes-december-2020/> [Accessed October 28 2022]

<sup>99</sup> Scottish Government (2021) Transvaginal mesh short-life working group minutes: February 26 2021(published October 2021). Available from: <https://www.gov.scot/publications/transvaginal-mesh-short-life-working-group-minutes-february-2021/> [Accessed 27 October 2022]

- 4.13 Given the above extracts from the minutes, on at least two occasions, the Accountable Officers had discussed the Review and their role within it.<sup>100</sup> Despite the fact that we were given the names of Accountable Officers to contact, there remained confusion, which on occasion continued for several months, as to who the point of contact should be. At one point we had four live contacts for one Board, whilst others seemed to have no awareness of the Review, or their requirement for involvement with it;

*“Can you please clarify what you want me to do? It will be useful to send me a hard copy with your request”*

*“There is not a specific person assigned to this task.”*

- 4.14 We therefore had no option but to request that the Scottish Government intervened, and identify to whom we should be directing our requests. They assumed the responsibility for resolving this matter<sup>101</sup> and by the end of November 2021, there was a significant increase in engagement. However, it did not resolve the matter of engagement from the Boards completely, and we requested further support from the Scottish Government to secure all Health Boards’ engagement. On the January 27 2022, the Director General for NHS Scotland sent out a letter to all Health Board Chief Executives encouraging them to engage with the Review. Some six months after this, Clinco received an email on July 27 2022, which noted that a Health Board’s Executive Medical Director was unaware that the Review was taking place. Resolving these matters were time-consuming for all parties concerned.
- 4.15 Once the named contacts were established, the process continued to be protracted as often, a single request for records did not always get acknowledged and so multiple follow-up requests had to be made to try and elicit a response. Despite these multiple requests, on further occasions, we had to ask the Scottish Government to intervene to help expedite our request for case records. Their interventions always resulted in a positive response from the Boards. All Boards ultimately provided a full response to the request made to them including any follow up requests that we made and we are grateful to all who assisted us with this task.
- 4.16 Clinco prepared a total of 32 progress reports for the Panel detailing that the first reports from the Boards were received by Clinco on December 2 2021 and the last set of records on January 20 2023.

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<sup>100</sup> It was attempted to retrieve published minutes from meetings held post February 2021 but we were unable to locate any.

<sup>101</sup> Clinco received a telephone call from a Senior Medical Officer on behalf of the Scottish Government providing assurance that they would assist in establishing primary contacts and their emails.

- 4.17 The experience of engaging with the Health Boards using the approach described above was both protracted and resource-intensive for the Panel and Clinco. We conjecture, that the Health Boards also found the process to have been onerous and overly complicated. It is regrettable that they did not reflect on their role more fully when the matter was initially raised with them during the meetings of the Short Life Working Group. This may have served to address any potential concerns at the time, and would have resulted in a more workable and less cumbersome process. We recognise that this Review was taking place just as Scotland was coming out of a lockdown and the consequential pressures that this placed, and continues to place, upon the NHS. Despite this, we remain of the view that poor communication and a lack of preparedness was responsible for at least some of this. The Panel were most concerned about the impact that the delay and lack of progress had on the trust and confidence of the participants.
- 4.18 Given our requests involved only 18 participants, the Panel conclude that this approach to engaging with the Health Boards would not be workable should a future Case Record Review be made available to a larger group of women.

*Engagement with general practices.*

- 4.19 Our request for retrieval of case records from general practices did not require us to approach any practices outwith Scotland. Most requests from us were acknowledged promptly, and records were received by Clinco on average within six weeks. A small number of practices sought further information or wished to contact the participant directly to obtain their consent prior to sending their records, otherwise this was a straightforward part of the retrieval process.

*Engagement with other case record holders*

- 4.20 We made four requests for case records to St Louis, USA, and received all of these within five weeks of our request. One request was made to the Spire Hospital in Bristol which was received within four weeks. Two requests were made to Nuffield Health in Glasgow. With one request we were advised that the records were no longer in existence (routinely destroyed after seven years); the other request was returned to us within six days. One request was made to the University Hospital London, and the records were received within five weeks. No duplicate or follow up requests were required to be sent to any of the above.
- 4.21 On occasion, if we were unable to retrieve what we believed to be records which were central to the review, we approached the participants for their assistance, as many of them had their own copies. All engaged with our request.

4.22 We are grateful to all the agencies and individuals who engaged with us.

## Chapter 5 - Review of the Case Records and feedback to the Participants

### Introduction

5.1 This chapter considers the methods that the Panel adopted to review the case records for each participant and how we communicated our findings to the participants.

### Clinical Proforma

5.2 The Clinical proforma was the last of the templates<sup>102</sup> that we created for the Review. It was the document that each clinical member of the Panel received and which detailed matters of concern that the participants wished us to address. The form was set out chronologically, starting with **consultation pre-surgery**, discussion of **any conservative treatments**, matters relating to **consent**, the **initial surgery**, **post-surgery** and any **mesh revision surgery**. It mirrored the detail contained in the information gathering form.<sup>103</sup> The clinical proforma contained only an identifying participant number and CHI<sup>104</sup> number so that we could cross check that we were considering the correct records for each participant. Participant names or healthcare professional's names were redacted.

5.3 We found this a useful document as it provided a focus in summarising discussions between me, the administrator and the participants, and the chronology not only mirrored the content of the information gathering form, but also the order in which we received the collated records. Some of the participants sent the Panel a list of specific questions that they wished us to address and these were included in the Clinical proforma, and in the bespoke reports shared with each participant after the Panel review.

5.4 This proforma was sent to the clinicians by the administrator or myself by email, in parallel with the collated records being made available via a secure digitised process. This part of the process worked smoothly.

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<sup>102</sup> Template is available in Appendix 1 of this Report.

<sup>103</sup> Described in Chapter 2.

<sup>104</sup> The Community Health Index (CHI) is a population register, which is used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index.

## Collated case records

- 5.5 Once Clinco had retrieved the case records that had been requested, they put them into a chronology which reflected their treatment journey. As noted earlier, case records were indexed into digitised volumes, of around 375 pages per volume. Once these were complete, Clinco sent them to our administrator via Egress.<sup>105</sup> The administrator then checked and confirmed receipt of the records to Clinco.
- 5.6 The Panel had discussed various options for sharing the records amongst ourselves. Due to the large volume of the records, printing these out and posting hard copies to each Panel member would be resource-intensive, both in term of printing out multiple copies, and the expense of securely posting such large files. There was also the matter of confidentiality and heightened risk associated with hard copies being consigned to the post. Hard copies also became outwith the control of the administrator, should any late additions need to be made. We agreed that keeping them in digital format was the best approach and addressed the concerns of managing large paper volumes and matters regarding confidentiality. The files were too large to be part of a usual secure attachment so an alternative method had to be found.
- 5.7 We agreed that using an Electronic Discovery Reference Model (EDRM)<sup>106</sup> would best suit our requirements. It is a process which allows the gathering, storage and assimilation of data into one accessible digital area. It is a practical choice where large amount of data has to be stored and reviewed. It is also flexible so that the management and protection of data can be refined to suit a specific project.
- 5.8 For the Case Record Review, the authority, control and management of the data was the sole responsibility of the administrator. Once she received the files from Clinco, she put them on the ERDM system and after checking they were visible and accessible, she facilitated access for the rest of the Panel members. The administrator was the only member of the Panel who could add, remove or revise documents. All documents remained in digital format and could not be downloaded. Like all new processes, it took us a little time to familiarise ourselves with it, but once we did, it was an uncomplicated, practical and successful way to access the case records.

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<sup>105</sup> Egress is a software system which assists with secure file sharing and handling.

<sup>106</sup> For further information please see Cole, B (2014) EDRM (electronic discovery reference model). Available from: <https://www.techtarget.com/searchcio/definition/EDRM-electronic-discovery-reference-model> [Accessed December 13 2022] See also, What is EDRM? (Electronic Discovery Reference Model) And How it Has Evolved (2022) Available from: <https://ipro.com/resources/articles/what-is-edrm-electronic-discovery-reference-model-and-how-it-has-evolved/> [Accessed December 13 2022]

- 5.9 Each clinical member of the Panel was asked that they review all case records independently and not to discuss them with each other until we met together as a full Panel. One clinician would provide context and a summary prior to the review of every participant's records. We then worked through the records in the chronology described in the clinical proforma. All clinicians had the opportunity to contribute equally to all the cases that we reviewed. My role during these discussions was as an independent facilitator and advocate for the participant ensuring, to the best of our ability based on the documentation available to us, that we had addressed all the issues that they had raised. Whilst the discussion focused upon the case records, it often extended into other areas and themes and our discussions from these can be found in Part II of this Report. Using a small handheld dictation machine, our discussions were recorded and transcribed by the administrator and then sent to me.
- 5.10 It was unsurprising that some of our discussions took three hours and that the transcripts were large documents, containing up to 40 pages. I then read these, formatted them into the chronology in which we considered them and summarised them in a final draft report. These were then returned to the clinicians to review and if they agreed that the report accurately captured the outcomes of the discussions, they were then signed off. Using this format, every case record report for each participant was the result of a unanimous Panel decision. Whilst this usually was preceded by discussion, agreement was usually achieved without too much difficulty. Once the Panel had agreed and signed off a report, it was sent to the participant with an email explaining next steps.

### **Next steps - the participant receives their report**

- 5.11 Once completed, the administrator emailed the report, password-protected, to the participant. The accompanying email encouraged the participant to take as much time as they needed to read and reflect upon their report. An invitation for a meeting to discuss the report with a clinician from the Panel and myself was offered and it was left to the preference of the participant whether or not they chose to avail themselves of this. They were also welcome to have someone in attendance with them as their support/advocate. During these meetings, if it was brought to the Panel's attention that we had misunderstood a material point, we again reviewed the evidence available to us and took a decision whether or not to amend the report. We did this on two occasions with the amendments appearing as a footnote so that it was clear what had been revised and why it had been revised. Finally, all participants were offered a copy of the case records that had been retrieved by Clinco and reviewed by the Panel. They were able to receive this digitally, or as a hard copy. Both methods were arranged by Clinco and forwarded directly to the participant. Seven



participants chose to receive a copy of their case records. Six participants chose to receive their records in hard copy and these were couriered to them and one requested hard copy and digital format. Whilst we recognise that, in some instances, participants may not wish to view their case records, the Panel remain surprised that more participants did not request their case records.

5.12 This completed the review of each participants their case records.

### **An alternative model**

5.13 The Panel believe that our approach to our review of the case records was thorough, comprehensive and successfully met our objectives as set out in the Review's Terms of Reference. However, the process was time-consuming, and aspects of record retrieval as previously described were inefficient. Again, we acknowledge that this involved a small pilot number of 18 participants. The final chapter of Part I of the report considers some alternative models that have been introduced in other jurisdictions but first we propose below an alternative method to retrieval and collate case records.

### **Alternative collation of records- Scotland**

#### *Short form retrieval*

5.14 Since part of our remit was to consider alternatives, the Panel have also explored the option of undertaking a short form alternative to the process that we used in the Case Record Review. This would involve a more focused review of a narrower part of the case records. Whilst it is demonstrably less resource intensive, some of the issues remain since it would be retrospective and address only issues which have been written in the case notes. It does not consider verbal communications nor does it address future care. The question remains if this would be a workable solution as one part of a set of comprehensive measures.

5.15 Clinco assisted us in this exercise by selecting at random one of our existing participants to benchmark this shorter alternative. In this example, the chronology, was reduced from 18 pages to 3½ pages, and the case records from a total of 2,021 pages to 39 pages. The total time Clinco took to produce the documentation, indexed and paginated bundle, imaging schedule and full chronology for the full version took 29.3 hours. The estimated alternative time for the 'short form' which contained no index and with pages left in a random order, but including a short form chronology, took about seven hours.

5.16 Whether the less detailed results are worth the time/cost savings remain to be decided. Much of the context of the treatment is lost in the short form, including

most of the history, and peripheral patient experience, but information regarding consent, conservative treatments, surgery (including revision surgery) would all be included. It would make the review more cost efficient for a larger number of patients and patients would be supported throughout this process and the peripheral patient experiences could be address through other means. What these could be are discussed in the next chapter.

### *Subject Access Requests (SAR's)*

- 5.17 Under the provisions of the General Data Protection Regulation (UK GDPR),<sup>107</sup> all patients have a right to access their health and care records. Most health boards in Scotland have readily available information online about how to access case records and include a template form to assist with the request.<sup>108</sup> Whilst they may differ in style and format there are central features to all of them including who may apply: they can be requested by the individual themselves, or someone acting on their behalf.<sup>109</sup> There is no requirement to provide a reason for the request. The information is normally provided within 30 days of receipt of the request. GDPR and the 2018 Act provides for a number of exceptions<sup>110</sup> including matters relating to those who lack capacity. Information can be withheld if there is a steadfast reason to believe that receiving case records may cause serious harm to the physical or mental health of the person to whom it applies. A SAR can include, all healthcare records, both from community healthcare (general practice, health visiting, pharmacy etc) or hospital healthcare (outpatient clinics, inpatient stays, emergency attendances and operation notes etc).
- 5.18 The Panel are of the view that given that each Health Board already has processes in place to receive and process such requests, it may make any future Review process more streamlined. However, what a patient receives will not be indexed or necessarily be in any chronological order. The Panel believe that it is critical to have a process whereby what is requested is what the individual wishes to see, and provides relevance and context to inform what

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<sup>107</sup> The Data Protection Act 1998 implemented the European Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data (Council Directive (EC) 95/46 1995).

<sup>108</sup> For example, please see Greater Glasgow Health Board information at <https://www.nhsggc.org.uk/media/264232/medical-records-gdpr-new-application-form-2020-12.pdf> and NHS Lothian can be found at <https://www.nhslothian.scot/YourRights/DataProtection/Pages/Subject-Access-Requests.aspx> [Accessed February 15 2023]

<sup>109</sup> This would be subject to relevant permissions /consent being obtained.

<sup>110</sup> The GDPR and Data Protection Act 2018 provides for a number of exemptions in respect of information falling within the scope of a SAR.

they would like to know. We therefore recommend, that, in conjunction with other initiatives,<sup>111</sup> the short form retrieval method is adopted.

**5.19 The Panel believe that it is critical to have a process whereby what is requested is what the individual wishes to see, and provides relevance and context to what they would like to know. We therefore recommend, that, in conjunction with other initiatives, the short form retrieval method is adopted.**

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<sup>111</sup> Chapters 6, 8 and 9 discuss these initiatives.

## Chapter 6 - Alternative approaches: International experiences and perspectives\*<sup>112</sup>

- 6.1 In its introduction, this Report acknowledged that the concerns expressed by women following transvaginal mesh surgery are not confined to Scotland or indeed the United Kingdom. For the purpose of this chapter we have considered the work that has been undertaken in Australia and New Zealand, some of which we believe could potentially be adapted to enhance and support the provision of mesh services within a Scottish context.

### The wider Australian response

- 6.2 The Queensland Government estimate that 150,000 women across Australia have received pelvic mesh implants in their treatment of pelvic organ prolapse (POP) or stress urinary incontinence (SUI) within the past twenty years.<sup>113</sup> This estimation gives rise to two points. First, it implies that a significant number of women across Australia have received a transvaginal mesh implant. Second - and arguably, more importantly - the percentage of those 150,000 women who may have experienced complications, remains unknown. This lack of certainty surrounding data capture was the catalyst for the Parliament of Australia to set up an Inquiry into the, *'Number of women in Australia who have had transvaginal mesh implants and related matters,'* launched on 15 February 2017.<sup>114</sup>
- 6.3 On the 28 March 2018, the *Senate Affairs Reference Committee's Report* was published, comprising five chapters and 13 recommendations.<sup>115</sup> The Senate Report acknowledged the complexities of this area of healthcare and suggested some ways in which they could be addressed - with Senator Rachel Siewert stating:

*"The committee hopes that the findings and recommendations that it has made as a result of this Inquiry serve women well by improving regulatory processes*

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<sup>112</sup> \* My sincere thanks to Dionne Revie, LLB, for the research and first draft of this chapter.

<sup>113</sup> Queensland Government, 'About pelvic mesh and complications,' (22 September 2021) Available from: <<https://www.qld.gov.au/health/services/specialists/pelvic-mesh-service/about-pelvic-mesh-and-complications>> [Accessed September 15 2022]

<sup>114</sup> Parliament of Australia, 'Number of women in Australia who have had transvaginal mesh implants and related matters'. Available from: <[https://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Community\\_Affairs/MeshImplants](https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants)> [Accessed September 15 2022]

<sup>115</sup> *Ibid.*

*and care pathways such that they are robust, evidence based, clinically sound and focused on good patient outcomes.”<sup>116</sup>*

### *A Lack of Data*

- 6.4 A significant finding was the lack of available data regarding the exact number of women who received a transvaginal mesh implant in Australia and how many also experienced complications.<sup>117</sup> A lack of data is not an issue isolated to Australia. We consider Scotland’s challenges with regard to this in Chapter 9 of this Report.
- 6.5 Queensland acknowledged the difficulties that a lack of or incomplete data represented when developing and providing resources to meet what is an unknown number of women’s needs.<sup>118</sup> In response to initially very little and inconsistent information being recorded, in early 2020, letters were sent to every woman residing in Queensland who had undergone surgery involving transvaginal mesh since 2000.<sup>119</sup> Whilst this may be seen to have merit, it did not have the anticipated outcome. Rather than providing clarity in terms of data capture and/or reassurance, this process led to a substantial increase in the number of women who raised concerns around their surgery and the possibility of complications. As a result, the whole process became unmanageable and “...*outstripped the capacity...*”<sup>120</sup>
- 6.6 Accurate data is vital to inform and shape responses. To address the lack of data, several measures were recommended. This included implementing a mandatory reporting system for women who experienced an adverse event,<sup>121</sup> the establishment of a national register of medical devices,<sup>122</sup> and broadening the sources of potential data to include private insurance companies, hospital databases, and patient records.<sup>123</sup>

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<sup>116</sup> *Ibid* - Chapter 5, Paragraph 5.152.

<sup>117</sup> *Ibid* - Paragraph 5.45.

<sup>118</sup> *Ibid* - Paragraph 5.46.

<sup>119</sup> Queensland Government – Recent Patient Contact (2021) Available from: <https://www.qld.gov.au/health/services/specialists/pelvic-mesh-service/about-pelvic-mesh-and-complications/recent-patient-contact> [Accessed June 6 2023]

<sup>120</sup> *Ibid*.

<sup>121</sup> *Ibid* - Paragraph 5.55.

<sup>122</sup> *Ibid* - Paragraph 5.66.

<sup>123</sup> *Ibid* - Paragraph 5.67.

### *Informed Consent and Information Disclosure*

- 6.7 It is widely acknowledged that informed consent and information disclosure are vital components of good clinical care.<sup>124</sup> The Senate Report<sup>125</sup> found that while many women received detailed information and counselling,<sup>126</sup> others received little to no information.<sup>127</sup>

*“The committee is dismayed by reports that some women were not advised that a transvaginal mesh implant was being used as part of their treatment.”<sup>128</sup>*

- 6.8 Australia and Scotland share a particular commonality with the Scottish Health and Social Care Alliance in their project, ‘*My Life, My Experience - Capturing Lived Experiences of Complication Following Transvaginal Mesh Surgery*’, finding 36 of 46 women who participated reported experiences of being given minimal information about treatment they received<sup>129</sup> and conversations with our Review participants highlighted similar concerns.<sup>130</sup> Arguably, a contributing factor to the lack of informed consent in both jurisdictions is the confusing nature and inconsistency of the terminology utilised by clinicians when discussing transvaginal mesh implants. Again, just as the Review had heard, transvaginal mesh implants were often described to women in Australia as a ribbon, tape, or sling - the connotations of which do not immediately imply a polypropylene device to non-medically trained individuals.
- 6.9 In response, the Senate Report provided a list of recommended points to be raised during discussions between healthcare professionals and patients to ensure full understanding of what is being discussed. Recommendations included providing full details of the proposed treatment and a clear rationale

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<sup>124</sup> This is explored further in chapter 8 of this Report.

<sup>125</sup> Parliament of Australia, ‘Number of women in Australia who have had transvaginal mesh implants and related matters’. Available from: <[https://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Community\\_Affairs/MeshImplants](https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants)> [Accessed September 15 2022]

<sup>126</sup> The Senate Report uses the word ‘counselling’ to mean advice, guidance, support and the disclosure of information.

<sup>127</sup> *Ibid* - Paragraph 5.79.

<sup>128</sup> *Ibid*.

<sup>129</sup> Alliance, ‘My Life, My Experience - Capturing Lived Experiences of Complication Following Transvaginal Mesh Surgery,’ (2019, *Alliance Scotland*), 14, Available from: <<https://www.alliance-scotland.org.uk/wp-content/uploads/2019/11/ALLIANCE-Mesh-Report-2019.pdf>> [Accessed October 3 2022]

<sup>130</sup> Please see Chapters, 1, 2 and 7 of this Report.

for such treatment, including alternative options and a final confirmation that the patient fully understands their treatment plan.<sup>131</sup>

### *Care pathways*

6.10 The need for effective care pathways was highlighted by the Senate Report. By using bespoke referral pathways, the patient's clinical needs could be addressed.<sup>132</sup> In an attempt to streamline this process, the Australian Commission on Safety and Quality in Health Care (ACSQHC) are developing a surgical pathway,<sup>133</sup> which will be based on a '*traffic light approach*'. In effect, this is triage system based on the priority of patients' clinical needs.<sup>134</sup>

*"In particular, the Senate committee understands the importance of ensuring treatment and support is available for all women currently living with mesh related complications."*<sup>135</sup>

6.11 Whilst this could potentially be an effective measure, the Panel recognise the need for support mechanisms for women who are waiting to be referred.

6.12 Whilst several recommendations were made by the Senate Report, Recommendation 13<sup>136</sup> provides a comprehensive and integrated list of services to be established. These include information and helplines for women, specialist counselling programs, multidisciplinary units, and guidance for medical professionals on the importance of data capture for surgical procedures.

6.13 A range of services have been introduced across Australia. Starting in September 2017, Western Australia established a confidential free telephone line as well as a Mesh Register to aid data capture. In December 2017, the State of Victoria established a mesh information service and helpline,<sup>137</sup> as well

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<sup>131</sup> Parliament of Australia, 'Number of women in Australia who have had transvaginal mesh implants and related matters,' Paragraph 5.87. Available from: [https://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Community\\_Affairs/MeshImplants](https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants) [Accessed September 15 2022]

<sup>132</sup> *Ibid* - 5.92.

<sup>133</sup> *Ibid* - 5.89.

<sup>134</sup> *Ibid*.

<sup>135</sup> *Ibid* - 5.137.

<sup>136</sup> *Ibid* - 5.151.

<sup>137</sup> Victoria Government, Australia & Dept of Health (Aus) (2022) *Better Health Channel - Transvaginal Mesh*. Available from:



as specialist programs to address reported complications following mesh surgery.<sup>138</sup> At the same time, the Government of New South Wales are issuing Safety Notices, regularly updated, regarding transvaginal mesh implants outlining what patients should do if they have concerns following surgery.<sup>139</sup> In January 2018, the Australian Capital Territory directly contacted women who were identified as having a mesh implant within the last ten years. In conjunction they developed a dedicated phone line and established an email where patients could register their concerns.<sup>140</sup> The Panel found these initiatives impressive and informative.

6.14 In 2019 a Progress Report highlighted that Recommendation 13 has been acted upon in most Australian jurisdictions, with services being created for the removal of mesh and provision of support.<sup>141</sup>

6.15 The Panel see the merit in additional support mechanisms being put in place for GPs and practice teams for when women raise concerns with them. We have included a link below to the template which is a resource for GP's and explains the possible symptoms and signs of women presenting with pelvic mesh-related conditions and if required, where to signpost them for further help.<sup>142</sup> It is also vital to provide patients with access to dedicated online information and support services which can be regularly updated.

**6.16 The Panel recommend additional support mechanisms being put in place for GPs and practice teams to aid understanding and address concerns women may raise with them following a transvaginal mesh surgery.**

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<https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/transvaginal-mesh> [Accessed June 9 2023]

<sup>138</sup> Safer Care, Victoria(Aus) (2018), *Transvaginal mesh: the Victorian response*. Available from: [https://www.safercare.vic.gov.au/sites/default/files/2018-08/Transvaginal%20mesh\\_FINAL.pdf](https://www.safercare.vic.gov.au/sites/default/files/2018-08/Transvaginal%20mesh_FINAL.pdf) [Accessed June 9 2023]

<sup>139</sup> New South Wales Government, (2023) *Safety Notice 002/23 UPDATED: Transvaginal mesh implants for Pelvic Organ (Vaginal) Prolapse* Available from: <https://www.health.nsw.gov.au/sabs/Documents/2023-sn-002.pdf> [Accessed June 9 2023]

<sup>140</sup> Australian Capital Territory Government Health (2022) (updated) *Transvaginal Mesh*. Available from: <https://www.health.act.gov.au/services-and-programs/womens-health/transvaginal-mesh> [Accessed June 9 2023]

<sup>141</sup> Department of Health and Aged Care, 'Progress report: Australian Government response to the Senate Community Affairs References Committee report,' (*Australian Government*, 2 December 2019) Available from: <<https://www.tga.gov.au/resources/publication/publications/progress-report-australian-government-response-senate-community-affairs-references-committee-report>> [Accessed October 7 2022]

<sup>142</sup> Patient Safety Commissioner (England) (2022) Mesh Patients Resource for GP's. Available from: <https://www.patientsafetycommissioner.org.uk/wp-content/uploads/2023/05/Mesh-Patients-Resource-for-GPs.docx> [Accessed June 8 2023]



6.17 Australia have recognised the importance of data capture with a Mesh Register becoming a key tool, not only to collect data, but to regulate how transvaginal mesh is utilised in clinical practice.

**6.18 It is recommended that Scotland maintains a Mesh Register which records surgery in Scotland, as well as surgery which has occurred in other parts of the UK and overseas.**

### Queensland's Pelvic Mesh Service

6.19 One of the most prominent responses to the recommendation for a comprehensive approach was with the establishment of the Queensland Pelvic Mesh Service, located at Varsity Lakes Day Hospital on the Gold Coast.<sup>143</sup>

*“The Queensland Pelvic Mesh Service is committed to partnering with women, providing multidisciplinary care and treatment through their recovery journey in a mutually respectful, transparent and supportive environment.”<sup>144</sup>*

6.20 The service focuses on a ‘partnership’ between women and healthcare professionals,<sup>145</sup> suggesting that the service promotes a collaborative approach to clinical care. Focusing on a ‘partnership’ in this context builds trust and empowers the patient as the decision-maker.

6.21 Adequate resourcing of any such service remains critical. The Queensland Pelvic Mesh Service is funded by Queensland Health with a 2022-23 budget allocation of \$3.14 million.<sup>146 147</sup> It remains to be seen whether this will be a sufficient resource to meet the aims of the service.

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<sup>143</sup> Queensland Pelvic Mesh Service <https://www.qld.gov.au/health/services/specialists/pelvic-mesh-service>

<sup>144</sup> Queensland Government, ‘About Pelvic Mesh and Complications,’ (2021) *Queensland Government*, Available from: <<https://www.qld.gov.au/health/services/specialists/pelvic-mesh-service/about-pelvic-mesh-and-complications>> [Accessed December 16 2022]

<sup>145</sup> Available from: <https://www.qld.gov.au/health/services/specialists/pelvic-mesh-service> [Accessed June 9 2023]

<sup>146</sup> Steven Miles, ‘Gold Coast to host service dedicated to women affected by pelvic mesh,’ (19 December 2018, *The Queensland Cabinet and Ministerial Directory*) Available from: <<https://statements.qld.gov.au/statements/86342>> [Accessed December 16 2022]

<sup>147</sup> Placing this figure into a broader context, Queensland Health’s full annual budget for 2022-23 is \$23.6 billion.

- 6.22 It is recognised that the waiting time to access complex mesh services in Scotland,<sup>148 149</sup> and throughout the UK, continue to raise concerns.<sup>150</sup> As a way of attempting to manage and allocate resources, the Queensland service has adopted a triage approach. Category 1 is allocated to the most severe complications, and Category 3 being those who experience milder physical symptoms. Every woman, irrespective of how mild or severe her complications may be and what category that places her into, undoubtedly wants to see the medical team as soon as possible. Considering the wait times associated with each category, Category 1 are those currently being seen by the medical team; Category 2 are those who wait between four to six months on average; those in Category 3 are currently not receiving appointments.<sup>151</sup>
- 6.23 Between April 2019 and April 2021, it was found that 484 women were treated by the medical team, 257 underwent cystoscopy, 91 underwent mesh revision surgery, 65 had complete excision and 25 had a partial excision and one sling division. 180 women were discharged.<sup>152</sup> Notably, the 484 women who received treatment account for just over half of the eligible referrals that the service received.<sup>153</sup>
- 6.24 A final point to note is that initial services tended to focus upon the provision of revision surgery.<sup>154</sup> However, the Queensland Government concluded that this approach may be misplaced.<sup>155</sup> They argued that whilst surgery may bring the psychological relief of having had mesh removed, it may not resolve other clinical matters, including the physical symptoms which were the reason for the initial surgery. This is something that the Panel have also recognised in their conversations with participants and will be discussed further in Chapter 9.

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<sup>148</sup> Scottish Parliament (29 Sept 2022) Mesh Treatment Clarity. Available from: <https://www.theyworkforyou.com/sp/?id=2022-09-29.20.0&s=job+Johnson> [Accessed April 25 2023]

<sup>149</sup> SPICe(2023) Health, Social Care and Sport Committee Complex Mesh Surgical Service – Summary of evidence . Available from: <https://www.parliament.scot/-/media/files/committees/health-social-care-and-sport-committee/complex-mesh-surgical-service-call-for-views.pdf> [Accessed 24 April 2023]

<sup>150</sup> Wise, J (2022) Specialist surgical mesh centres are not working, MPs are told *BMJ* 376:o314 Available from: <https://www.bmj.com/content/376/bmj.o314> [Accessed January 29 2023]

<sup>151</sup> Yu Hwee Tan, Malcom I. Frazer, 'Establishing the Queensland Pelvic Mesh Service: Preliminary experience,' (2022) *Aust NZ J Obstet Gynaecol*, Vol. 62 (2), p.294-299.

<sup>152</sup> *Ibid.*

<sup>153</sup> *Ibid.*

<sup>154</sup> *Ibid* - p.298.

<sup>155</sup> *Ibid.*

## New Zealand – a restorative justice approach?

- 6.25 In 2017, New Zealand became the first country to ban the use of all surgical mesh products for transvaginal POP repair and a single incision mini-sling for the treatment of SUI, following regulatory action from New Zealand's Medicines and Medical Devices Safety Authority (MEDSAFE).<sup>156</sup>
- 6.26 New Zealand operate what is referred to as a 'no-fault system' – a different legal mechanism to the adversarial system that is used to resolve litigation in Australia and across all four jurisdictions of the United Kingdom. Since 1974, New Zealand has operated a scheme which provides assistance with the cost of treatment and rehabilitation for all personal injuries, regardless of fault.<sup>157</sup> Specifically, The Accident Compensation Corporation (ACC) is charged with the responsibility of compensating victims of harm under this system. As of the 30 April 2019, it was estimated that the ACC paid \$23.6 million NZ dollars on 959 claims.<sup>158</sup> 63% of such claims were associated with POP or SUI repair.<sup>159</sup> The ACC have strict eligibility criteria which must be satisfied for a successful compensation claim to be made. Specifically, evidence of harm must be present, the injury caused must have been a direct result of the treatment provided, such injury must be as a result of failure and finally, a list of exclusions is provided ranging from injury as a necessity of treatment, to treatment which failed to reach the desired outcome.<sup>160</sup>
- 6.27 It is important to understand this legal background since it provides the context in which the New Zealand response has been made.
- 6.28 Whilst the extent of reported adverse events appears to be broadly similar to that of Australia and Scotland, there have been some innovative approaches in an attempt to acknowledge these in New Zealand. Of particular interest for this

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<sup>156</sup> New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE) (2018) Regulatory action on surgical mesh products. Available from: [www.medsafe.govt.nz/hot/alerts/UrogynaecologicaSurgicalMeshImplants.asp](http://www.medsafe.govt.nz/hot/alerts/UrogynaecologicaSurgicalMeshImplants.asp) [Accessed February 5 2023]

<sup>157</sup> Wallis K, A (2017) No-fault, no difference: no-fault compensation for medical injury and healthcare ethics and practice. *Br J Gen Pract.* 2017 Jan; 67(654): 38–39 Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5198606/#:~:text=NEW%20ZEALAND'S%20NO%20FAULT%20ALTERNATIVE&text=The%20scheme%20provides%20assistance%20with,been%20covered%20under%20the%20scheme.> [Accessed February 3 2023]

<sup>158</sup> Jane Akre, 'New Zealand Surgical Mesh Restorative Justice Report Released,' (13 December 2019, *MeshNewsDesk*) Available from: <<https://www.meshmedicaldeviceneedsdesk.com/articles/new-zealand-surgical-mesh-restorative-justice-report-released>> [Accessed December 16 2022]

<sup>159</sup> *Ibid.*

<sup>160</sup> The Accident Compensation Corporation, 'Pelvic Surgical Mesh Treatment Injury - A guide to ACC cover - Information for Health Professionals,' (October 2020, ACC) Available from: <<https://www.acc.co.nz/assets/provider/pelvic-surgical-mesh-ti-cover-acc8210.pdf>> [Accessed December 16 2022]

Review, New Zealand have also conducted a project to address concerns over potential harm specifically through a restorative justice approach.<sup>161</sup>

6.29 Regarding New Zealand's wider response to address adverse events following mesh surgery, some recurring themes between Australia and New Zealand are recognisable, including the challenges of a lack of data capture and acknowledging the need for a collaborative approach. Unlike Australia which sought to provide solutions on a state-by-state basis, New Zealand's response encompassed the whole of New Zealand. It comprised a project, a workshop, and two reports – which, when considered together, aimed to provide comprehensive measures to address and resolve issues by way of an integral provision of healthcare services.

6.30 The starting point for New Zealand's approach can be traced back to the Ministry of Health's 2019 project, launched with the aim of hearing directly from patients who had experienced adverse consequences following mesh surgery. Designed with an underlying framework of restorative justice,<sup>162</sup> the project was undertaken between August and October 2019 and involved 600 people who were affected by mesh.<sup>163</sup> They were invited to share their individual experiences through 'Learning Circles' and online 'Story Databases'.<sup>164</sup> The majority of participants were women and also included those who had been indirectly affected. By involving participants with diverse perspectives, the project's objective was to assess the

*"...severity of the harm and the impact on the lives of those who experience complications from surgical mesh."<sup>165</sup>*

6.31 After collating the responses gained through the project, a workshop was conducted on the 20 November 2019. Attendance included the Ministry of

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<sup>161</sup> Please refer to Chapter 1 of this Report for a discussion on how we applied principles of restoring trust in our engagement with those women who participated in the Review.

<sup>162</sup> This is also discussed in Chapter 2 of this Report.

<sup>163</sup> Available from: <https://www.health.govt.nz/system/files/documents/publications/responding-to-harm-from-surgical-mesh-dec19.pdf> [Accessed June 7 2023] pg 11

<sup>164</sup> Available from: <https://www.health.govt.nz/system/files/documents/publications/responding-to-harm-from-surgical-mesh-dec19.pdf> [Accessed June 7 2023] pg 11

<sup>165</sup> Jo Wailing, Chris Marshall, Jill Wilkinson, 'Hearing and Responding to the Stories of Survivors of Surgical Mesh,' (*Ministry of Health*, 12 December 2019) Available at: <https://www.health.govt.nz/publication/hearing-and-responding-stories-survivors-surgical-mesh> [Accessed December 16 2022]

Health, the organisation 'Mesh Down Under',<sup>166</sup> and The Health Quality & Safety Commission.<sup>167</sup> The workshop provided a platform upon which the findings of the project could be openly discussed. As noted already in chapter 2, the outcomes from both the workshop and the restorative project were summarised in 2020 in a report which outlined the benefits which could be derived from adopting a restorative approach.<sup>168</sup> Its conclusion also considered the preventative future measures through six key areas, namely;

- the credentialing<sup>169</sup> of surgeons;
- the creation of multidisciplinary mesh services;
- mechanisms used to maximise the principle of 'informed consent';
- harm should be acknowledged;
- a culture of safety in healthcare systems and;
- responding to mesh concerns in the present and the future.<sup>170</sup>

6.32 The success of the project was founded on a collaborate approach to capture people's stories. Participants were invited to share their experiences through a range of diverse forums.<sup>171</sup> This suggests that access and getting the right environment are key to a restorative justice approach. The Panel recognises that not all women feel comfortable sitting in close proximity with someone who was closely involved in their care or to discuss medical issues that are very

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<sup>166</sup> For a history of the development of this organisation please see, Berry , C (2019) Women together: A history of women's organisations in New Zealand. Available from: <https://nzhistory.govt.nz/women-together/mesh-down-under> [Accessed February 5 2023]

<sup>167</sup> Jo Wailing, Chris Marshall, Jill Wilkinson, 'Hearing and Responding to the Stories of Survivors of Surgical Mesh,' (*Ministry of Health*, 12 December 2019) Available from: <https://www.health.govt.nz/publication/hearing-and-responding-stories-survivors-surgical-mesh> [Accessed December 16 2022]

<sup>168</sup>Jo Wailing, Chris Marshall, Jill Wilkinson, 'Healing after harm: An evaluation of a restorative approach for addressing harm from surgical mesh. Kia ora te tangata: He arotakenga i te whakahaumanu,' (2020), *The Diana Unwin Chair in Restorative Justice*, Victoria University of Wellington, Available from: <https://www.wgtn.ac.nz/restorative-justice/our-work/research-evaluation/restorative-practice-and-surgical-mesh/healing-after-harm-evaluation-report-moh-pdf> [Accessed December 16 2022]

<sup>169</sup> Assessing an individual's skill knowledge or performance level.

<sup>170</sup> Jo Wailing, Chris Marshall, Jill Wilkinson, 'Hearing and Responding to the Stories of Survivors of Surgical Mesh,' (*Ministry of Health*, 12 December 2019) Available from: <https://www.health.govt.nz/publication/hearing-and-responding-stories-survivors-surgical-mesh> [Accessed December 16 2022]

<sup>171</sup> *Ibid* - p.14.

intimate. By utilising databases and online platforms, it removed that proximity and instead provided alternative methods of engagement. Individuals could access and share information of their choice at any given time.

- 6.33 The restorative element focused on enabling the women to share their experiences. This was found to provide a “...*nuanced understanding of events*”,<sup>172</sup> suggesting that discussing such matters in a carefully considered environment may be of benefit not only for the participants themselves but to allow others to gain an understanding.
- 6.34 The New Zealand project produced 19 points of action.<sup>173</sup> Some of these are parallel to those produced within the Australian report, however, New Zealand provides some notable additions including:
- the potential need to provide counselling to those experiencing mesh complications;
  - the need to recognise the complexity and sensitivity of the issues involved;
  - the need to reiterate the importance of informed consent and provide training to support and uphold information disclosure and understanding; and
  - the requirement to update the law to ensure it is in-keeping with modern medical device regulation.
- 6.35 In conclusion, Australia and New Zealand share much in terms of approach, not only with each other, but with Scotland and throughout the UK. The Panel particularly favoured the collaborative approach seen in New Zealand, with responsibility for care shared and managed amongst a number of healthcare agencies including complex mesh services, health providers, patients and government initiatives. Each country made good use of online information services which appear to be regularly updated. Patient involvement is integral to both Australia’s and New Zealand’s approach.
- 6.36 There is a degree of commonality about the issues of concern raised across all countries:
- the need for data capture;

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<sup>172</sup> *Ibid* - p.23.

<sup>173</sup> Jo Wailing, Chris Marshall, Jill Wilkinson, ‘Hearing and Responding to the Stories of Survivors of Surgical Mesh,’ (*Ministry of Health*, 12 December 2019), p.44 - 45, Available from: <https://www.health.govt.nz/publication/hearing-and-responding-stories-survivors-surgical-mesh> [Accessed December 16 2022]

- effective review of data capture to inform future initiatives for care;
- clear processes for information disclosure and consent;
- pathways for referral and treatment need to be created;
- credentialing for clinicians performing revision surgery;
- patient involvement;
- process to promote sharing of best practice for all of the above; and
- effective use of websites to collate and share all this information.

**6.37 The Panel were supportive of the practical and integrated response proposed by the New Zealand review and suggest that Scotland should reflect with a view to adopting similar initiatives.**

## PART II

### **Introduction**

The administrator and I spent over two years working together with the participants on the Case Record Review. Their ongoing engagement with us revealed a number of themes which came up repeatedly, some of which the Panel also found reflected in their case records. We have discussed these under three main headings, and devoted a chapter to each.



## Chapter 7 - The Lived Experience of the Women

### Introduction

- 7.1 This chapter considers the legacy of experiences that the participants in this Review have described to us. It is not easy to fully portray an experience lived by another person but we have had the benefit of being able to draw upon many hours of recorded transcripts of conversations between ourselves and the women who participated in the review. Sometimes a phrase or expression perfectly captured the essence of a point made so, where possible, we have included words and quotations from the women themselves. We also appreciate that this journey, for many, continues and the final chapter of this Report considers how their care is being managed at present, and how it may be managed in the future. Although it is not possible to alter something that has already been experienced, understanding its legacy and impact may help those providing care and complex mesh services to meet the needs of those who are referred to them.
- 7.2 Although no two people are exactly alike, our conversations showed that many of the women had a journey or experiences in common. The following paragraphs represent emergent concerns: themes and language that participants used repeatedly when reflecting on their personal experiences.

### Emotional experiences

- 7.3 For women who have to manage more severe forms of urinary incontinence, the impact is relentless, for, if left untreated, it will usually continue to get worse. Often this may be viewed as a side effect of a vaginal delivery when giving birth or an inevitable part of growing older<sup>174</sup> and some women become very resilient and adept in finding ways to manage their condition. Urinary incontinence requires continuous practical management to stay dry and there is a constant worry of leakage. This can have a significant impact on self-esteem, dignity, and quality of life.<sup>175</sup> For some women, having to discuss their symptoms may cause embarrassment, awkwardness and shame.<sup>176</sup> For all of

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<sup>174</sup> Empowered Women's Health (2021) Why Women Aren't Reporting Loss of Bladder Control and How to Help, Available from: <https://www.volusonclub.net/empowered-womens-health/why-women-arent-reporting-loss-of-bladder-control-and-how-to-help/> [Accessed April 5 2023]

<sup>175</sup> Coyne KS, Kvasz M, Ireland AM, Milsom I, Kopp ZS, Chapple CR. (2012) Urinary incontinence and its relationship to mental health and health-related quality of life in men and women in Sweden, the United Kingdom, and the United States. *Eur Urol.* 61(1):88–95. <https://doi.org/10.1016/j.eururo.2011.07.049> Epub Jul 26.

<sup>176</sup> The Cumberlege Report recognised this point and more recently in a 2023 study by Toyne, F, Izett-Kay, Barker, KL and McNiven, A (2023). The experience of women reporting damage from vaginal mesh: a reflexive thematic analysis. *The Lancet* Available from:

these reasons and more, women may avoid seeking help with symptoms, and often endure their incontinence for many years before seeking help.<sup>177</sup>

### Changing perceptions of self and personal loss of health and wellbeing

- 7.4 A significant and one of the most poignant themes arising from our conversations with women was the profound bewilderment that accompanied any discussion of their health and wellbeing.

*'I've lost my self-worth, my self-esteem, me and everything. I don't even know who I am. There's nothing now. I missed my son's graduation. I've missed out on family occasions. All aspects of my life.'*

- 7.5 Many talked about living with both physical loss and psychological restrictions, and the challenges of not only having to adapt, but to try and come to terms with these. Participants described how these have directly impacted upon aspects of life including intimacy, family, social and professional life.

*'It's so hard when you were a professional woman who has raised a family, ran a home, part of society to just be this insignificant little nothing and, the thing is there are some family and friends who think "What's she moaning about now?" You get left behind. It's like "I'm not going to ask her to come on that girlie holiday". I wouldn't go anyway because I wouldn't be able to cope but you just feel left behind then. In a lot of areas in your life. It is really a rippling effect.'*

- 7.6 Social isolation features predominantly in some cases. This would not have been helped by living with the consequences and restrictions imposed by the Covid-19 pandemic, but there were practical consequences too. Managing incontinence often took additional time and careful planning in order to feel sufficiently confident and comfortable to leave their home and engage in social interaction.

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<https://www.thelancet.com/action/showPdf?pii=S2589-5370%2823%2900095-0> [Accessed April 4 2023]

<sup>177</sup> For example, in this article, it was shown that 25-35% women delayed reporting their urinary incontinence for 5 years or more before seeking medical advice. Please see, Norton PA, MacDonald LD, Sedgwick PM, Stanton SL. (1988) Distress and delay associated with urinary incontinence, frequency and urgency in women *BMJ* 297: 1187-9. See also Brocklehurst, J.C (1993) Urinary incontinence in the community--analysis of a MORI poll. *BMJ* 1993; 306 Available from: <https://doi.org/10.1136/bmj.306.6881.832> [Accessed 7 June 2023]

*'If you try to do something it's how long's the journey, where's the nearest toilet, are the facilities going to be clean. In the car, I've got a bag and it's permanently packed with clean trousers, pants, wipes even down to the fact that I take shoes with me because if it goes it goes into your shoes and you think people must wonder why I've always got a small holdall thing in her car. It goes everywhere with me.'*

- 7.7 Some described less willingness to take part in family or social events because they did not want to offer an explanation about their decreased mobility.

*'I was invited to a wedding and I'm making sure I've got my crutches, rather than the chair because people then think you're rude.'*

*'You are a prisoner in your own body... you can't go places because you need the toilet.'*

- 7.8 friendships with someone who faced similar challenges was often easier than mixing with strangers and having to provide an explanation why they couldn't sit comfortably for extended periods, or having to account for impaired mobility. A number of women that we spoke to referred to loss that other women had experienced. They described feelings of guilt that their own circumstances did not seem so bad.

- 7.9 The effort of engaging in family/social activities often left some women having to contend with days of feeling exhausted;

*'[Family time]- It's my time back again and if it's a day that we have with [family] followed by two days in bed then that's what it's going to be.'*

*'People only saw the times when we turned up at Parliament and we would say, you know, you put your face on, you put your persona on, you put on your nice clothes- you're not in your pyjamas, you're not doing any of that stuff and people only see that. So, we can all project an image.'*

- 7.10 More positively, many spoke of the benefits of friends and family who provided 'a bridge' between pre-ill health and the present.

*'It's the only tiny, tiny good thing that's come out of it is individual friendships.'*

- 7.11 Loss of job and professional life was a significant blow for many women and came up time and time again;

*'...to get my dream job and suddenly have that taken away from me. It left me just feeling really angry and I still have that. I just miss it so much.'*

*'I can't walk and yet my career is the one thing whenever I talk about it I end up crying and [a friend said] "You've adapted. Basically, you can still go and see your Mum but you drive instead of walking, but your career was ripped away from you and you were never able to go back".'*

7.12 Part of this was also the impact on their financial independence;

*'I'm going to be 60 next January and I'd have thought that I'd still be working and building up for retirement as opposed to getting out early with very little pension... In fact, I've spent my pension to pay for the translabial scan.'*

### Support and Management of emotional wellbeing

7.13 Some of the women we spoke to are now reaching a point in their clinical care where they are being advised that there is nothing else that can be done for them surgically, or if a revision surgery is performed then this may result in a return or increase of previous symptoms.

*'It would appear in my case removal will worsen my situation almost definitely and my best bet is just to learn to live this way.'*

*'I am feeling a little lost if I am honest. What a mess and what I would truly give for a time machine.'*

*'I have to accept that this is what my life is like now and move on'. ...It has been a rollercoaster of physical pain and emotional pain and I think sometimes we can deal with the physical pain to a degree but the emotional pain takes a lot longer to heal.'*

7.14 Such acute accounts concerning a loss of identity is, regrettably, not a new or unique phenomenon, and experiences of those suffering and living with a chronic illness have been well documented elsewhere and for many decades

now.<sup>178</sup> Recent and more specific studies have drawn attention to the experiences that women have reported following mesh surgery.<sup>179 180</sup>

- 7.15 Understanding and acknowledging such loss should inform conversations around availability and nature of support to work with women to try and help them re-establish what they consider to be an acceptable quality of life. Emotional support needs to be provided to help develop and readjust to a different sense of self. Some of the participants had or were receiving emotional support through psychological counselling. All believed that whilst not always emotionally easy, engaging in counselling had been beneficial.

## Insomnia

- 7.16 Nearly all of the women we spoke to described having trouble sleeping.<sup>181</sup> The extent and reasons for this varied significantly. One participant described that she usually did not sleep at all throughout the night until dawn brought some relief and ability to sleep. Others spoke of a number of women reaching out to each other on email providing a support network throughout the night. The administrator and I regularly received emails from participants that were sent in the small hours of the night.

## Weight management

- 7.17 Matters relating to weight management and support arose in two contexts. The first was in relation to whether or not a woman should have been offered transvaginal mesh surgery if she had a raised body mass index (BMI). The Panel are unaware of any current literature which indicates that weight is either a contraindication or may contribute to a poorer outcome. We observed that a

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<sup>178</sup> For example, a thoughtful overview is broken down into themes by Charmaz, K., (1983) Loss of self: a fundamental form of suffering in the chronically ill. *Sociology of Health and Illness* Vol. 5 No. 2 PP168-195

<sup>179</sup> Cumberledge Report at p.4.

<sup>180</sup> Toyne,F, Izett-Kay, Barker, KL and McNiven, A (2023) The experience of women reporting damage from vaginal mesh: a reflexive thematic analysis. *The Lancet* Available from: <https://www.thelancet.com/action/showPdf?pii=S2589-5370%2823%2900095-0> [Accessed April 4 2023]

<sup>181</sup> See for example, Toyne,F, Izett-Kay, Barker, KL and McNiven, A (2023) The experience of women reporting damage from vaginal mesh: a reflexive thematic analysis. *The Lancet* Available from: <https://www.thelancet.com/action/showPdf?pii=S2589-5370%2823%2900095-0> [Accessed April 4 2023] at p.4

study in 2020<sup>182</sup> to evaluate guidelines on the use of vaginal mesh implants, found that only two guidelines recommended weight loss.<sup>183</sup>

- 7.18 Two participants discussed whether they should have received mesh surgery given that they had a raised body mass index (BMI) at the time.
- 7.19 In the case records that the Panel reviewed, we saw no documentation of a specific discussion regarding weight management or support for women to lose weight prior to surgery. This is not to say that there may not be more general good reasons to offer weight management and support prior to any surgery taking place.<sup>184</sup> We did discuss as a Panel that it would generally be considered sensible advice to try and achieve as healthy a weight as possible prior to any major surgery because it reduced risks from the anaesthetic risk, clots and infection.
- 7.20 The second area referred to was management of weight post-surgery. All but one of the participants spoke about having reduced mobility although the extent of this varied significantly. For some, this impeded the ability to exercise as they had done previously and for others, the issue was about the impact that increase in weight had on their self-esteem and wellbeing. A number of women felt that they would benefit from exercise and dietary support and advice.

## Pain

- 7.21 There is extensive literature<sup>185</sup> providing clinical accounts for the potential causes of pain following mesh including alternative surgery for vaginal prolapse.<sup>186</sup> For the purposes of this Report, the focus will be on how the participants described their pain to us, their experiences of the communication and management of their pain.
- 7.22 All 19 participants spoke of experiencing pain. Some described pain in a specific area of their body - such as their groin, hips, pelvis. Others reported

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<sup>182</sup> Siapakidou, S., Campani – Nygaard, C Pape J, *et al* (2021) Evaluation of guidelines on the use of vaginal mesh implants for pelvic organ prolapse using the AGREE II instrument. *Int J Gynecol Obstet.* 154:400–411

<sup>183</sup> These were The Association of the Scientific Medical Societies in Germany and European Association of Urology.

<sup>184</sup> For example, risks associated with anaesthesia or more generally associated surgical risks.

<sup>185</sup> Shi C, Zhao Y, Hu Q, Gong R, Yin Y, Xia Z. (2021) Clinical analysis of pain after transvaginal mesh surgery in patients with pelvic organ prolapse. *BMC Women's Health.* Jan 30;21(1):46. Available from: [doi: 10.1186/s12905-021-01192-w](https://doi.org/10.1186/s12905-021-01192-w). PMID: 33516228; PMCID: PMC7847570. [Accessed April 24 2023]

<sup>186</sup> Reid, F.M., Aucott, L., Glazener, C.M.A. *et al.* (2023) PROSPECT: 4- and 6-year follow-up of a randomised trial of surgery for vaginal prolapse. *Int Urogynecol J* **34**, 67–78. Available from: <https://doi.org/10.1007/s00192-022-05308-0> [Accessed April 24 2023]



widespread pain and unexplained lethargy and some women were subsequently diagnosed with fibromyalgia.<sup>187</sup> The Panel note that a recent study from Kings College London, suggests that fibromyalgia is an autoimmune disorder<sup>188</sup> and that the National Institute for Clinical Excellence (NICE) recognises fibromyalgia as a potential complication following mesh surgery.<sup>189</sup>

- 7.23 Some pain was acute (lasting less than 12 weeks), and some was chronic (lasting more than 12 weeks). The pattern of the pain also varied, with some women describing continuous pain and some describing intermittent pain. The nature of the pain also varied, with some reporting the pain as ‘*sharp*’, or ‘*stabbing*’.

*‘My pain never goes. I’ve always got pain in my groin, in my back and nerve damage in my legs’.*

- 7.24 Women spoke of their difficulty in processing and recollecting information, attributing it to the side effects of the pain medications that they were taking. The consequences and effects of the medications were often distressing and disruptive to daily life.

*‘You can imagine how I struggle having to take morphine. I don’t want to live on opiates. It’s poison at the end of the day.’*

- 7.25 Many expressed a keenness to keep the use of medication to a minimum where possible. Others spoke of being proud and an appreciation of their circumstances if they had been able to achieve this.

*‘I hate taking painkillers or anything like that. The fact that I was on this long term that was getting into my head as well and I didn’t want to be taking this for the rest of my life. I managed to wean myself off the Oxycodone over a matter of a few months but I still had to keep the other stuff going until I had the*

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<sup>187</sup> ‘Fibromyalgia is a condition that causes widespread pain and extreme tiredness. There is no cure and symptoms can vary from person to person. It’s not clear what causes fibromyalgia. It can start after a stressful event like an injury, illness or the death of a loved one.’ NHS UK – Available from: <https://www.nhs.uk/conditions/fibromyalgia/#overview> [Accessed 6 April 2023]

<sup>188</sup> Kings College News Centre (2021) *New study shows Fibromyalgia likely the result of autoimmune problems* Available from: <https://www.kcl.ac.uk/news/new-study-shows-fibromyalgia-likely-the-result-of-autoimmune-problems> [Accessed June 9 2023]

<sup>189</sup> National Institute for Clinical Excellence (NICE), (2021) *Treating complications from mesh used for stress urinary incontinence, Options for women referred to specialist centres, Patient decision aid.* Available from: <https://www.nice.org.uk/guidance/ng123/resources/treating-complications-from-mesh-used-for-stress-urinary-incontinence-options-for-women-referred-to-specialist-centres-patient-decision-aid-pdf-6725286117?fbclid=IwAR0aCXrorVkJXTvzJttOtid2zNzBg7U4uGLWjymIXTgkudQd1VKquW0Au4k> [Accessed June 9 2023]

*operation and then I managed, through the Pain Clinic, to get off the Pregabalin so I'm back to no painkillers now!*

- 7.26 Pain permeated into all aspects of the participant's lives. Looking to the future, one participant explained;

*'[t]hat's the main goal - to have some form of life without too much pain.'*

- 7.27 The management of acute and chronic pain differ. Chronic pain is defined as pain that carries on for longer than 12 weeks despite medication or treatment.<sup>190</sup> Acute pain tends to be of a shorter duration and as a result of a trauma, for example, surgery or injury, and is sometimes defined as a warning of disease. Regardless of whether the pain is acute or chronic, there is extensive literature about the importance of the healthcare professional acknowledging and accepting that the patient is in pain.<sup>191</sup> <sup>192</sup> It is widely recognised that patients respond better to care and treatments if they feel believed and validated.<sup>193</sup> <sup>194</sup>
- 7.28 As we have noted already, women we spoke to, did not feel believed or validated. But it was broader than that, -they were frustrated, angry and despondent because they felt that the cause of their pain had not been resolved. On reviewing participant records, in the majority of cases, the Panel observed that participants had often undergone numerous appointments and investigations, but that often these had been inconclusive, and although treatments had been tried, their pain continued unresolved leaving participants uncertain and confused.
- 7.29 The Panel recognised that impact of loss of trust had negatively impacted on the perception of whether or not their pain was being taken seriously. The

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<sup>190</sup> NHS Inform (2022) Chronic Pain. Available from: <https://www.nhsinform.scot/illnesses-and-conditions/brain-nerves-and-spinal-cord/chronic-pain> [Accessed April 24 2023]

<sup>191</sup> Waybe G., (2023) Acute Pain Nursing care plan. Nurses Labs. Available from: <https://nurseslabs.com/acute-pain/> [Accessed April 24 2023]

<sup>192</sup> Sullivan M, Ferrell B. (2005) Ethical challenges in the management of chronic nonmalignant pain: Negotiating through the cloud of doubt. *J Pain* ;6(1):2–9. 10.1016 Available from: [/j.jpain.2004.10.006](https://doi.org/10.1006/j.jpain.2004.10.006) [Accessed April 24 2023]

<sup>193</sup> Henry SG, Matthias MS. (2018) Patient-Clinician Communication About Pain: A Conceptual Model and Narrative Review. *Pain Med.* Nov 1;19(11):2154-2165. Available from: [10.1093/pm/pny003](https://doi.org/10.1093/pm/pny003). PMID: 29401356; PMCID: PMC6454797 [Accessed April 24 2023]

<sup>194</sup> P. Mistiaen, M. van Osch, L. van Vliet, J. Howick, et al (2015) The effect of patient–practitioner communication on pain: a systematic review. *European Journal of Pain.* Available from: <https://onlinelibrary.wiley.com/doi/full/10.1002/ejp.797> [Accessed June 8 2023]



Panel also recognised that a lack understanding of why investigations were being done, or treatments were being tried, would also contribute to this perception. Communication could be improved in this regard. This will be discussed in Chapter 8 of this Report.

### Recognised Diagnostic Challenges

- 7.30 The Panel are aware that of the 18 women who had their case records reviewed, stress incontinence was often only one of several urogynaecological issues that the participants were suffering from. It was often difficult to disentangle these issues from our review of the case records, and indeed the Panel recognised that they can be difficult to disentangle in real life too, for example when seen in a specialist clinic. In addition to urogynaecological problems, many of the participants also experienced symptoms in other parts of their body, and sometimes across their whole body. The Panel recognised that it is not always possible to make a conclusive diagnosis of what is causing more generic symptoms, such as pain, and, as has just been discussed above in this chapter, this can cause acute distress and frustration for patients.
- 7.31 All surgery will produce scarring as part of the recovery process, and this can cause a degree of nerve pain, which will normally resolve over time. The critical question, is how much above and beyond the normal scarring process does the insertion of foreign material into the body either accelerate or cause those nerve pain symptoms? It is not known. A second point is whether there are any patient groups that would retrospectively suggest a higher susceptibility to adverse outcomes in terms of pre-existing conditions? The Panel recognise that further research is needed in this area.<sup>195</sup>

### Member of a mesh support group/organisation

- 7.32 About three quarters of the women we spoke to had some form of association with a mesh support group;<sup>196</sup> the nature and extent of that association varied from person to person. Two women asked us if their case records specifically indicated that they had such an association. On the case records made available to us for each of these women, both sets of records did note an association.

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<sup>195</sup> The Panel are aware that research is ongoing into issues such as the role of vaginal microbiomes and whether vaginal preparation at the time of surgery influences post-operative complications.

<sup>196</sup> The most common association was with the Scottish Mesh Survivors. See: <http://www.scottishmeshsurvivors.com/>

## Chapter 8 - Communication, Clarity of Language, and the Process of Information Disclosure and Consent

### Introduction

8.1 The importance of communication which is accurate, transparent and understood is the foundation of good clinical care. It applies to a broad range of situations including a common understanding in the use of language and terminology. It also applies to the giving or withholding of consent by people being offered care. Patients expect and are entitled to receive information about their clinical care and can only make an informed decision if they have sufficient information regarding their treatment, any alternatives, and potential risks. They are also entitled to access information that is stored about them in their clinical case records.<sup>197</sup> How to achieve this, and many other aspects of good communication, is not without its challenges and guidelines can be found both within clinical professional guidelines and the law. This chapter will consider some of these, first more generally, and then specifically in relation to the Panel's observations and findings following our review of case records.

### Clarity of language

8.2 The importance and benefits of using clear and understandable language between a clinician and their patient are well documented.<sup>198 199</sup> NHS Scotland has produced a Health Literacy Action Plan for Scotland.<sup>200</sup>

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<sup>197</sup> This aspect has been addressed in Chapters 2-5 of Part I of this Report.

<sup>198</sup> Atreja, A., Bellham N., Levy S., (2005) Strategies to Enhance Patient Adherence: Making it Simple *MedGenMed*. 7(1): 4. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1681370/> [Accessed April 11 2013]

<sup>199</sup> The Health Literacy place. *Use Simple Language*. Available from: <https://www.healthliteracyplace.org.uk/toolkit/techniques/use-simple-language/> [Accessed April 11 2023]

<sup>200</sup> NHS Scotland (2016) Making it Easier A Health Literacy Action Plan for Scotland. Available from: <https://www.gov.scot/binaries/content/documents/govscot/publications/strategy-plan/2017/11/making-easier-health-literacy-action-plan-scotland-2017-2025/documents/00528139-pdf/00528139-pdf/govscot%3Adocument/00528139.pdf> [Accessed April 11 2023]

8.3 Literature suggests that a significant number of patients leave a consultation unclear as to what has been discussed.<sup>201 202</sup> It has been generally recognised by medical and nursing Royal Colleges and other health professional bodies that the use of medical ‘jargon’ may be both confusing and unhelpful<sup>203</sup> and that the use and understanding of a term by a healthcare professional may not be how it is understood by a lay person. The Royal College of GP’s undertook a study in 2014 noting that,

*“Doctors can unintentionally use words that are unfamiliar to their patients, without realising that the meaning is not clear. Some concepts familiar and obvious to doctors may be alien to patients.”*<sup>204</sup>

8.4 This Report has already considered the impact of the loss of trust and how it pervaded so many aspects of the participant’s healthcare and experiences. Since we recognised this, the Panel sought to understand ways in which trust could be re-established. We believe that precise and commonly understood usage of language is imperative. When reviewing the case records, the Panel considered whether what we agreed would be commonly understood usage of language had, in fact, been used.<sup>205</sup> There were a number of matters which arose in the review of case records which were reliant on the use, clarity and understanding of language and the Report will consider each of these in the chronology in which they occurred.

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<sup>201</sup> Atreja, A., Bellham N., Levy S., (2005) Strategies to Enhance Patient Adherence: Making it Simple *MedGenMed.* 7(1): 4. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1681370/> [Accessed April 11 2013]

<sup>202</sup> Richard C., Glaser E., Lussier MT 2016) Communication and patient participation influencing patient recall of treatment discussion. *Health Expectations* 20 4 760-770. Available from: <https://onlinelibrary.wiley.com/doi/full/10.1111/hex.12515> [Accessed April 11 2023]

<sup>203</sup> Available from: Royal College of General Practitioners. Health literacy: report from an RCGP led health literacy workshop. June 2014.

<sup>204</sup> The Royal College of GP’s undertook a study in 2014 noting that, “Doctors can unintentionally use words that are unfamiliar to their patients, without realising that the meaning is not clear. Some concepts familiar and obvious to doctors may be alien to patients.” Available from: Royal College of General Practitioners. Health literacy: report from an RCGP led health literacy workshop. June 2014.

<sup>205</sup> Rimmer A (2014). Doctors must avoid jargon when talking to patients, royal college says. *BMJ* available from: <https://www.bmj.com/content/348/bmj.g4131> [Accessed April 11 2023] “Doctors may use familiar words in unfamiliar ways,” it said. “For example, when health practitioners use the term ‘chronic’ they frequently mean ‘persistent,’ whereas a common alternative understanding of the word is to mean ‘severe.’”

## Pre-surgery communication

### *Terminology regarding TVT and TVT-O*

- 8.5 The Panel observed two issues here: firstly, how the mesh devices themselves are defined, and secondly, how they are defined and explained to patients by their clinician.
- 8.6 With regard to the first, if patients are to receive a polypropylene mesh device – they will receive one of two types, both of which were previously commonly used to treat urinary incontinence. Both are very similar in their name, but have important differences in terms of how they are surgically placed. One is a Tension Free Vaginal Tape (TVT), the other is a Tension Free Vaginal Tape – Obturator<sup>206</sup> (TVT-O). Both types became widely available as commercially produced kits<sup>207</sup> and were named and defined by the industry<sup>208</sup> that created them.
- 8.7 The surgery required to place these devices differ. The TVT requires two small cuts in the lower abdomen above the pubic bone while the TVT-O requires two small cuts in the groin area. Hence the Panel recommends that the difference between these two procedures (and therefore their potential complications) needs to be made explicit during the consent process.
- 8.8 When we reviewed the case records, we observed in some cases that the counselling that a patient received prior to surgery used these nomenclatures interchangeably, which was incorrect and created confusion. Given the difference in surgical procedures and the risk attached to each, clear and unambiguous counselling should have been given regarding the difference in these devices and the nature of the surgery that is required to implant them.
- 8.9 The second issue is the reference<sup>209</sup> to the devices being both referred to as a ‘tape’ and a ‘mesh’. Part of this can be explained because ‘tape’ was part of the

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<sup>206</sup> The obturator nerve is in the groin. It enables sensation and muscle movement in the inner thigh.

<sup>207</sup> Rovner E, de Tayrac , R ., Kirschner-Hermanns, R (2020) Is polypropylene mesh material fundamentally safe for use as a reconstructive material in vaginal surgery: ICI-RS2019? *Neurourology and Urodynamics*. 2020;39:S132–S139. At p. 132 available from: <https://onlinelibrary.wiley.com/doi/epdf/10.1002/nau.24312> [Accessed 6 April 2023]

<sup>208</sup> Ross, S., Magali, R., Ducey, A ( 2015) The short life cycle of a surgical device – Literature analysis using McKinlay’s 7-stage model. *Health Policy and Technology*. 4 168-188 Available from: <https://reader.elsevier.com/reader/sd/pii/S2211883715000222?token=EA59CE6F15989E2F94CE9F9EC11876B6BA18708C0A450D6B6B546C2AFB91EEC7CD996D793EBE319D347851048E7E3CD2&originRegion=eu-west-1&originCreation=20230406133908> [Accessed April 6 2023]

<sup>209</sup> This is considered further in the ‘gold standard’ section below

name given to these devices by the industry who created them (transvaginal tape or transvaginal obturator tape) so clinicians may have been more familiar with that term. However, this matter highlights the importance of language, and how it would most usually be understood in common parlance. When described to them, women spoke of hearing the word ‘tape’ and visualising something completely different; *‘a wee bit of tape didn’t sound too bad’* and did not associate what was being described to them as polypropylene mesh device. They were not informed of the size the device.<sup>210</sup> Significantly, only one of the women was told that this was a device which was designed to be permanent and not to be removed.

- 8.10 One woman spoke of having a ‘*procedure*’ with no explanation that this involved any form of implanted device.

*‘I thought I was having a procedure and not an implant. I never got anything that said that this was a permanent implant. I always thought that it was a procedure like vaginal reconstruction.’*

- 8.11 None of the women involved in this Case Record Review were shown an example of the device that was going to be used. The Panel recognise that many women would want to visualise the device that is going to be inserted and the ‘feel’ of the mesh, and that they should be offered the opportunity to see it prior to surgery.

#### *The ‘gold standard’*

- 8.12 All of the participants in this Review reported having urinary incontinence.<sup>211</sup> 16 out of the 19 women we spoke to said that mesh surgery was described to them as the ‘*gold standard*’ treatment which would alleviate their symptoms. One lady said it was described to her a ‘*miracle cure*.’ Women were advised that a significant benefit of this type of surgery was a significantly reduced time in hospital (from a couple of weeks with previous ‘gold standard’ and more complex colposuspension surgery, to having their surgery as a day-case procedure). For those with family and work commitments, as all of our participants had – this was, understandably, a very attractive option.

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<sup>210</sup> Although the length of the mesh to be used in surgery is standard, the length of the mesh inserted into the patient ultimately depends on the patient anatomy, as it will be ‘cut to fit’.

<sup>211</sup> This has been defined as the involuntary leakage of urine in an inappropriate place and time. Javanmardifard, S., Gheibizadeh M., Shirazi, F., Kourosh Z, Ghodsbin, F (2022) Experiences of Urinary Incontinence Management in Older Women: A Qualitative Study, *Public Health* Available from: <https://doi.org/10.3389/fpubh.2021.738202> [Accessed April 5 2023]

*'It's such a minimal thing. You know, it's literally the choice of the burch<sup>212</sup> which was going to keep me off work for 6 weeks. I had newly qualified.'*

*'I was told it would be really quick. It would be between 20 minutes and half an hour and how it would improve my quality of life. I was told it was the Gold Standard procedure. [The surgeon] really sold it to me because I remember going home and saying to myself this sounds absolutely amazing.'*

8.13 So why was this procedure described in such terms? The answer may lie in that not only was the early information that was given to patients largely informed and written by the industry that created the device, but critically, it was described using only positive language. This was because there appears to be no requirement for the information to be explicit regarding disclosure of potential risks.

*'Pharmaceutical manufacturers must include clinical trial evidence, including risks, on the Summary of Product Characteristics (SmPC). Yet there is no specification that device manufacturers need disclose all risks in corresponding Information for Use (IFU) leaflets.'*<sup>213</sup>

8.14 The term 'gold standard' was quickly in common usage, to such an extent that it features as part of the titles in clinical and legal research<sup>214</sup> and can be seen in countless others within the body of their texts.

## Mesh revision surgery

8.15 We have used the term 'mesh revision' both in our individual reports sent to participants and also in this Report. We use it to describe any surgery to repair, or to remove, part or whole of the mesh device.

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<sup>212</sup> A Burch procedure suspends and stabilizes the urethra (the tube carrying urine from the bladder to the outside of the body). The urethra is stabilized by using permanent sutures to connect the tissues surrounding the urethra to a strong ligament attached to the pubic bone.

<sup>213</sup> O'Neill, J. (2021) Lessons from the vaginal mesh scandal: enhancing the patient-centric approach to informed consent for medical device implantation. *International Journal of Technology Assessment in Health Care*, 37(1), at p. 2 Available from: <https://www.cambridge.org/core/services/aop-cambridge-core/content/view/85C4A34DE54AB3476217FB524B0310C9/S0266462321000258a.pdf/lessons-from-the-vaginal-mesh-scandal-enhancing-the-patient-centric-approach-to-informed-consent-for-medical-device-implantation.pdf> [Accessed April 11 2023]

<sup>214</sup> For example, Marks, B Goldman H (2012) What is the gold standard for posterior vaginal wall prolapse repair: mesh or native tissue? *Curr Urol Rep.* 13(3):216-21. Available from: [doi: 10.1007/s11934-012-0248-y](https://doi.org/10.1007/s11934-012-0248-y). [Accessed April 6 2023] or, Webber-Brown, C (2015) England's 'gold standard' TVT device - how safe is it? Available from: <https://www.lexology.com/library/detail.aspx?g=b8f28eff-0f32-46dc-a55b-ddd867d65389> [Accessed April 6 2023]



- 8.16 If a case record documents that there was a ‘complete’ removal of mesh, or that mesh was removed in its ‘entirety’, to a lay person (and to most clinicians) this, not unreasonably, would be understood as total removal. That is to say all of it has been removed. From a specialist clinical perspective, the Panel recognise that the language may not necessarily mean the same thing. This may depend on the type and extent of surgery undertaken. If a vaginal-only procedure is performed, only the vaginal or sub urethral portion of the mesh can be removed.<sup>215</sup> If the surgical procedure has not involved groin incision or dissection, then no part of the groin portion has been or can be removed.
- 8.17 The Panel found that in some cases, there was a significant confusion, misunderstanding or inaccuracy in terms of what was documented in the case records and what the women (and some of their clinicians) understood. The women were expecting an outcome which could never have resulted from the type of surgical procedure which was, in fact, undertaken. Again, it is worth reiterating that the Panel only had access to what is written in the case records which may exclude aspects of verbal communication.

*‘[On telling a friend], I’ve had a full removal and she said have you got groin incisions? She said let me see and she said that’s not full removal... and she asked if I had any pictures and I sent her a picture. It was confirmed that I had a partial[removal] and my world just fell.’*

- 8.18 The type of surgery to be undertaken has to be made explicit to the patient in any procedure undertaken. Failing to do this mean that the patient does not have all of the material information and therefore cannot make a fully informed decision regarding whether or not to agree to the type of surgery being proposed.
- 8.19 We are aware that we have said this throughout this Report but it bears repeating - a further consequence of a failure to clearly communicate is the impact that this will have on the patient-clinician relationship. Trust may be diminished or eroded altogether. It is vital to be clear from the outset about what the patient should expect following a surgical procedure and that they are informed, as soon as possible following the surgery, of its outcome. If the patient is left uncertain, they may subsequently turn elsewhere for information for example, to social media, to other women who have had the surgery, or to established support groups. Although the Panel recognised the significant support that these options can potentially bring, we cannot underestimate the lasting impact of the erosion of trust or the patient’s willingness to engage in the future with healthcare, should they then experience adverse outcomes. This

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<sup>215</sup> With the exception if the mesh was infected.

results in patients not being given the opportunity to discuss the medical, surgical or psychological treatments that are available to help them.

- 8.20 Some of the case records documented discussions where the participant was advised it was not possible to remove all of the mesh. We reviewed a case record which stated that it *'cannot be guaranteed to obtain a 100% removal'*. This is not correct. Whilst the mesh revision surgery may not be without challenge, it is not accurate to say that the totality of the mesh cannot be removed.
- 8.21 Some records provided more of a mixed message noting discussions and counselling with the patient that they would undergo a 'total' removal of mesh, with subsequent documentation in the operation note that 'most' of the mesh had in fact been removed or 'as much as was possible' of the mesh had been removed.

*'Every time I saw [the surgeon] who said "Well, I'm not really sure how much is left". I said "My discharge letter says about 1 mm" and [the surgeon] said "Well, no. We had 6 cm from your right side and 4 cm from your left".'*

- 8.22 One participant recalled waking up from the anaesthetic, and seeing the surgeon giving them a *'thumbs up'*, and saying that it had *'all gone'*. In some cases, it was difficult to ascertain from participant's case records when exactly they subsequently became aware that all of their mesh had not been removed.
- 8.23 All of these women described their euphoria in believing that all their mesh had been removed, and their profound disbelief and dismay when they found that this was not in fact the case.
- 8.24 The Panel are in complete agreement that operation notes must exactly reflect the complexity and outcome of the surgery. If a dissection has been difficult there has to be absolute clarity about this in the surgical notes, even if that clarity involved uncertainty with regard to outcome. If it is stated in the surgical notes that there is confidence that all the mesh has been removed, then that must be accurate. If there is uncertainty, then that should be clearly documented too – and subsequently explained to the patient. It is not appropriate after reading the operation note to be left in any doubt as to what surgical procedure has taken place.

- 8.25 The Panel recommends that there needs to be a clear understanding and precision regarding the language used to describe the procedure being proposed. If there is discussion regarding a potential procedure to remove mesh, it has to be made explicit what type of surgery is to be undertaken and the proposed extent of what is going to be removed.**



## Redacted materials

- 8.26 We have included the matter regarding redacted materials in this section because correspondence that is redacted affects the quality of communication that passes between a patient and their healthcare provider. More specifically, in this piece of work, the quality of the information that passes between the data guardians (the organisations holding the medical records, be they Health Board or general practices) and the Panel undertaking the case record review. Whilst an individual's case record will predominately be about them, it is likely to comprise other personal data too. For example, it may contain the names of the clinicians providing their care, and it may contain the names of third parties in their personal life.
- 8.27 In practice, redaction usually means that information has been blacked out or removed from a case record. Traditionally this is done manually by a member of the care team, based on judgement of what is appropriate to remove, but it can also be performed using software packages. Redaction is used to remove identifying information that relates to third parties, or to remove information which could cause 'serious harm' to the mental or physical health<sup>216</sup> of the individual to whom the records apply or others,<sup>217</sup> if it were disclosed. The Data Protection Act provides an assumption of 'reasonableness' in relation to disclosure when the third party is the patient's clinician (i.e., this information would normally be made available) otherwise 'reasonableness' remains to be decided on a case by case basis when it refers to other third parties.
- 8.28 Professional organisations acknowledge that identifying which third party information should be removed, and how much information should be subject to redaction, can be challenging:

*'The extent of redaction will depend on who has asked for the records, who the third party is, and where that information came from.'*<sup>218</sup>

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<sup>216</sup> Data Protection Act 2018. Access can be limited or denied if it would be 'likely to cause serious harm to the physical or mental health of the data subject or another individual', unless it is information of which the patient is already aware.

<sup>217</sup> Each case needs to be considered individually and the Information Commissioner's Office (ICO) provides guidance on this. Available from: <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/right-of-access/information-about-other-individuals/> [Accessed April 20 2023]

<sup>218</sup> Medical Defence Union (2022) Redacting Third Part Information from Notes. Available from: <https://www.themdu.com/guidance-and-advice/guides/redacting-third-party-information-from-notes#:~:text=Redaction%20should%20be%20considered%20for,be%20removed%20can%20be%20difficult.> [Accessed April 20 2023]

- 8.29 There is no established standard or guidance for removing third party information and every person approaches this process differently. The provisions of the Data Protection Act 2018, leaving it up to each organisation to come to a decision.
- 8.30 Some participants described to us that they had requested information regarding their care and treatment and of then subsequently receiving correspondence which had been significantly redacted. Some of the women provided examples of these for the Panel and we agreed that the redactions had indeed been significant. The redactions were not confined to one or two sentences, but in some cases entire paragraphs had been blacked out. Women described feeling confused and upset as to why this had occurred. The Panel are of the view that withholding information, regardless of how valid a reason to do so, without explicit explanation will leave a cloud that something is hidden.

**8.31 The Panel recommends that, if requested by the patient, the organisation provides an explanation to the patient (or person authorised by the patient to request it on their behalf), why certain information has been redacted.**

## Consent - the legal landscape

- 8.32 The development of the case law in the area of consent and information disclosure has been a long slow burn dating from the mid-1950s<sup>219</sup> where legal tests<sup>220 221</sup> relied on 'reasonableness' to define the both the duty and standard of care that a healthcare professional owed to their patient. Initially the courts afforded a huge amount of latitude to the medical profession to decide exactly what this standard was.

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<sup>219</sup> *Hunter V Hanley* 1955 SC 200 and *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582

<sup>220</sup> *Hunter V Hanley* 1955 SC 200. In order to establish liability in circumstances where deviation from normal practice is alleged, three facts have to be established: It must be proved that there is a usual and normal practice; It must be proved that the defender has not adopted that practice; and Most importantly, it must be established that the course the professional had adopted is one which no professional person of ordinary skill would have taken if he/she had been acting with ordinary care. The onus rests on a pursuer to establish these three facts, and without all three his case will fail.

<sup>221</sup> *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582. The judge noted, "I myself would prefer to put it this way, that he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art." McNair J.

- 8.33 In the 1990s this started to change through a series of cases which not only saw the courts claim their right<sup>222</sup> to determine the standard of care but also acknowledge human rights<sup>223</sup> and the ‘autonomous’ individual. The legal axis moved away from the reasonable professional determination of what a patient should be told, to what the reasonable patient had a right to know.<sup>224</sup>
- 8.34 This gradual movement culminated in the case of *Montgomery*<sup>225</sup> in 2015 which swept away any previous legal determination of what constituted information disclosure. A test of ‘materiality’<sup>226 227</sup> replaced it, focussing on that particular, individual patient and what they would want to know. In other words, what is important to the particular patient in terms of investigations, treatments, including alternatives and importantly, an explanation of the likelihood of the risk of complications.
- 8.35 The consequences of this shift have been far-reaching. Literature suggests that while the rate of increase of other clinical negligence claims has remained steady, cases relating to consent have risen four times as fast since the *Montgomery* decision and where failure to inform was added as a contributory claim, the rise was nearly ten-fold.<sup>228</sup>
- 8.36 It has a significant impact on financial cost to the NHS. A study considered costs for the four-year period before and after the *Montgomery* case, which concluded that NHS (England) costs due to settled claims for failure to inform increased from £25 million/year to £28 million/year and in the subsequent

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<sup>222</sup> *Bolitho v. City and Hackney Health Authority* [1996] 4 All ER 771 established that a court is not bound to hold that a doctor can escape liability for negligence simply by producing evidence from a number of experts that his opinion and actions accorded with accepted medical practice.

<sup>223</sup> *YF v Turkey* ECHR 22 Jul 2003

<sup>224</sup> *Chester v Afshar* [2004] 3 WLR 927

<sup>225</sup> *Montgomery v Lanarkshire Health Board* [2015] UKSC 11. The test of ‘materiality’ was created.

<sup>226</sup> A doctor was now “under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative treatments “. The test of materiality was described as “whether in the circumstances of the particular case, a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor is or should be aware that the particular patient would be likely to attach significance to it “.

<sup>227</sup> A subsequent case provided context as to the nature and duty if this test- *Duce v Worcestershire Acute Hospitals NHS Trust* [2018] EWCA Civ 1307 at para 33- 1. what risks associated with an operation were or should have been known to the medical professional in question. This is a matter falling within the expertise of the medical professionals; and 2, Whether the patient should have been told about such risks by reference to whether they were material. This is a matter for the Court to determine. The issue is not therefore the subject of the *Bolam* test and not something that can be determined by reference to expert evidence alone.

<sup>228</sup> Wald, DS., Bestwick, JP, Kelly, P (2020) The effect of the Montgomery judgment on settled claims against the National Health Service due to failure to inform before giving consent to treatment. *QJM: An International Journal of Medicine*, Volume 113, Issue 10, October 2020, Pages 721–725, at p. 721 Available from: <https://doi.org/10.1093/qjmed/hcaa082> [Accessed 8 June 2023]

4 years to £62 million/year.<sup>229</sup> The increase has not been due to an increase in the cost per claim, but due to the increase in the number of claims. The Royal College of Surgeons (England), in a press release considering the implications of the Montgomery case suggested that, NHS Litigation Authority,<sup>230</sup> paid out more than £1.4 billion in claims during 2015/16. This is an increase of approximately £320 million over the preceding year.<sup>231</sup> Whilst this is significant, a longer-term view will allow a fuller analysis to be undertaken in this regard.

8.37 In the meantime, the remedy is not simple and can be time-consuming. A signed consent form from a patient does not amount to valid consent for treatment and is not sufficient evidence of such in a court of law. Consent is a culmination of process comprising many strands, all of which require to be detailed within the case records. Language, as ever, is important, and it is wrong to speak of the patient being ‘consented’ because it describes something being *done* to the patient as opposed to a decision taken *by* the patient.<sup>232</sup>

8.38 One such solution is to ensure that contemporaneous medical notes and correspondence properly detail the informed consent process undertaken.<sup>233</sup> This has many advantages for both the clinician and for the patient. Should there be a need to review the case records, it would provide a record not only of the decision taken but how that decision was reached. Case records are at the heart of modern case law regarding information disclosure and the courts have questioned<sup>234</sup> how a clinician could confidently answer important

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<sup>229</sup> Wald, DS., Bestwick, JP, Kelly, P (2020) The effect of the Montgomery judgment on settled claims against the National Health Service due to failure to inform before giving consent to treatment. *QJM: An International Journal of Medicine*, Volume 113, Issue 10, October 2020, Pages 721–725, at p. 721 <https://doi.org/10.1093/qjmed/hcaa082> [Accessed 8 June 2023]

<sup>230</sup> The body which handles clinical negligence claims against NHS trusts.

<sup>231</sup> Royal College of Surgeons(England), (2016) *Surgeons warn NHS failing to implement patient consent rules, risks facing increase in litigation pay-outs* Available from: <https://www.rcseng.ac.uk/news-and-events/media-centre/press-releases/surgeons-warn-nhs-failing-to-implement-patient-consent-rules/> [Accessed April 15 2023]

<sup>232</sup> Choudry M, Latif A, Hamilton L *et al* (2016) (Documenting the process of patient decision making: a review of the development of the law on consent. *Future Hosp J.* Jun;3(2):109-113. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6465837/> [Accessed April 15 2023]

<sup>233</sup> Godfrey, J (2020) The Odyssey of Informed Consent Post Montgomery – Have We Reached Ithaca? *Medico Legal magazine*. Available from: <https://www.medicolegalmagazine.co.uk/all-medico-legal-magazine-articles/the-odyssey-of-informed-consent-post-montgomery-have-we-reached-ithaca> [Accessed April 14 2023]

<sup>234</sup> *Malik v St George’s University Hospital NHS Foundation Trust* [2021] EWHC 1913 (QB), the clinician concerned did not keep handwritten notes or typed notes of the consent consultation. HHJ Blair QC commented that: “this is a practice which it seems to me is fraught with risks of being unable confidently to answer important questions many years later without having the benefit of a contemporaneous set of detailed notes”.

questions, often many years later, without having the benefit of a contemporaneous set of detailed notes.

- 8.39 Keeping a detailed set of medical notes of the dialogue, including what leaflets were given (and including a copy of these in the records), what counselling and advice was given about the procedure, and which risks and potential complications were discussed that led to an informed decision being made. This should then be replicated in a letter to the patient and copied to the patient's GP. The Panel are aware that this is an approach which has already been supported by professional bodies and in their guidelines, and is being increasingly adopted in clinics, Trusts and Boards.<sup>235</sup>

**8.40 The Panel recommend keeping a detailed set of medical notes of the dialogue, including what leaflets were given (and including a copy of these in the records), what counselling and advice was given about the procedure, and which risks and potential complications were discussed that led to an informed decision being made. This should then be replicated in a letter to the patient and copied to the patient's GP.**

### Professional Guidelines

- 8.41 The courts were not in isolation as movement towards a patient-centred practice had already started to occur pre-*Montgomery*. Following the legal outcome of the case, a number of organisations including the medical royal colleges updated their guidelines and information to reflect the judicial decision.<sup>236</sup>

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<sup>235</sup> The Royal College of Surgeons (England) note in addition to completing the consent form, surgeons should maintain a written decision making record that contains a contemporaneous documentation of the key points of the consent discussion – and the patient's decision, even if the patient decided not to undergo a procedure or have any treatment. This could be in the form of a letter to the patient and their GP/referring doctor. The record should also contain documentation of any discussion around consent with the patient's supporters and with colleagues. Any written information given to the patient should also be recorded and copies should be included in the patient's notes. Royal College of Surgeons (England) Consent: Supported Decision-Making A GUIDE TO GOOD PRACTICE at p.18 Available from: [file:///C:/Users/abri/Downloads/Consent\\_2016\\_combined%20P2.pdf](file:///C:/Users/abri/Downloads/Consent_2016_combined%20P2.pdf) [Accessed April 15 2023]

<sup>236</sup> See for example, Medical Defence Union, (2023) *Montgomery and Informed Consent*. Available from: <https://www.themdu.com/guidance-and-advice/guides/montgomery-and-informed-consent#:~:text=In%20its%20guidance%20Decision%20making,option%20to%20take%20no%20action.>; Medical Protection Society, (2017) *An Essential Guide to Consent*. Available from: <https://www.medicalprotection.org/uk/articles/an-mps-essential-guide-to-consent> [Accessed June 9 2023]

- 8.42 The Royal College of Physicians and Surgeons, Glasgow produced guidance which clearly acknowledges that signing a consent form is not enough and that ‘*consent is more than signature and more than a form.*’<sup>237</sup> It continues that: ‘*the only way to know what a patient wants is to talk to them, to ask them and, most importantly of all, to listen to them.*’<sup>238</sup>
- 8.43 There is recognition from the professional organisations and beyond that this requires additional work and time that, for clinicians, is already at a premium.<sup>239</sup> Whilst no healthcare practitioner is exempt from adhering to this professional and legal duty,<sup>240</sup> the challenges and impact cannot be underestimated and there is an extensive literature addressing this matter.<sup>241</sup> Constrained resources<sup>242</sup> and the impact of Covid -19 does nothing to relieve the pressure on healthcare professionals. Some of this may be tempered by the fact that the General Medical Council’s (GMC) patient-centred duty was in fact highlighted in *Montgomery* which cited passages from the GMC's 2008 and 2013 guidelines<sup>243</sup> indicating that patient-centred duties were already well embedded into professional guidelines. Even if professional duties were already there, it is recognised that they have been expanded.

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<sup>237</sup> Royal College of Physicians and Surgeons of Glasgow, Medical Consent, *More than a signature and more than a form*. Available from: <https://rcpsg.ac.uk/college/speaking-up-for-the-profession/policy-reports-and-publications/consent> [Accessed April 15 2023]

<sup>238</sup> Royal College of Physicians and Surgeons of Glasgow, Medical Consent, *More than a signature and more than a form*. Available from: <https://rcpsg.ac.uk/college/speaking-up-for-the-profession/policy-reports-and-publications/consent> [Accessed April 15 2023]

<sup>239</sup> The Royal College of Surgeons (England) Consent: Supported Decision-Making A GUIDE TO GOOD PRACTICE at p.18 Available from: [file:///C:/Users/abri/Downloads/Consent\\_2016\\_combined%20P2.pdf](file:///C:/Users/abri/Downloads/Consent_2016_combined%20P2.pdf) [Accessed April 15 2023]

<sup>240</sup> There is a debate about whether the legal and professional duties are or should be the same. There is no doubt that they have a highly influential effect upon each other. See, Le Gallez I, Skopek J, Liddell K *et al*, (2021) *Montgomery’s Practical and Legal Impact: A Systematic Review at 6 Years*. *J Eval Clin Pract*. 2022;28:690–702. At p.695. Available from: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/jep.13620> [Accessed April 15 2023]

<sup>241</sup> The literature is extensive representing the range of healthcare specialities. Nicholas M. The surgical care practitioner seeking consent: an appropriate delegate? *J Perioper Pract*. 2018;28(10):273-277; Edozien L. (2016) Special issue: patient consent after Montgomery. *Clin Risk*. 22 (1-2) pp 1-3. A systematic review is available from: Le Gallez I, Skopek J, Liddell K *et al*, (2021) *Montgomery’s Practical and Legal Impact: A Systematic Review at 6 Years*. *J Eval Clin Pract*. 2022;28:690–702. At p.695. Available from: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/jep.13620> [Accessed April 15 2023]

<sup>242</sup> Choudry M, Latif A, Hamilton L *et al* (2016) (Documenting the process of patient decision making: a review of the development of the law on consent. *Future Hosp J*. Jun;3(2):109-113. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6465837/> [Accessed April 15 2023]

<sup>243</sup> GMC (2008) (now withdrawn) *Consent; Patients and Doctors making decision together*. Available from: [https://www.gmc-uk.org/-/media/documents/consent-patients-and-doctors-making-decisions-together-2008---2020\\_pdf-84769495.pdf](https://www.gmc-uk.org/-/media/documents/consent-patients-and-doctors-making-decisions-together-2008---2020_pdf-84769495.pdf) [Accessed April 15 2023]



8.44 Following *Montgomery*, the GMC also issued new guidance to doctors entitled “Decision Making and Consent”,<sup>244</sup> replacing its guidance on consent last issued in 2008. The GMC note that the guidelines are framed around seven principles of decision-making and consent, namely: the process should: (i) be patient-centred; (ii) be based on meaningful dialogue specific to the individual patient; (iii) the patient has a right to be listened to and allowed the necessary time and information to reach a decision; (iv) share relevant information about the benefits and harms of proposed options and reasonable alternatives, including the option to take no action; (v) be offered to all patients, irrelevant of presumed capacity; (vi) advocate the patient’s best interest if they lack capacity; and (vii) patients whose right to consent is affected by law should be supported to be involved in the decision-making process, and to exercise choice if possible. There are clear echoes of *Montgomery* in the wording. The emphasis is clear in these guidelines, and with the others above, that the emphasis is on patient centred care and the principle of shared decision making. What does this mean in practice?

8.45 Patients medical records are discussed in section 50 of the GMC Guidance where it states:

*‘Keeping patients’ medical records up to date with key information is important for continuity of care. Keeping an accurate record of the exchange of information leading to a decision in a patient’s record will inform their future care and help you to explain and justify your decisions and actions.’*<sup>245</sup>

and continues in section 51 noting that:

*‘[Clinicians] should take a proportionate approach to the level of detail you record.’*<sup>246</sup> Good medical practice states that *you must include the decisions made and actions agreed - and who is making the decisions and agreeing the*

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<sup>244</sup> General medical Council (2020) Decision making and consent: Guidance on professional standards and ethics for doctors. Available from: [https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english\\_pdf-84191055.pdf](https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf). [Accessed April 15 2023]

<sup>245</sup> GMC (2020) Decision making and consent: Guidance on professional standards and ethics for doctors. Section 50 -Recording Decisions. Available from: <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent/recording-decisions> [Accessed June 9 2023]

<sup>246</sup> GMC (2020) Decision making and consent: Guidance on professional standards and ethics for doctors. Section 51 -Recording Decisions. Available from: <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent/recording-decisions> [Accessed June 9 2023]

*actions - in the patient's clinical records. This includes decisions to take no action.*<sup>247</sup>

## Consent and information disclosure - the approach of the Panel

8.46 The Panel also based our assessment of the consent process in each of the individual participant reports on the principles described in the GMC's "*Decision Making and Consent*" Guidelines (2020).<sup>248</sup> We adopted a chronological approach which encompassed the different strands of the consent process.

These included:

- Were conservative options and investigations exhausted prior to any discussion of surgical options?
- What options were discussed in terms of alternative treatments?
- What discussion was documented in relation to potential risks involved with surgery (if relevant) and at what stage were these added?
- Was there evidence of discussion and counselling documented in the case records?
- Was that supported with any written information, for example patient decision making aids?
- Who signed the consent form (if present), and when was it signed?
- Was there adequate time for the patient to reflect on the discussions, and the opportunity given to ask further questions between the initial discussion and signing the consent form?

8.47 We recognised that at the time that some of the earlier surgeries took place, it was common practice to use a 'generic' consent form that did not specifically have a section to document the risks and complications relating to the surgery. That is to say, the consent forms were not specifically written for the purpose of any particular surgical procedure and they lacked a specific space on the form to note the risks and possible complications. Consequently, there was a lot of variation in what was included on consent forms, with specific risks sometimes being added in a handwritten format. This does not mean that any discussion did or did not take place but it was difficult to ascertain what had been discussed. Consent forms have evolved considerably over time and post

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<sup>247</sup> GMC (2020) Decision making and consent: Guidance on professional standards and ethics for doctors. Section 51 -Recording Decisions. Available from: <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent/recording-decisions> [Accessed June 9 2023]

<sup>248</sup> General Medical Council (2020) Decision making and consent: Guidance on professional standards and ethics for doctors. Available from: [https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english\\_pdf-84191055.pdf](https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf). [Accessed April 15 2023]



the case of *Montgomery* and for the reasons described above, there is an increased use in procedure specific consent forms.

- 8.48 The majority of earlier cases that we reviewed contained generic consent forms. The Panel recognise that this would have been the standard consent form at that time and we saw from our own review of case records that later cases were beginning to document more detail regarding discussion potential alternative treatments and noted the occurrence of discussion and support pre-surgery. We found this to be encouraging in terms of improvement in practice with increasingly robust processes in place.
- 8.49 The Panel observed some recurring themes in relation to the consent process which will now be addressed.

*Patient Information Leaflets / Decision making aids- merits of having a version control.*

- 8.50 The benefits of having patient information leaflets, or decision-making aids, as a way of enhancing shared decision-making and enhancing patient understanding regarding the merits of proposed interventions is undisputed.<sup>249</sup> They should not be a substitute for dialogue and discussion<sup>250</sup> but serve to assist with recall regarding conversations that took place during a consultation.<sup>251</sup> They have also been shown to both improve adherence to treatments but conversely to play a role in deciding whether or not to undergo a treatment. So, whilst there is an underpinning agreement that such decision aids are a valuable part of the shared decision-making process, there is less consensus about what this means in terms of the information that such decision-making aids should contain.

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<sup>249</sup> Sustersic, M *et al*, (2017) How best to use and evaluate Patient Information Leaflets given during a consultation: a systematic review of literature reviews *Health Expect.*; 20(4): 531–542 at p 531. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5512995/> [Accessed February 5 2023]

<sup>250</sup> Horwitz A, Reuther L, Andersen SE. [Patient information leaflets seen through the eyes of patients in a general practice]. *Ugeskr Laeger*. 2009 Feb;171(8):599–602.

<sup>251</sup> Raynor DK, Blenkinsopp A, Knapp P, *et al*. A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines. *Health Technol Assess*. 2007;11:1–160 Available from: <https://pubmed.ncbi.nlm.nih.gov/17280623/> [Accessed 5 February 2023]

8.51 UK National Institute for Health and Care Excellence (NICE) recommend the use of high-quality patient decision aids in clinical practice.<sup>252</sup> <sup>253</sup> National Guidance<sup>254</sup> provides that the information contained in these leaflets should be updated to reflect evidence-based best practice.<sup>255</sup> Recognising the importance of having a systematic development process in place, The Cumberlege Report concluded that it;

*“sees no reason for there ever to be more than one collaboratively produced and agreed patient decision-making aid for each surgical procedure or medical intervention and that NICE should lead in facilitating that clinical consensus.”<sup>256</sup>*

8.52 The Panel are in full agreement with this and note that NICE published their patient decision aid- *Surgery for stress urinary incontinence – Patient decision aid*, in 2019.<sup>257</sup>

8.53 The Panel noted NICE did not include a version control element in their patient leaflets within this patient decision aid. Leaflets produced should contain the date when they were first written and then any subsequent revisions should result in a new version of the document being produced. This, in turn should be dated and numbered to reflect the version. This, in turn allows them to be accurately recorded in the case note, which version of a leaflet is given to the patient.

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<sup>252</sup> National Institute for Health and Care Excellence (NICE). Shared decision making: NICE Guideline. UK: NICE; 2021 17/06/2021. Available from: <https://www.nice.org.uk/guidance/ng197/resources/shared-decision-making-pdf-66142087186885> [Accessed 5 February 2023]

<sup>253</sup> Harris E, Conway D, Jimenez-Aranda A., (2022) Development and user-testing of a digital patient decision aid to facilitate shared decision-making for people with stable angina. *BMC Med Inform Decis Mak* **22**, 143 (2022). Available from: <https://doi.org/10.1186/s12911-022-01882-x> [Accessed April 16 2023]

<sup>254</sup> National Institute for Health and Care Excellence (NICE). Shared decision making: NICE Guideline. UK: NICE; 2021 17/06/2021. Available from: <https://www.nice.org.uk/guidance/ng197/resources/shared-decision-making-pdf-66142087186885> [Accessed 5 February 2023]

<sup>255</sup> Carmora C, Crutwell J, Burnham, M *et al* (2021) Shared decision-making: summary of NICE guidance *BMJ* 373:n1430 Available from: <https://www.bmj.com/content/373/bmj.n1430> [Accessed April 16 2023]

<sup>256</sup> Gov.uk (2020) First do no harm: Independent Medicines and Medical Devices Safety Review Report. Available from: <https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report> [Accessed January 13 2023] at para. 2.22

<sup>257</sup> National Institute for Clinical Excellence, (2019), *Surgery for stress urinary incontinence – Patient decision aid*, Available from: <https://www.nice.org.uk/guidance/ng123/resources/surgery-for-stress-urinary-incontinence-patient-decision-aid-pdf-6725286110> [Accessed April 16 2023]

- 8.54 On reviewing the case records, we observed that where it was noted that the patient was given an information leaflet, a copy of exactly what they had received was rarely to be found in the case notes. Without this, it was difficult to know what the patient has been advised regarding the risks, benefits or alternatives to treatment. Knowing which version was shared would indicate which format the leaflet took, and exactly what information was contained within it. It is recognised that this approach has now been adopted by many Health Boards.<sup>258</sup>
- 8.55 Decision-making aids do not need to be confined to the written word and digital diagrams which can include details, animations and diagrams providing a clear visual to the patient on what their proposed surgery would involve, are also now available.<sup>259</sup> The information is given to the patient but is also mapped digitally so there is a contemporaneous record of the information being given, that it was received, that it was opened and then there are prompts for the patient to confirm that they have read it, and to ask if they have any questions. If these digital diagrams are also stored digitally, it means that the record cannot be lost or misplaced as would have potentially been the case with a paper diagram.

**The Panel recommends:**

- 8.56 **Surgical units should keep a version control of their patient information Leaflets and that this should be noted in the case records so that when looking back, it can be seen precisely what information was given to a patient at any point in time.**
- 8.57 **The use of patient decision-aids, checklists and information leaflets should be provided in advance of the consultation, so that the time available in the consultation can be optimised. This helps to ensure that patients are empowered with the information they need to decide and have shared responsibility for their care.**
- 8.58 **The creation of a national specific consent form, for use across the country, to reduce variation, and improve consistency of information covered during the counselling process.**
- 8.59 **To create the conditions in the NHS to enable an informed consent process, namely adequate training, and adequate time, supported by high quality decision aids and consent forms.**

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<sup>258</sup> For example, see Dumfries and Galloway, Patient Information Policy Available from: [https://www.nhs.uk/wp-content/uploads/2019/07/Patient\\_Information\\_Policy.pdf](https://www.nhs.uk/wp-content/uploads/2019/07/Patient_Information_Policy.pdf) [Accessed February 15 2023]

<sup>259</sup> For example, see those produced by EIDO Healthcare. Please note this reference is to serve merely as an example and not as any endorsement nor review. Available from: <https://www.eidohealthcare.com/case-studies/improving-patient-understanding-using-effective-medical-animations/> [Accessed September 8 2022]

## Chapter 9 - Acknowledging the Past and Looking to the Future

### Introduction

- 9.1 A lot of work has been undertaken narrating the lives and experiences of women who have experienced complications following transvaginal mesh surgery. By its nature, this has tended to take a retrospective approach, reflecting on mostly what has occurred for some women following their transvaginal mesh surgery and to a lesser extent why this has occurred. Our Review has, to some extent, followed the same retrospective path. In the two years that I corresponded with the participants, it was striking how willing they were to get involved, not only in sharing their own experiences, but forwarding online links and all sorts of information that they thought would be of value to the Report. I felt their frustration at not being able to have a more proactive role in redressing past events in order to have influence in how future care and support is provided.
- 9.2 This chapter looks to the future and reflects on ways to improve the management of women's care, recognising the legacy of treatment and the impact that this has had on women's faith and trust in their healthcare. The future role of the complex mesh surgical services in Scotland and how it integrates with local services will also be addressed. The importance of data capture is recognised. Not only is this an essential requirement to inform the allocation and provision of resources but to ensure that aftercare and follow up is available for those who have received treatment, both within and outwith Scotland. Pathways for treatment and referral need to be clearly articulated and publicly available.

## Complex Mesh Surgical Service Provision

- 9.3 The establishment of complex mesh service provision can be seen as an example of an established model which aims to draw together specialist services, ideally relating to the care, treatment and support for a particular complex condition. Good models for such centres of excellence can be seen in other areas such as oncology, reproductive and maternity services. Creating the opportunity to draw resources together in one place can offer a more aligned and comprehensive service in relation to a particular speciality, in this case, complex mesh service provision.
- 9.4 As discussed in Chapter 7, by the time a woman arrives at a specialist centre it is often the culmination of a long and complex journey of surgeries, referrals and investigations.
- 9.5 To be referred to a mesh centre is, for many women, the end goal of what is likely to have been a long clinical journey. Recognition that there have been adverse consequences for them, usually of a complex nature, is an important part of this journey, as it provides reassurance that they have arrived at a place where complexities can be addressed.
- 9.6 There is one Complex Mesh Surgical Service (CMSS) in Scotland, this is in addition to nine centres providing complex mesh services in England. The CMSS is currently based in Glasgow and overseen by Greater Glasgow and Clyde Health Board. It took over from the service that was previously provided jointly by NHS Lothian and NHS Greater Glasgow and Clyde Health Boards, and became available on an incremental basis as a service for women from August 2020.<sup>260</sup> There are some assumptions made that such centres were the result of the recommendations contained in the Cumberlege Report.<sup>261</sup> This is not accurate. The CMSS was already evolving in Scotland prior to this.

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<sup>260</sup> Scottish Government (2020) National Mesh Removal Service- Press announcement. Available from: <https://www.gov.scot/news/national-mesh-removal-service/> [Accessed April 16 2023]

<sup>261</sup> The Cumberlege Report was published 8<sup>th</sup> July 2020. Gov.uk (2020) First do no harm: Independent Medicines and Medical Devices Safety Review Report. Available from: <https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report> [Accessed January 13 2023]

- 9.7 The Cumberlege Report referred to this aspect of clinical care as establishing a 'one stop shop'<sup>262</sup> to signpost and refer patients to other services. The benefits of a multi-disciplinary approach housed in one location were also recognised in Scotland in the Health and Social Care Alliance report in January 2021.<sup>263</sup> The Panel find the term 'one stop shop' problematic for it does not accurately describe the current function of the CMSS. Use of this terminology also creates unrealistic expectations as to what services are currently offered within the CMSS. It also appears to us, to be a little discourteous to both patients and healthcare providers but critically, it may give the impression that all services are located and provided within a central specialised service. This is not the case. The CMSS is a surgical service - as is reflected in its title - and whilst, there are specialist nurses, physiotherapy and emotional support services, they are centred around preparation for, providing and recovery from, a surgical procedure.<sup>264</sup> Broader availability of services may, and does, rely upon local service provision and the CMSS itself relies upon a patient referral system from local services. The referral pathway requires patients to arrive at the CMSS with all the information gathered in advance by their local health board, ready to be assessed at the CMSS where their eligibility for mesh revision surgery will be discussed. For this reason, we prefer the term 'integrated services' to 'one-stop-shop'. By this we mean a collaborative relationship between the CMSS, the local health boards and other agencies, including patient groups.
- 9.8 Whilst established,<sup>265</sup> the operation of the referral system appears to us, to be confusing and may benefit from further explanation so that it is clear where the responsibility for patient care may lie at any given point and what might be expected from their care journey.

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<sup>262</sup> Gov.uk (2020) First do no harm: Independent Medicines and Medical Devices Safety Review Report. Available from: <https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report> [Accessed January 13 2023] at p.12.

<sup>263</sup> Alliance Scotland (2021) My health, my path, my life. Available from: <https://www.alliance-scotland.org.uk/wp-content/uploads/2021/03/MESH-Report-March-21.pdf> [Accessed April 16 2023]

<sup>264</sup> For example, the website contains a section on Lifestyle but its focus remains on providing '*information is to help you know what you might be able to do in the days or weeks before any mesh related surgery. This will speed up your recovery and help you get the best outcome possible.*' Available from: <https://www.nhsggc.scot/hospitals-services/services-a-to-z/national-complex-mesh-surgical-service/your-visit-to-the-mesh-service/> [Accessed April 28 2023]

<sup>265</sup> Available from: <https://www.nhsggc.scot/hospitals-services/services-a-to-z/national-complex-mesh-surgical-service/your-visit-to-the-mesh-service/> at Downloads/Specialist-Mesh-Removal-Referral-Process.pdf [Accessed April 28 2023]



- 9.9 Across the UK, the centres were the subject of criticism from early on in their inception<sup>266 267</sup> with continuing concerns highlighted both within the media and elsewhere.<sup>268 269 270</sup> The Panel recognise that these centres are in relatively early stages of development. When reviewing its outcomes and key indicators of measurement on its performance to date, the impact that Covid-19 has had on the CMSS remains significant and was particularly so for a centre in its relative infancy. The CMSS was unable to provide any surgery between January 2022 and August 2022 and from 22<sup>nd</sup> December 2022 until February 9<sup>th</sup> 2023, due to Greater Glasgow and Clyde Health Board-wide elective procedure restrictions related to Covid restrictions, and the significant winter pressures.<sup>271</sup>
- 9.10 Our focus considers the current service provision of the CMSS and its role within future care. Our focus rests therefore primarily with the Scottish service but we recognise how important it is for the services across the UK to share best practice, including a consistent approach to data capture.
- 9.11 Prior to arriving at a mesh centre, participants described to us a clinical journey which for many, involved treatments from multiple clinicians, within multiple hospitals, across multiple Boards or Trusts. These could be nationally within Scotland, or further across the UK. In the last two years a number of women have also travelled out with the UK for mesh revision surgery. Unsurprisingly, this has resulted in a legacy of fragmented care and confused communication - both written and verbal. Attending a complex mesh surgical service provides some opportunity to address that legacy through the re-building of relationships and re-establishment of trust.

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<sup>266</sup> Wise J (2022) Specialist surgical mesh centres are not working, MPs are told *BMJ* 2022; 376: Available from: <https://doi.org/10.1136/bmj.o314> (Published 04 February 2022) [Accessed April 18 2023]

<sup>267</sup> Samson K, (2022) 10 Problems with England's Specialist Mesh Centres. Patient Safety Learning, The Hub. Available from: <https://www.pslhub.org/learn/patient-safety-in-health-and-care/womens-health/kath-sansom-10-problems-with-nhs-england%E2%80%99s-specialist-mesh-centres-r7742/> [Accessed April 20 2023]

<sup>268</sup> SPICe (2023) Health, Social Care and Sport Committee Complex Mesh Surgical Service – Summary of evidence. Available from: <https://www.parliament.scot/-/media/files/committees/health-social-care-and-sport-committee/complex-mesh-surgical-service-call-for-views.pdf> [Accessed 24 April 2023]

<sup>269</sup> BBC News (April 2023) Mesh survivors' trust 'completely depleted' Available from: - <https://www.bbc.co.uk/news/uk-scotland-65346616> [Accessed June 10 2023]

<sup>270</sup> Scott M (2022) Minister under pressure over NHS failure to send a single mesh victim to US, *Sunday Post*. Available from: <https://www.sundaypost.com/fp/minister-under-pressure-over-nhs-failure-to-send-a-single-mesh-victim-to-us/> [Accessed June 10 2023]

<sup>271</sup> Dates received from the Complex Mesh Surgical Service- Scotland.

9.12 Whilst we recognise that a necessary focus has been on the provision of mesh revision surgery, the women who will require, or are suitable for this type of surgery will be small in number. Arriving at the decision that surgery may not be the best option will be highly distressing for some women. There should be a clear process available to support, practically and emotionally, the women who may not be a suitable candidate for surgery, or who decide that this is not the optimal choice for them.<sup>272</sup> Looking forward, it is hoped that the importance of the integrated provision of services will be clearly recognised for women for whom surgery may not be a possible or preferred option, and that non-surgical options will also be readily available and equally supported.

*Webpage /Website - Complex Mesh Surgical Service in Scotland*

9.13 A positive step was the launch of a webpage for the CMSS in Scotland in late December 2022, which is hosted through NHS National Services Scotland (NSS).<sup>273</sup> In December 2022, it contained a description of its of its origins and purpose. Confusingly its contents were updated on May 31 2023 and this changed the page significantly:

*'The Complex Mesh Surgical Service hosted by NHS Greater Glasgow and Clyde (GG&C) is the nationally designated centre in Scotland for women with mesh complications...'*<sup>274</sup>

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<sup>272</sup> SPICe (2023) Health, Social Care and Sport Committee Complex Mesh Surgical Service – Summary of evidence. Available from: <https://www.parliament.scot/-/media/files/committees/health-social-care-and-sport-committee/complex-mesh-surgical-service-call-for-views.pdf> Accessed 24 April 2023

<sup>273</sup> NHS Scotland (2022) Complex Mesh Surgical Service. Available from: <https://www.nss.nhs.scot/specialist-healthcare/specialist-services/complex-mesh-surgical-service/> [Accessed December 16 2022]

<sup>274</sup> NHS Scotland (2022) Complex Mesh Surgical Service. Available from: <https://www.nss.nhs.scot/specialist-healthcare/specialist-services/complex-mesh-surgical-service/> [Accessed December 16 2022]



9.14 A statement on the webpage also pledged to work to incorporate the findings and recommendations from the Health and Social Care Alliance Report.<sup>275</sup> 152 women who had experienced mesh complications following their surgery participated and engaged with The Alliance to share their views. The views had much in common with those that had been highlighted in the Cumberlege Report<sup>276</sup> the previous year.

*'Trust;*

*The importance of being listened to;*

*A joined-up approach between the mesh service and local NHS Boards;*

*A holistic approach recognising that mesh complications are life changing;*

*A clear pathway of care.*<sup>277</sup>

9.15 These form the essence of recurring concerns and it is positive to see that the CMSS has pledged to work in partnership to ensure swift implementation of recommendations which may serve to address these.

9.16 The webpage is a welcome online presence and it is hoped that this site can be further developed to include details of the complex mesh surgical service's work as it develops, along with intimation and inclusion of publications, testimonials and future projects.

9.17 The webpage also notes that *'The service is for women who have been referred for specialist surgical mesh removal.'*<sup>278</sup> The CMSS is clear that it is not providing a more comprehensive or integrated service; its focus is only upon mesh revision surgery.

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<sup>275</sup> Health and Social Care Alliance Scotland (2021) My Path, My Health, My Life: Learning from the experiences of women to plan future mesh services. Available from: <https://www.alliance-scotland.org.uk/wp-content/uploads/2021/03/MESH-Report-March-21.pdf> [Accessed December 16 2022]

<sup>276</sup> Gov.uk (2020) First do no harm: Independent Medicines and Medical Devices Safety Review Report. Available from: <https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report> [Accessed January 13 2023]

<sup>277</sup> Health and Social Care Alliance Scotland (2021) My Path, My Health, My Life: Learning from the experiences of women to plan future mesh services. Available from: <https://www.alliance-scotland.org.uk/wp-content/uploads/2021/03/MESH-Report-March-21.pdf> [Accessed December 16 2022] at pp 3 & 4

<sup>278</sup> NHS Scotland(2022) Complex Mesh Surgical Service. Available from: <https://www.nss.nhs.scot/specialist-healthcare/specialist-services/complex-mesh-surgical-service/> [Accessed December 16 2022]

- 9.18 At the time of writing, there is also a separate website offered through Greater Glasgow and Clyde.<sup>279</sup> Unfortunately, this is difficult to locate and lacks visibility when using online search engines. The Panel were unaware of its existence until a link was forwarded to us from the CMSS in May 2023. It is difficult to distinguish between the NHSGGC webpage<sup>280</sup> and the Greater Glasgow and Clyde Health Board website.<sup>281</sup> The webpage and the website contain different information. There is no link contained in either to refer from one to the other. Both contain valuable and informative content.
- 9.19 Online resources are an excellent way of enhancing communication. It is important that information relating to the clinic's services, processes and the patient experience are accessible and transparent to patients and the public. This will better inform patients and engage them with the service. However, the Panel recognise that it requires dedicated time and resource to maintain the accuracy and quality of websites and that there is currently the potential for duplication.
- 9.20 Updates and information regarding services, pathways, patient feedback, research and education must not be underestimated. Resources should be consolidated into a single website. This website should clearly outline where responsibility lies for patient care at each stage through both referral and treatment pathways. A good example can be found on The New Zealand Female Pelvic Mesh Service website.<sup>282</sup>
- 9.21 Work should be undertaken to make this information more accessible, consistent and better integrated across the NHSGGC and the CMSS.

**9.22 The Panel believe that all information should be drawn together into a single website. This website should be clear about where the responsibility lies for patient care at each stage through the referral pathway.**

**9.23 The Panel recommend that dedicated funding should be made available so that work may be undertaken to make this website accessible, connected and regularly updated and maintained with up-to-date information.**

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<sup>279</sup> See: [https://www.nhsggc.scot/page\\_category/national-surgical-mesh-removal-service/](https://www.nhsggc.scot/page_category/national-surgical-mesh-removal-service/) [Accessed April 27 2023]

<sup>280</sup> See: <https://www.nss.nhs.scot/specialist-healthcare/specialist-services/complex-mesh-surgical-service/> [Accessed April 27 2023]

<sup>281</sup> See: [https://www.nhsggc.scot/page\\_category/national-surgical-mesh-removal-service/](https://www.nhsggc.scot/page_category/national-surgical-mesh-removal-service/) [Accessed April 27 2003]

<sup>282</sup> See: [The New Zealand Female Pelvic Mesh Service – Te Whatu Ora - Health New Zealand \(newdunedinhospital.nz\)](https://www.newdunedinhospital.nz/) [Accessed June 9 2023]

## Clinical care pathway

- 9.24 A good starting point is the creation of a clear and structured care pathway from the moment the patient arrives at a specialist mesh centre. The importance of rebuilding trust cannot be overstated and patients need to have a step-by-step explanation as to what to expect, including a discussion of the possible options available to them. This may or may not include a surgical option but the choice remains the patients. Honesty, transparency and clarity is essential if the reality of their circumstances is not what they had hoped it would be.
- 9.25 Many women have spoken about a lack of what is often termed a ‘pathway’ of care. Pathways are usually devised on a combination of two elements: one element is to assist clinicians in terms of best practice in how to move a patient from one part of the healthcare system to another, and one element to facilitate multidisciplinary working. It is a combination of the two elements that makes it a resource-efficient way for the healthcare service to provide high quality care in an equitable way it is not a rigid system and can and should be subject to revision as best practice evolves.
- 9.26 As noted above, the CMSS established a webpage in December 2022<sup>283</sup> where it is explained that they are working in partnership with NHS GG&C Health Board colleagues to provide treatment (care) pathways and national referral pathways which will also cover follow up arrangements after discharge from the centre.<sup>284</sup> The Panel interpret this to mean that, as yet, there is no treatment pathway, but this this is currently being addressed. On their website there is documentation describing a pathway for referral.<sup>285</sup> We have indicated above that this could be made clearer to indicate where the responsibility for care lies, for example, with a local service or the specialist mesh service. We remain unclear whether a pathway for care and treatment has been developed for the CMSS, and this urgently needs clarified.

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<sup>283</sup> NHS Scotland (2022) Complex mesh surgical service. Webpage. Available from: <https://www.nss.nhs.scot/specialist-healthcare/specialist-services/complex-mesh-surgical-service/> [Accessed April 18 2023]

<sup>284</sup> NHS Scotland (2022) Complex mesh surgical service. Website. Available from: <https://www.nss.nhs.scot/specialist-healthcare/specialist-services/complex-mesh-surgical-service/> [Accessed April 18 2023]

<sup>285</sup> See: <https://www.nhsggc.scot/downloads/national-mesh-removal-referral-pathway/> [Accessed April 18 2023]

9.27 **The Panel recommends that information around referral and treatment pathways and clarified and published on the website. This needs to be specific to the processes of the CMSS and designed from the patient perspective. Where responsibility lies at each stage should be identified and signposted effectively. This should be regularly updated and maintained.**

### Pathway for training and credentialing of surgeons providing complex mesh surgery

9.28 The Cumberlege Report recognised that consideration should be given to credentialing surgeons for complex mesh surgery<sup>286</sup> and the Panel fully agree.

9.29 It is recognised that all surgeons providing complex surgery for urinary incontinence and vaginal and uterine prolapse must be members of the appropriate subspecialist society, and all urogynaecologists must have British Society of Urogynaecology (BSUG) membership. All urologists forming part of the specialist multi-disciplinary team must have membership of the Female, Neurological and Urodynamic Urology section of the British Association of Urological Surgeons.

9.30 The Royal College of Obstetricians and Gynaecologists((RCOG), in collaboration with partners, including the Royal College of Surgeons, have developed a Mesh Complications Management Training Pathway.<sup>287</sup> Their background paper observes,

*“The specialised commissioning process [for units to apply to establish as complex mesh surgical services] states that there is a requirement for training for Mesh Complications: ‘Individual Trusts providing Mesh Services must use the Trust appraisal system to ensure surgeons are appropriately trained and current in their practice; adhere to clinical guidance; comply with national data requirements and report complications’.”<sup>288</sup>*

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<sup>286</sup> Gov.uk (2020) First do no harm: Independent Medicines and Medical Devices Safety Review Report. Available from: <https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report> [Accessed January 13 2023] Section 5.102.

<sup>287</sup> Royal College of Obstetricians and Gynaecologists(2021) *Mesh Complications Management Training Pathway* Available from: <https://www.rcog.org.uk/media/5uhpq4m1/mesh-complications-management-training-pathway.pdf> [Accessed April 18 2023]

<sup>288</sup> Royal College of Obstetricians and Gynaecologists(2021) *Mesh Complications Management Training Pathway* Available from: <https://www.rcog.org.uk/careers-and->

9.31 We observed that patients with personal experience of mesh complications also provided input to the development of this pathway.

9.32 The pathway curriculum consists of four 4 'capabilities to practice' and these are outlined below:

- The doctor has the knowledge, skills and attitudes required for clinical assessment of patients presenting with suspected mesh-implant complications;
- the doctor is able to investigate mesh complications, and interpret the results of tests, appropriately;
- the doctor is competent in non-surgical management of mesh complications; and
- the doctor is competent to undertake mesh removal surgery as part of a multidisciplinary team.<sup>289</sup>

9.33 The Panel notes that the matter of credentialing appears to have been approached and approved in Scotland. It was raised in the Scottish Government's Transvaginal Short Life Working Group. The minutes from December 2020 record:

- *“Colleagues from the Royal Colleges and specialist associations have been in contact with the GMC about establishing a GMC regulated and accredited credential for mesh removal surgery.*
- *“The credential will define what skills clinicians need to develop, how the skills will be measured, and how we can benchmark the acquisition of the skills. The accreditation will be registered in the GMC register of specialists, indicating that surgeons are credentialed to undertake mesh surgery.*
- *“The aim is that this will recognise the skills of our surgeons, it will provide support for the Service and it will increase public confidence. There was consensus that credentialing is a positive development to move forward and*

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[training/training/curriculum/mesh-complications-management-training-pathway-pilot/background-and-purpose/](#) [Accessed April 18 2023]

<sup>289</sup> Royal College of Obstetricians and Gynaecologists(2021) *Mesh Complications Management Training Pathway* Available from: <https://www.rcog.org.uk/media/5uhpq4m1/mesh-complications-management-training-pathway.pdf> [Accessed April 18 2023]

*build trust. The length of time that the credential may take to come in to force was raised in discussion.”<sup>290</sup>*

9.34 As discussed throughout this Report, there has to be trust and faith from those using any service which provides mesh revision surgery. Training and credentialing of surgeons therefore is a critical element and its process has to be clearly articulated, not only for clinicians but also for women using the service.

**9.35 The process of training and credentialing of surgeons in Scotland is a critical element and its process has to be clearly articulated, and made available, not only for clinicians, but also for women using the service.**

### Attending an appointment

9.36 This section reflects on appointment attendance at any venue, and does not relate exclusively to the CMSS. Chapter 8 described in detail the importance of good communication and disclosure of information to enable an informed choice being made by the patient. The Panel recognise the current tension between the need to ensure a robust process of information disclosure and informed consent, and the current constraints in appointments within an already-stretched National Health Service. The provision of good patient decision aids, graphics and time to reflect upon them can only achieve so much. What matters most is the opportunity for patients to ask questions, have their concerns heard, and fully understand the potential benefits and risks of treatment.

9.37 Factors that could enhance the retention of information shared are also important to consider, such as a written summary of the discussion copied to the patient, the option of recording a consultation for the patient’s own record, encouraging the patient to attend with a trusted person.

9.38 The General Medical Council’s guidance on shared decision making and consent provides that:

*‘To help patients understand and retain relevant information you should:*

- *share it in a place and at a time when they are most likely to understand and retain it. Anticipate whether they are likely to find any of it distressing and, if so, be considerate when sharing it;*

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<sup>290</sup> Scottish Government (2020) Transvaginal Short Life Working Group Minutes December 2020. Available from: <https://www.gov.scot/publications/transvaginal-mesh-short-life-working-group-minutes-december-2020/>. [Accessed April 18 2023]

- *accommodate a patient's wishes if they would like to record the discussion and if they would like anyone else – a relative, partner, friend, carer or advocate – to be involved in discussions;*
- *share it in a format they prefer - written, audio, translated, pictures or other media and give them time and opportunity to consider it before and after making their decision.*<sup>291</sup>

9.39 We have already addressed the final bullet point in terms of the format of decision-making aids and the use of diagrams and digital media.<sup>292</sup> Our conversations with the participants highlighted a recurring concern about feeling uncomfortable, or being challenged, when they asked if they could record a meeting, often to be met with a non-favourable response. This then either resulted in them leaving an appointment unsure about the information they were given and what it meant for them, or they recorded the conversation surreptitiously. Neither of these outcomes are ideal and are contrary to the spirit of shared decision making and enhanced communication between the patient and their healthcare provider. As can be seen above the General Medical Council guidelines state that if the patient wishes to record the conversation then this should be accommodated.<sup>293</sup> Ideally this should be done with mutual agreement of the clinician and the patient, and clinicians should be supported and enabled to make this possible.

9.40 Section 27 of the GMC guidelines also encourages the presence of carers, advocates or support should be patient wish it. The CMSS advise that they ask patients if they would like to record the conversation and are encouraged to do so. The Panel supports this.

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<sup>291</sup> General Medical Council, (2020) Decision Making and Consent Guidelines at section 27. Available from: [https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english\\_pdf-84191055.pdf](https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf) [Accessed June 10 2023]

<sup>292</sup> Please see Chapter 8 of this Report.

<sup>293</sup> General Medical Council, (2020) Decision Making and Consent Guidelines at section 27. Available from: [https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english\\_pdf-84191055.pdf](https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf) [Accessed June 10 2023]



9.41 **The Panel believes that patients should be clearly informed of the options available during their appointment prior to attending the CMSS, for example, to be accompanied by a trusted person and to record discussions that take place during the appointment. Such options will help to enable the patient to retain and reflect on the information and treatment options discussed. It is recommended that this information is included on the single website.**

## Data capture

- 9.42 As highlighted throughout this Report, data capture plays an essential role in understanding workload and health outcomes, and influences the future allocation of resources, and development of care pathways. A report by Healthcare Improvement Scotland (HIS) published in 2020<sup>294</sup> <sup>295</sup> acknowledges the benefit of data capture but also acknowledges the difficulties in capturing and obtaining accurate data. In this context, the difficulty in data capture was in part attributed to the complexity of the codes used to record mesh surgery.<sup>296</sup> NHS Scotland Information Services suggest that between April 2009 and March 2019, 8384 mesh procedures for Stress Urinary Incontinence (SUI) and 1519 mesh procedures for Pelvic Organ Prolapse (POP) were undertaken in Scotland.<sup>297</sup> <sup>298</sup>
- 9.43 The actual number of mesh revision surgeries that have taken place across the world remains unknown. This is an issue not confined to Scotland. As noted above, some of this can be explained because of the complexity of codes used

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<sup>294</sup> Healthcare Improvement Scotland (2020) Transvaginal Mesh Implants Oversight Group Final Report. Available from: [file:///C:/Users/abri/Downloads/20200421-TVMO-End-of-Project-FINAL-Report-2-0%20\(3\).pdf](file:///C:/Users/abri/Downloads/20200421-TVMO-End-of-Project-FINAL-Report-2-0%20(3).pdf) [Accessed April 24 2023]

<sup>295</sup> This group disbanded in 2019 on conclusion of its work and with its major tasks absorbed by the Scottish Government Accountable Officers' Group.

<sup>296</sup> Healthcare Improvement Scotland (2020) Transvaginal Mesh Implants Oversight Group Final Report. Available from: [file:///C:/Users/abri/Downloads/20200421-TVMO-End-of-Project-FINAL-Report-2-0%20\(3\).pdf](file:///C:/Users/abri/Downloads/20200421-TVMO-End-of-Project-FINAL-Report-2-0%20(3).pdf) [Accessed April 24 2023] at p.9

<sup>297</sup> Angelova, N *et al* (2021) User testing a patient information resource about potential complications of vaginally inserted synthetic mesh, *BMC Womens Health*. 2021; 21: 35. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7831188/#CR3> [Accessed February 5 2023]

<sup>298</sup> NHS Scotland Information Services Division (2019) Transvaginal Services in Scotland. Available from: <https://www.isdscotland.org/Health-Topics/Hospital-Care/Publications/2019-10-08/2019-10-08-Transvaginal-Mesh-Procedure-Summary.pdf> [Accessed April 24 2023]



to record procedures.<sup>299</sup> This has been highlighted as an issue for a number of years. Notably it was also highlighted in the Cumberlege Report in 2020, and in Scotland, two years later, a Scottish Parliament Briefing (SPICe) paper concluded that '*the number of women suffering complications is not known, because there is currently no reliable information*'.<sup>300</sup>

9.44 The Health Improvement Scotland paper on data capture proposed to:

- *Undertake work to ensure a consistent approach to coding. One possible solution is to limit the number of codes available for each procedure.*
- *Continue to monitor data on the number of mesh and non-mesh procedures for SUI and POP, and the number of readmissions and removals relating to these procedures.*
- *Seek confirmation from the relevant NHS boards, where records indicate a transvaginal mesh procedure has been used.*
- *Identify the number of women being treated for these conditions through alternative methods, and how relatively effective these methods are.*
- *Include the following areas of data collection in any review of the data:*
  - *Primary care data (e.g. volume of consultations relating to SUI and POP; insertion of pessaries or other treatments).*
  - *Non-surgical procedures for SUI and POP.*<sup>301</sup>

9.45 The lack of consensus regarding data accuracy, or any clear plan to improve data capture is of concern.

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<sup>299</sup> Healthcare Improvement Scotland (2020) Transvaginal Mesh Implants Oversight Group Final Report. Available from: [file:///C:/Users/abri/Downloads/20200421-TVMO-End-of-Project-FINAL-Report-2-0%20\(3\).pdf](file:///C:/Users/abri/Downloads/20200421-TVMO-End-of-Project-FINAL-Report-2-0%20(3).pdf) [Accessed April 24 2023] at p.9

<sup>300</sup> SPICe Spotlight (2022) Surgical mesh Complications. Available from: <https://spice-spotlight.scot/2022/06/30/surgical-mesh-complications/> [Accessed April 24 2023]

<sup>301</sup> Healthcare Improvement Scotland (2020) Transvaginal Mesh Implants Oversight Group Final Report. Available from: [file:///C:/Users/abri/Downloads/20200421-TVMO-End-of-Project-FINAL-Report-2-0%20\(3\).pdf](file:///C:/Users/abri/Downloads/20200421-TVMO-End-of-Project-FINAL-Report-2-0%20(3).pdf) [Accessed April 24 2023] at p.11

*Data capture from surgery provided out with Scotland*

- 9.46 On the 12 July 2021, the Scottish Government announced that patients were to be given the option to consult with private surgeons outwith Scotland, and to receive mesh revision surgery, with contracts awarded to Spire Health Care in Bristol, and the Mercy Hospital in Missouri, America.<sup>302</sup> From our conversation with the participants and review of their case records, the Panel understand that mesh revision surgery carried out by these independent service providers, may also be accompanied by other forms of surgical procedure.

9.47 **The Panel believe that it is crucial that there is an agreed system of NHS follow-up and ongoing support in place for patients who are returning from a mesh revision surgery which has taken place outside Scotland and that this data is captured, collated and forms part of a comprehensive evaluation mechanism.**

***Reporting of ‘adverse events’***

- 9.48 The reporting mechanism for adverse events appears similarly unclear, with several issues identified by HIS, including  
*“incomplete reporting, difficulties identifying details of the original implant, and possible duplication of reporting to Incident Reporting and Investigation Centre (IRIC) and Medicines Health Regulatory Authority”*.<sup>303</sup>
- 9.49 There appears to be some progress in this area with a national system in place since 2019<sup>304</sup> that requires Health Boards to report significant adverse events. The aim is to make sure that there is consistency of process and quality in the

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<sup>302</sup> Scottish Government, News (12 July 2021) Mesh Removal Surgery. Available from: <https://www.gov.scot/news/mesh-removal-surgery/#:~:text=Contracts%20awarded%20for%20option%20of,Dr%20Dionysios%20Veronikis%20performs%20surgery.> [Accessed April 26 2023]

<sup>303</sup> Healthcare Improvement Scotland (2020) Transvaginal Mesh Implants Oversight Group Final Report. Available from: [file:///C:/Users/abri/Downloads/20200421-TVMO-End-of-Project-FINAL-Report-2-0%20\(3\).pdf](file:///C:/Users/abri/Downloads/20200421-TVMO-End-of-Project-FINAL-Report-2-0%20(3).pdf) [Accessed April 24 2023] at p.15

<sup>304</sup> Healthcare Improvement Scotland (2019) Learning from adverse events through reporting and review. A national framework for Scotland: December 2019. Available from: [https://www.healthcareimprovementscotland.org/our\\_work/governance\\_and\\_assurance/learning\\_from\\_adverse\\_events/national\\_framework.aspx](https://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/national_framework.aspx) [Accessed April 24 2023]

data submitted. This system went live in January 2020 with monthly data being received from all organisations.<sup>305</sup>

### ***Data collection and follow up***

- 9.50 Retrospective data collection remains challenging, but essential to be able to resource and understand what is required in terms of the nature and volume of future care and support. The potential for all complex specialist mesh centres across the UK to collaborate in collecting outcome data for their collective caseloads in relation to treatments received, is significant. This data will not only inform the development of future clinical care, but could also be used for educational purposes and to inform where further research is needed.

### **How is success defined: evaluating success from patient or clinician perspective?**

- 9.51 A final point in this chapter sees the Panel return to the need for clarity of language and how we view this as fundamental when discussing whether or not the outcome of a revision surgery was deemed 'successful'. The interpretation of this will depend on the perspective taken and it can mean several and different things to the treating healthcare team or to the patient. To add to the complexity of how success is defined and perceived by patients, it will also be influenced by the views of their friends and family, support groups, public organisations and the media. It remains significant because how success is understood and defined will influence the accuracy of data capture too, in terms of health outcomes.
- 9.52 For our purposes, we confined our consideration of success on how either a patient or a healthcare professional would interpret it. For the women who had one or more mesh revision surgeries, culminating in a complete removal of their mesh, all spoke of the psychological relief brought about from the removal of a 'foreign body'. This may be viewed as 'success' from their perspective, regardless of whether or not it resulted in an improvement in urinary symptoms, pain or mobility.<sup>306</sup> If the patient regards a treatment or procedure as

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<sup>305</sup> Healthcare Improvement Scotland (2022) Adverse Events Notification System: Update Report. Inspection and Reviews. Available from: <file:///C:/Users/abri/Downloads/20211028-AE-NS-Update-RPT-1-0.pdf> [Accessed April 24 2023]

<sup>306</sup> The panel understand that some clinical units have questionnaires which may be specific to prolapse quality of life questionnaires and specific incontinence quality of life questionnaires.

successful, this alone will often have a positive impact on the relationship between the patient and their clinician and, in turn promote a willingness to trust advice given on future treatment and care.

- 9.53 **The Panel recommends the implementation of the Health Improvement Scotland Guidelines on data capture to also include national learning from significant adverse events.**
- 9.54 **The requirement for all CMSSs across the UK to collaborate on agreed consistent data gathering, including on longer term outcomes from treatment**
- 9.55 **Agreement on how 'success' should be defined and measured, from both a clinician and patient perspective.**

9.56 The Panel are aware that the Health, Social Care and Sport Committee of the Scottish Parliament committed to review the service and support provided by the Scottish Complex Mesh Surgical Service (CMSS). The Committee launched a consultation which closed on 24<sup>th</sup> March 2023<sup>307</sup> and a summary of their evidence is now available.<sup>308</sup> The Panel recognise that many of the matters raised with us throughout this Case Record Review, also appear in the consultation evidence, suggesting that many of these issues may remain unresolved. However, the Panel observe that the CMSS has undertaken its own surveys regarding patient experience and implemented a subsequent action plan and should be considered in any evaluation.<sup>309</sup>

## Participants Evaluation and Feedback

9.57 We were keen to seek feedback from the women on their experience of participating in the Case Record Review. To this end, we designed a simple feedback form that contained eight ranked questions, relating specifically to the

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<sup>307</sup> Scottish Parliament (2023) Experiences of the Complex mesh surgical service. Available from <https://yourviews.parliament.scot/health/experience-complex-mesh-surgical-service> [Accessed April 18 2023] The questions on the consultation covered: About you, Your symptoms, Referral and access, Mesh removal surgery, Support following your surgery, Issues and more information.

<sup>308</sup> SPICe (2023) Health, Social Care and Sport Committee Complex Mesh Surgical Service – Summary of evidence . Available from: <https://www.parliament.scot/-/media/files/committees/health-social-care-and-sport-committee/complex-mesh-surgical-service-call-for-views.pdf> [Accessed April 24 2023]

<sup>309</sup> NHSGGC Patient Experience Public Involvement Team. (2022) Complex Mesh Surgical Service Patient Experience Questionnaire Cycle 2 Report. Available from: [file:///C:/Users/abri/Downloads/National-Mesh-Service-Patient-Feedback-Cycle-2-Report-July-22%20\(1\).pdf](file:///C:/Users/abri/Downloads/National-Mesh-Service-Patient-Feedback-Cycle-2-Report-July-22%20(1).pdf) [Accessed June 13 2023]

women's experience of meeting with the moderator and administrator, plus two additional questions that allowed for individual feedback on their experience of the Case Record Review more generally. The form used can be seen in Appendix 1. The ranked questions 1-8 were adapted, with permission, from the Care and Relational Empathy (CARE)<sup>310</sup> person-centred process measure, that was designed and researched in Scotland. It was originally designed to measure empathy in the context of the therapeutic relationship during a one-on-one consultation between a clinician and a patient. Originally developed and rigorously tested for use by GPs, it has since been successfully used by other medical staff, allied health professionals (AHPs) and nurses.

- 9.58 All of the women (18 in total) who participated in the Case Record Review were invited to complete the feedback questionnaire. We received nine completed feedback forms, a response rate of 50%. The replies were anonymised and shared in confidence with one of the Panel clinicians to collate and analyse. The rationale for this approach was to allow an independent analysis of the feedback that related largely to the meeting with the moderator (and author of the report).

### Specific feedback on the women's meetings with the Moderator

- 9.59 This part of the feedback relates to questions 1-8, with options to rank as 'Poor', 'Fair', 'Good', 'Very Good' or 'Excellent'. The results are summarised below.

- 9.60 At your first meeting, how good was the Moderator at:

**Q1 Making you feel at ease** (*introducing herself, explaining her position, being friendly and warm towards you, treating you with respect; not cold or abrupt*)

Of the 9 responses received: 8 chose 'excellent' (89%); 1 chose 'very good' (11%).

**Q2 Letting you tell your "story"** (*giving you time to fully describe your condition in your own words; not interrupting, rushing or diverting you*)

Of the 9 responses received: 8 replied as 'excellent' (89%); 1 chose 'very good' (11%).

**Q.3 Really listening** (*paying close attention to what you were saying*)

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<sup>310</sup> See: [The CARE Measure Website \(stir.ac.uk\)](https://www.stir.ac.uk/care/) [Accessed April 24 2023]

Of the 9 responses received: 8 replied as 'excellent' (89%); 1 chose 'fair' (11%).

**Q.4 *Being interested in you as a whole person*** (*asking/knowing relevant details about your life, your situation; not treating you as "just a number"*)

Of the 9 responses received: 8 replied as 'excellent' (89%); 1 chose 'very good' (11%).

**Q.5 *Fully understanding your concerns*** (*communicating that he/she had accurately understood your concerns and anxieties; not overlooking or dismissing anything*)

Of the 9 responses received: 8 replied as 'excellent' (89%); 1 chose 'poor' (11%).

**Q6 *Showing care and compassion*** (*seeming genuinely concerned, connecting with you on a human level; not being indifferent or "detached"*)

Of the 9 responses received: 9 replied as 'excellent' (100%).

**Q.7 *Being positive*** (*having a positive approach and a positive attitude; being honest but not negative about your problems*)

Of the 9 responses received: 8 replied as 'excellent' (89%); 1 chose 'fair' (11%).

**Q8 *Explaining things clearly*** (*fully answering your questions; explaining clearly, giving you adequate information; not being vague*)

Of the 9 responses received: 8 replied as 'excellent' (89%); 1 chose 'poor' (11%).

9.61 Of note, all the more negative responses were from the same participant.

### **More general feedback on the Case Record Review Process**

9.62 Two additional free text questions were also asked to try and ascertain how useful the women had found the process as a whole:

**Q.9** *What have you found **most valuable** about this process?*

**Q.10** *What do you think **could be improved** about this process?*

### **Themes identified around perceived value of the process (Q9)**

- 9.63 The most commonly reported theme was of feeling “listened to”. Related themes were feeling “understood”, feeling “heard”, “not being dismissed” being “encouraged to ask questions and share my concerns and expectations”, being “treated with dignity and respect”, and having the opportunity to “share my experience”. Women reported experiencing the Moderator as “available”, “interested”, “compassionate” and “not paying lip service”.
- 9.64 One woman reported a sense of closure and being able to “*move forward with my life*”. Two women reported finding it helpful to have answers to specific questions that she had for the Panel about her mesh removal, and one reported finding it useful to have “*some things [she] suspected confirmed*”.
- 9.65 One woman said that she was grateful that the Panel had specifically written in her report of the recognition of the physical and emotional challenges that the women had experienced. Another reflected that “*the Panel left no stone unturned when they reviewed my case notes*” and that the “*integrity*” of the Panel has helped her to cope with her report, parts of which were upsetting for her to read. One woman reflected on her follow-up meeting with the moderator and one of the clinicians from the Panel, after receiving her report as “*clarif[ying] things further, which I appreciated*”.
- 9.66 One woman commented on finding the objectivity of the Panel useful in the review of her case records, “*having someone not directly involved in my care casting an eye over what has been written in my notes*”.

***Themes identified around suggestions for improvement of the process (Q10)***

- 9.67 Whilst one woman felt no improvements could be made, with the “*process work[ing] well and effectively*”, the majority of women offered suggestions for how it could be improved.
- 9.68 Particularly negative feedback about the process was received from one woman: she felt that being involved in the Case Record Review had further eroded her trust in the medical profession (and others), and found the process of re-living her mesh journey re-traumatising.
- 9.69 The most common theme expressed by the women was frustration at the length of time the process had taken from invitation to be involved, to receipt of their final report.
- 9.70 One woman reflected on how she had felt “*exposed*” after her full medical records were requested from birth, and reflected that in retrospect a targeted more relevant selection of her case records would have been adequate to undertake this work.
- 9.71 Three women specifically mentioned the challenges of having to have the meetings online via the ‘Zoom’ platform during the Covid19 pandemic, and one expressed concern for how computer-literacy might have impacted on confidence or engagement with the process. This was in direct contrast to it being “*absolutely amazing to have the last meeting face to face*”.
- 9.72 Some women expressed disappointment at the content of their final report, whilst acknowledging that it could only contain the “*black and white*” information available to the Panel to review. One woman suggested that a separate section within the report may have been helpful, that contained their account of the information that had been shared verbally, but was not mentioned in their case records, as “*this is our truth*”.
- 9.73 One woman expressed a desire to know “*what, if anything, has changed as an outcome of this review?*”. Another expressed a hope that the knowledge and understanding gained by the moderator during the process would be “*put to good use*”, offering specific suggestions to support women through “*informal patient support/help group, podcasts, holistic therapies, PIP [benefit] advice, dietary advice.*”



## ANNEX 1 – DOCUMENT TEMPLATES

University for the Common Good



22<sup>nd</sup> February 2021

By Email

**Invitation from the moderator to participate in the Transvaginal Mesh Case Record Review**

Following on from the Cabinet Secretary for Health and Sport's letter of 10<sup>th</sup> February 2021, this is a personal invitation to ask you whether you would like to take part in the Review. With this invitation, I have included a form which provides some further detail on what the Review will involve and how it will be progressed.

The Review aims to provide clarity on individual case records and the mesh removal procedure performed by providing an opportunity for you to set out your concerns, to have your records reviewed and to allow for discussion, explanation and mutual understanding.

If you choose to participate, a consent sheet is also included at the end of the form which I would be obliged if you would return to the review administrator, Irene Brown. Irene's email is [Irene.Brown@gcu.ac.uk](mailto:Irene.Brown@gcu.ac.uk). Your participation in the Review is entirely voluntary and if you do not want to take part then you need to do nothing further.

Further information about the Review can also be found on the website- <https://tmcrr.scot> Please note that we are currently revising the '*structure and process*' section of the Terms of Reference and I will keep all participants advised on this progress personally and through the '*updates*' tab of the website. I am grateful to all of those who have shared their comments or been in touch with me.

If you would like to participate in the Review and once we have received your completed consent form, I will write to you again to invite you to an initial meeting with me to discuss the review process and to address any questions that you may

have. It is important that you feel supported and comfortable during these meetings you are therefore welcome to bring someone of your choice to accompany you.

Due to our current circumstances, this will need to take place virtually. Please let us know if you have any concerns about using technology for this stage of the process.

Finally, I wish to express my thanks to you in advance and promise that if you decide to participate in the Review, I will listen and, along with the members of the Review Panel, we will aim to provide clarity and answers.

Yours sincerely

A handwritten signature in cursive script that reads "Alison Britton". The signature is written in black ink and is positioned above the printed name and title.

**Alison Britton**

**Moderator Transvaginal Mesh Case Record Review**

Professor of Healthcare and Medical law, Glasgow Caledonian University

## Transvaginal Mesh Case Record Review

### Participant letter and consent form



#### **Why have I received this?**

You have received this letter because you attended a meeting with the First Minister in November 2019. You are now being invited to take part in the Transvaginal Mesh Case Record Review.

#### **Why has this review been set up?**

The Scottish Government has arranged this review following the meetings with the First Minister in November 2019. During the meetings, women raised concerns that entries in their case records may not accurately reflect the treatment they had received.

#### **What will the review look at?**

The Review Panel will look at your concerns about information in your case records and how the entries in your records have been reported to you, specifically about whether your mesh was fully or partially removed.

You will be given a participant form to fill in to provide your concerns in advance, and those concerns will provide the basis for your review.

The review will involve an open discussion, where your case records will be explained and considered.

#### **What won't the review look at?**

This is not intended as a review of your overall experience and full medical history. It will focus on your concerns about the full or partial removal of mesh and how this has been recorded in your case records.

If you are concerned about any other part of your care or treatment, you should contact your health board. The Review Panel administrator can give you details of how to do this. Taking part in this review does not affect your rights to raise a complaint with your health board or start any legal proceedings.

The Review Panel will not make any specific recommendations for further treatment. You should continue to see your GP and other healthcare professionals to make sure you receive appropriate care.

### **Do I have to take part?**

No. The review is voluntary and it is up to you to decide whether or not you think this would be helpful to you. If you want to take part in the review, fill in and return the consent form enclosed with this letter. If you do not want to take part, you do not need to take any action.

### **Who will be on the Review Panel?**

The Review Panel will be made up of the following people.

- **Moderator**  
Alison Britton, Professor of Healthcare and Medical Law, Glasgow School for Business and Society, Glasgow Caledonian University
  
- **Administrator**  
Irene Brown, Administrator, Directorate of School Professional Services, Glasgow Caledonian University
  
- **Clinicians**  
Professor Anthony Smith, Professor of Urogynaecology (Manchester Academic Health Sciences Centre), consultant gynaecologist (retired)  
  
Mr Ian Currie, Consultant Obstetrician & Gynaecologist, Buckinghamshire Hospitals NHS Trust  
  
Dr Carey Lunan, GP, Scotland

### **How have the Panel members been chosen?**

The Review Panel members have been chosen based on their individual qualities, expertise, knowledge, authority and standing.

### **What will the review involve?**

If you return your consent form to confirm that you want to be part of the review, you will be sent a participant form to fill in. That form will ask you to set out your main concerns and the evidence you would like reviewed.

It is important that you feel supported throughout this process. The Scottish Independent Advocacy Alliance can provide support, and we encourage you to use their service if you need help with any part of the review process. An advocate from the Scottish Independent Advocacy Alliance will be able to support you in expressing your concerns and filling in the participant form. If you would like to use this service, please let the administrator know.

### **What happens after I fill in and return the consent form?**

You will be invited to a 'virtual meeting' with the moderator to discuss the review process. Please tell the administrator if you have any concerns about using technology for this stage of the process.

The virtual meeting will be held online.

After the virtual meetings, the moderator will ask the relevant health boards to provide the evidence the Review Panel needs to look into your concerns. The healthcare professional responsible for your case records will be asked whether they would like to give their own opinion and address your concerns. All information that identifies you will be removed by the health boards.

The moderator will then invite you to join in another virtual meeting, to make sure that the Panel have the relevant case record entries from the health boards. Once you have confirmed this, the records will be passed to the Review Panel. Each clinician on the Review Panel will check the records separately and fill in a form to set out their understanding of the records.

The full Review Panel will then meet to discuss the records and reach a decision about how accurate your records are.

After the decision is reached, you and anyone supporting you will meet with the moderator, the administrator and one clinical member of the Review Panel so the decision can be explained to you and the records can be discussed. It is expected that this will also be a virtual meeting.

The findings of the review will also be clearly set out in a report that will be sent to you and the health board. You will have the opportunity to comment on this report after you have carefully considered it.

Finally, the moderator will write to you to ask you for feedback on the review process. Your feedback will help influence future reviews.

### **What information will not be shown in my case records?**

Any information which identifies you or others, such as names, addresses and dates of birth, will be removed from your records. So the Review Panel will not know whose case records they are looking at (until you meet with them) or who the healthcare professional responsible for the records is.

Your CHI number (which is your unique identification number for the NHS) will be left on your records to make sure that the moderator and administrator can link your records with your participant form.

### **Can I bring someone with me?**

Yes, you are encouraged to bring someone with you for support. An advocate from the Scottish Independent Advocacy Alliance can also support you. If you would like support from an advocate, please let the administrator know.

Making sure that you have the support you need is an important part of the review process.

### **Can I change my mind about taking part?**

Of course. The review is entirely voluntary and you can stop taking part in it at any time.

### **What will happen if the Review Panel thinks my case records are not accurate?**

If the Review Panel thinks that your case records do not accurately reflect the treatment you received, they will send their report on the review to your health board for them to consider. The entry relating to your case records will be flagged so that those involved in your future care can see that you have been involved in the review. In all cases, the report will be added to your medical records.

### **Who will have access to my case records?**

The five members of the Review Panel will have access to your records during the review.

Confidentiality is a priority, and your details will be kept private. There are arrangements in place to make sure that there is no unauthorised access to your information.

If you ask to see the personal information we hold about you, another authorised member of staff within Scottish Government may need access to your information.

More information about how your personal information can be used is given in our privacy notice. This is on our website at <http://tmcrr.scot> or you can ask us for a copy.

### **What happens if I'm not happy with the review?**

You will have an opportunity to raise any comments and questions about the review with the Review Panel. If you are not happy with the Panel's final response to your comments and questions, you can make a complaint to Scottish Public Services Ombudsman (SPSO).

If you have any other complaints about your case records, or about the care and treatment you have received, you should contact your health board. The administrator will give you the information you need to do this. If you are unhappy with your health board's response, you can ask the SPSO to consider your complaint.

**Can I speak to the media about the case record review?**

You are asked not to speak to the media about this review until the entire process has ended. This is to make sure that media coverage does not harm the review for other participants.



### Consent form

#### Your details

Full name:		
Address:		
Date of birth:		

By signing below and returning this form you are confirming that you want to take part in the Transvaginal Mesh Case Record Review.

Your signature:	
Date:	

#### Permission to release information to a third party

To carry out a comprehensive review, the Review Panel will need to see your medical records. The Panel members have a legal duty to keep your information confidential.

By signing below you are:

- giving NHS [BOARD NAME: ] permission to pass your medical records to the Review Panel so they can carry out the Transvaginal Mesh Case Record Review; and
- confirming that you do not object to the Review Panel seeing your confidential medical records.

Your signature:	
Date:	

## Transvaginal Mesh Case Record Review

### Participant form



Name:

CHI number:

Your health board:

By returning your consent form, you confirmed that you want to take part in the Transvaginal Mesh Case Record Review. This review is entirely voluntary. If you have changed your mind about taking part, you do not need to fill in and return this form.

This form is for you to set out your concerns and the evidence the Review Panel need for the review. It is important to remember that the review is not intended to look into your overall experience and full medical history. It will look into your concerns about the full or partial mesh removal and how this has been recorded in your case records.

If any concerns you have about your mesh removal are not covered by the questions in this form, please write these concerns in the section provided for this on page 3.

The information you provide in this form will be given to the Review Panel. The Review Panel will do their best to answer the concerns you raise and will explain the

entries in your case records. The Review Panel will focus on what has been reported in your case records about your mesh removal, and any further information which makes you think that your records are inaccurate.

It is important that you feel supported while taking part in the review. The Scottish Independent Advocacy Alliance can support you throughout the review process. If you would like their support when filling in this form, the administrator can put you in touch with them.

**Your concerns**

Where did you have mesh removal surgery and when?  
(Give all dates if you have had surgery more than once.)

What are your concerns about your mesh removal?

What information makes you think that your case records, or correspondence about your mesh removal, are incorrect?

What evidence do you think the Review Panel needs to see?  
(Please be as specific as possible. If you can provide dates – accurate or approximate – this will help the Review Panel get the correct information from your health board.)

**Further information**

If you have any other concerns about your mesh removal that have not been covered in the questions above, please give details below.

**Your signature**

Sign below to confirm that you understand that the information in this form will be used for the review and the relevant health boards will be asked to provide the relevant entries in your medical records.

Signature:.....

Date:.....

Thank you for taking the time to fill in this form.

When the review has ended, we would like your feedback on your experience of the review. The feedback will influence future reviews.

Are you are happy for us to contact you for feedback?

Yes

No

A report on the overall process will be published. In this report we would like to include references to the concerns raised by participants. **All the information in the report will be completely anonymous.**

Are you are happy for anonymous information about your concerns to be included in the final report?

Yes

No

Answering no to the questions above will not affect your participation in the review.

Please return this form to Irene Brown, at (EMAIL ADDRESS), by [DATE].

## ADVOCACY TEMPLATE

***‘Advocacy means getting support from another person to help you express your views and wishes, and help you stand up for your rights. Someone who helps you in this way is called your advocate.’***

<https://www.mind.org.uk/information-support/guides-to-support-and-services/advocacy/what-is-advocacy/>

***‘The role of an advocate is to offer independent support to those who feel they are not being heard and to ensure they are taken seriously and that their rights are respected. An advocate will ensure a person has the tools to make an informed decision; it is not about making the decision for the person.’***

<https://www.ageuk.org.uk/wp-assets/globalassets/leeds/original-blocks/get-involved/volunteer/the-role-of-an-advocate-1.pdf>

### Introduction

Advocacy is part of everyday life. It is an ordinary activity. Many of us will at some point in our lives look to the support of someone we trust to help us speak up for ourselves to get our voice heard about decisions or actions that affect our lives. Even the most confident and articulate among us can feel less able to cope when we are ill or feeling under pressure. In these circumstances it can be difficult to ask questions about our concerns. It is at these times that the support of an advocate can make all the difference to someone's quality of life.

Having an advocate can help someone feel more supported and confident in being able to share their story with us, based on their own wishes and views.

On behalf of the panel and all of those involved in the Case Record Review, we would like to express our thanks to you for supporting the participant that has asked you to be their advocate.

It can be helpful to discuss the main issues of concern with the participant beforehand so that that you both feel clear about what the priorities are for the participant. Any questions that the participant would like answered can also be listed, as this can be a useful *aide memoire* on the day.

### ***Conflicts of interest***

As we have said, advocacy plays an important role in supporting people to express their views and in providing a source of support which gives them the confidence to speak out. Advocacy is vital in nurturing trust and effectively supporting people to ensure their views are considered and that they are heard. It should also provide an environment in which they can confidently raise any concerns they may have with their advocate in the knowledge that there are no conflicts of interest. As part of the Case Record Review process, during the first interview, we will routinely ask the participant if they would also like the opportunity to speak to us in private (ie without the advocate present) as this is considered good practice.

One of the most important elements of performing an advocacy role is that you are as independent and impartial as possible from the situation. As a Panel we regularly review and declare any potential conflicts of interest as part of this process. We are keen to follow the same principles for those in the important role of advocate, and we would be grateful if you could consider the following questions and share any potential conflicts of interest at the start of the process. This helps us to ensure that we are all acting in a way that is open and transparent, and in the best interests of the participant.

1. Is your relationship to the participant professional or personal?
2. Are you gaining any financial benefit from undertaking this role as the participant's Advocate or receiving income that could reasonably raise an expectation of a conflict of interest with your duties of independence and impartiality as an advocate?
3. Have you personally received any form of medical treatment which forms the subject of this Review (i.e. transvaginal mesh surgery) that could reasonably raise an expectation of conflict of interest with your duties as an independence and impartiality as an Advocate?<sup>311</sup>

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<sup>311</sup> See: <https://www.mind.org.uk/information-support/guides-to-support-and-services/advocacy/what-is-advocacy/#:~:text=Advocacy%20means%20getting%20support%20from,way%20is%20called%20you%20advocate> [Accessed May 13 2021]



# Transvaginal Mesh Case Record Review

## Consenting to your case records being disclosed – some questions answered

### Why do my case records need to be disclosed?

Your case records contain personal, sensitive information. They can only be disclosed (shared with others) with your permission. If you decide to take part in the case record review, your records are an essential part of the review as they contain evidence of your medical treatment and your experience with transvaginal mesh.

### How will my case records be shared?

Your case records are held by the healthcare provider responsible for your treatment – whether that is your GP or the hospital. They will send your records to a professional case records consultancy, Clinco, for them to turn into a standard format for the review. You can find out more about Clinco from their website at [www.clinco.co.uk](http://www.clinco.co.uk).

### What measures are in place for the records to be kept safely?

Clinco is accredited to ISO27001, which is an international standard in data protection. Your records will be processed in line with an information-security system.

### Will the case records be made anonymous before being reviewed?

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See: <https://www.ageuk.org.uk/bp-assets/globalassets/leeds/original-blocks/get-involved/volunteer/the-role-of-an-advocate-1.pdf> [Accessed May 13 2021]

The Health Board will try to remove names and identifying information from the case records, but these appear many hundreds or thousands of times in a set of records and are often handwritten.

### Who will be able to read my case records?

Clinco and all three clinicians on the Review Panel will read the records for the purpose of preparing your individual report. The Moderator and Administrator may need to read all or part of the records to get a clearer understanding of the issues which will arise in the course of the review.

### Who will be able to read any reports or other documents arising from or referring to my case records?

The Review Panel will keep any comments, background information or feedback you provide confidential. Your specific concerns, in your own words, will be made available to Clinco.

The written report on your case will be made available to you. You will then discuss it with the Moderator, Administrator and one clinician on the Review Panel. Once the report has been finalised, to take account of your discussions, a copy will be placed with your case notes (if appropriate).

### What happens to my case records once the review is over?

Printed copies will be securely shredded and digital copies will be permanently deleted.

### I think I'd like to take part – what happens next?

Ask any further questions, to make yourself sure that you'd like to take part in the review. You can ask the administrator or moderator by email at [irene.brown@casrecordreview.scot](mailto:irene.brown@casrecordreview.scot). If and when you feel ready, you can also email [this mailbox](#). to confirm you want to take part. After this, you will be sent a form for you to provide information about your case. You will be asked to say where you received transvaginal mesh treatment, and the specific issues which arose in connection with that treatment.

Once you have returned the filled-in form to the Administrator, you will receive a letter asking you to agree to Clinco getting your case records.

**Can I change my mind and withdraw my consent?**

You can withdraw your consent at any time by emailing [irene.brown@caserecordreview.scot](mailto:irene.brown@caserecordreview.scot). Your case records will then be shredded.



# Transvaginal Mesh Case Record Review

## Consent for GP to disclose case records

To (address of GP surgery):

.....  
.....  
.....

Patient details	
Name	
Date of birth	
Address and postcode	

Dear Dr.....,

I agree to you sending copies of my full case records, including all consultation records, out-of-hours records, test results and other correspondence, to Clinco at:

**Clinco**  
**Innovation House**  
**Discovery Park**  
**Sandwich**  
**Kent**  
**CT13 9ND.**

If you prefer, you can email the records to [sharonphilpott@clinco.co.uk](mailto:sharonphilpott@clinco.co.uk).

I confirm that I am giving my permission for you to release my health records and that I know how they will be used.

Thank you for your help.

Signature: .....

Date: .....



# Transvaginal Mesh Case Record Review

## Consent for hospital to disclose case records

To (hospital address):

.....

.....

.....

Patient details	
Name	
Date of birth	
Address and postcode	
Hospital number	

I agree to you sending copies of my full case records, including all clinical, nursing and surgical records, test results, imaging, correspondence and internal investigation records, to Clinco at:

**Clinco**

**Innovation House**

**Discovery Park**

**Sandwich**

**Kent**

**CT13 9ND.**

If you prefer, you can email the records to [sharonphilpott@clinco.co.uk](mailto:sharonphilpott@clinco.co.uk).

I confirm that I am giving you permission to release my health records and that I know how these will be processed.

Thank you for your help.

Signature: .....

Date: .....







# Transvaginal Mesh Case Record Review

## Your information and specific concerns

Your personal details	
Name	
Date of birth	
Address and postcode	

Details of your GP	
GP's name	
GP practice address and postcode	

Details of the hospital where you underwent transvaginal mesh treatment	
Hospital name	
Hospital address and postcode	
Your hospital number	
Period of treatment	From: To:

Details of any other hospital where you received transvaginal mesh treatment or aftercare	
Hospital name	
Hospital address and postcode	
Your hospital number	

Period of treatment	From: To:
Brief details of treatment	

In the boxes below, briefly summarise any issues you had with the following.

**Before treatment**

The information provided by healthcare professionals	
The process of giving consent	
Any other issue	

<b>The treatment</b>	
The type of mesh implant used	
The choice of surgery	
The standard of surgical care	
Any other issue	
<b>After treatment</b>	
The standard of aftercare	
The information provided by healthcare professionals	
Any other issue	
<b>Mesh removal or other remedial treatment</b>	
The extent of the removal	
The standard of surgical care	
Any other issue	
<b>Any other comments about your treatment</b>	

In the boxes below, please summarise any concerns you have about the following.

**The completeness of your case records**

**The accuracy of your case records**

**Any other aspect of your case records**

# CLINICAL PROFORMA

Participant CHI:

--

Panel Member:

--

Date:

--

What are the concern(s) raised by the participant – summary?

- The completeness of the case records
- The accuracy of the case records
- Any other aspect of the case records

What evidence does the participant want the Panel to review?

**Before treatment –**

- The information provided by Healthcare professionals
- The process of giving consent
- Any other issue

**The treatment –**

- The type of mesh implant used
- Options regarding treatment
- The standard of surgical care
- Any other issue

**After treatment –**

- The standard of aftercare
- The information provided by Healthcare professionals
- Any other issue

**Mesh removal or other remedial treatment –**

- The extent of the removal
- The standard of surgical care
- Any other issue

What are your findings based on the case records?

--

Are the concern(s) raised supported by the evidence?

--





**Declaration of Interests Form**

Transvaginal Mesh Case Record Review

Please ensure that this form is completed with all interests that may be relevant, regardless of timescales.

I, [FULL NAME], as a member of the Transvaginal Mesh Case Record Review Panel, hereby declare my private and business interests as at (date) \_\_\_\_\_ are as follows:

Potential Conflict of Interest	Yes/No	If Yes, Please Provide Details
<p>Sources of Income:</p> <p>Do you receive income from outside your employer and Scottish Government that could reasonably raise an expectation of a conflict of interest with your duties of independence and impartiality as part of the review Panel?</p>		
<p>Office Holder:</p> <p>Do you hold office in a public or private organisation that reasonably raises an expectation of a conflict of interest with your duties as part of the review Panel?</p>		
<p>Trusteeships:</p> <p>Are you a Trustee or a Director of any trustee company in which a member of your family is a beneficiary that could reasonably raise an expectation of a conflict of interest with your duties as part of the review Panel?</p>		
<p>Agreements:</p> <p>Are you, or a member of your immediate family, party to any contract, agreement or understanding that gives rise to an obligation or an expectation of reward that could reasonably raise an expectation of a conflict of interest with your duties as part of the review Panel?</p>		

Transvaginal Mesh Case Record Review

<p>Other Interests:</p> <p>Do you, or any member of your immediate family, hold any other substantial financial or other interest that could raise an expectation of a conflict of interest with your duties as part of the review Panel?</p>		
<p>Director's Duties:</p> <p>Have you ever been disqualified from acting as a Director, or acting in the management of a company?</p>		
<p>Medical Interests:</p> <p>Have you, or any member of your immediate family, been subject to any form of medical treatment which forms the subject of this review which could raise an expectation of a conflict of interest with your duties as part of the review Panel?</p>		

I, [FULL NAME], hereby declare that to the best of my knowledge and belief the information I have provided above is true and correct.

I undertake to advise fellow members of the review Panel in writing if a conflict or potential conflict of interest arises during the course of this review and, if it is considered appropriate by the Panel, to thereafter stand down in any decision making process in which I may be compromised.

I understand that this information will be published on the Case Record Review website.

Signature:

Date:

### Evaluation and Feedback for the Case Record Review

Please mark **X** in the box for the response that best applies for Q1-8. Q9-10 are for your own words. Please answer all questions if you can.

At your first meeting, how good was the Moderator at:	Poor	Fair	Good	Very Good	Excellent
Q1 <b>Making you feel at ease</b> (introducing herself, explaining her position, being friendly and warm towards you, treating you with respect; not cold or abrupt)					
Q2 <b>Letting you tell your "story"</b> (giving you time to fully describe your condition in your own words; not interrupting, rushing or diverting you)					
Q.3 <b>Really listening</b> (paying close attention to what you were saying)					
Q.4 <b>Being interested in you as a whole person</b> (asking/knowing relevant details about your life, your situation; not treating you as "just a number")					
Q.5 <b>Fully understanding your concerns</b> (communicating that he/she had accurately understood your concerns and anxieties; not overlooking or dismissing anything)					
Q6 <b>Showing care and compassion</b> (seeming genuinely concerned, connecting with you on a human level; not being indifferent or "detached")					
Q.7. <b>Being positive</b> (having a positive approach and a positive attitude; being honest but not negative about your problems)					

Q8. <b>Explaining things clearly</b> (fully answering your questions; explaining clearly, giving you adequate information; not being vague)					
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Q.9 What have you found **most valuable** about this process?

Q.10 What do you think **could be improved** about this process?

**Thank you for taking the time to complete this evaluation.**



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