PE1517/SSSS
Cabinet Secretary for Health and Sport submission of 17 February 2021

When I became Cabinet Secretary for Health and Sport I was determined that issues concerning transvaginal mesh, and the women harmed by its use, would receive the attention that they deserve. This is reflected by the fact that a very early action I took was to announce a complete halt to the use of transvaginal mesh in Scotland. That halt has remained in place and, in the time since I announced it, the difficulties faced by the women have remained a key focus of my attention.

As the end of this session of the Parliament approaches, I want to offer a report on the actions, in addition to the halt, that the present Scottish Government has taken in respect of transvaginal mesh and the progress that has been made since the Chief Medical Officer and I last wrote to you in November 2020.

Specialist Pelvic Mesh Removal Service

As I set out in my letter of 27 November, NHS Scotland has established a national specialist service for women who have suffered complications arising from use of transvaginal mesh. This new service, which is being funded for the first three years by the Scottish Government is being delivered by a Multi-Disciplinary Team (MDT) located within NHS Greater Glasgow and Clyde. The service assesses women's needs and, where appropriate, and subject to shared decision making and informed consent, performs mesh removal surgery. The establishment of the service was unavoidably delayed by the COVID-19 pandemic, but a number of patients have received mesh removal surgery, and the service will now develop and expand further.

The service is intended to be holistic in nature. It will take account of social as well as health needs, and it will benefit from additional dedicated staff including specialist nursing, physiotherapy, pain management, pharmacy, clinical psychology and administrative support. I can also confirm that there will be four uro-gynaecology consultants employed within the new service by the end of February 2021, and they will make an important contribution to the MDT.

Clinicians in our specialist service are developing close working relationships with colleagues in similar services being established by NHS England. This will provide the opportunity for "benchmarking" through comparison of outcomes, direct observation, peer review, and development of consensus with regard to the indications, risks, benefits and techniques associated with full and partial mesh removal. This collaboration will continue as the services in other parts of the UK are introduced. There is also agreement by those involved that patient information and decision aids must reflect this collaboration and the consensus reached. The National Institute for Health and Care Excellence (NICE) has rightly gained recognition for expertise in this area and they are leading on this work which involves patient representation. Scottish clinicians have also contributed. It is intended that the same information and decision aids will be used throughout the NHS and by all patients in the four nations. Officials will also take forward development of a patient focused "map" of their care pathway. This will be created from a patient perspective

with signposting to assist navigation. I think this will be an important and complementary addition to other work.

Additional Treatment Options

Our new service will enable women to access the treatment that they want and need in Scotland and as close to home as possible. However, and as your committee has rightly observed, there are some women who – as a result of the trauma they have experienced – do not wish to be treated here. With the measures outlined here, I do sincerely hope that women and their families will feel confident and safe in the new NHS Scotland service. But I also agree with the Committee that, in these circumstances, alternative arrangements for care should be available, so that all patients are able to receive the treatment they need.

The development of links between the Scottish specialist service and the equivalent service in England will mean that any woman who expresses a preference to be treated outside Scotland will be able to request referral to the English NHS service. NHS England has recently confirmed the location of the specialist centres that will form this service and it is expected that other designated centres will follow.

Exceptionally, and as I confirmed in November, the Scottish Government and NHS Scotland are taking steps to provide an additional option for patients that will include the possibility of referral outside the NHS, which includes the possibility of referral outside the UK.

I can confirm that NHS National Services Scotland (NSS) intends, at the earliest opportunity, to issue an invitation to tender for specified mesh removal services. The process will follow standard commissioning procedures set by NSS, whereby all applications wil be assessed by a Clinical Advisory Panel (CAP), and will be open to relevant centres in the UK and abroad. All applications will require supporting evidence of necessary standards in relation to quality of care and patient safety. Integration of surgery with pre- and post-operative care will be essential and I am clear that treatment that does not involve engagement and collaboration with a responsible MDT will not be acceptable.

Credentialing

In light of concerns that have been raised in the Parliament and elsewhere, I have written to the General Medical Council (GMC) and the Royal College of Obstetricians and Gynaecologists (RCOG) to express my support for work, already underway, to introduce a GMC approved credential in mesh removal surgery.

Credentialing will define the skills required to perform mesh removal surgery, and set out how these skills can be acquired and assessed. By formally recognising the skills of our surgeons, credentialing will provide assurance for the service, reassurance for patients, it will reduce the risk of harm and it will help improve public confidence. Introduction of an approved credential is therefore a priority and officials will monitor progress closely.

Patient Engagement

The importance of lived experience cannot be overstated and I am clear that patient voices must be listened to as we develop the new specialist service and wider NHS support for women in Scotland. As a consequence and building on learning gained from their earlier report, *My Life, My Experience*, the Health and Social Care Alliance ('the Alliance') has been commissioned to work with women so that we can secure a better understanding of their needs, wants and concerns. In turn this will facilitate co-design of the new service and as issues are addressed and resolved, I hope trust and confidence will increase.

In December last year the Alliance met with patients who were recently treated in the new centre in Glasgow. A further focus group meeting was held last month, on 28 January. This second meeting was intended for a broader cohort of women with mesh complications and it was held in conjunction with an online survey which closed on 7 February.

The findings from this work are awaited but, as noted above, they will be used to help shape and refine the new service. However, this will not be the end to patient involvement. The Scottish Government will ask the Alliance to establish a stakeholder participation group which will continue to gather views on the specialist service and these will be considered in conjunction with the results from patient satisfaction surveys as well as other relevant outcome data. Information gathered from these linked sources will not only be important in quality assurance but it will also advise measures necessary for quality improvement.

Case Record Review

I have announced commencement of the case record review, as set out in detail by the Chief Medical Officer in his 27 November letter. Details of the panel conducting the review are provided at https://tmcrr.scot/ This review has been instituted in response to concerns expressed by some women who believed from entries in their case records that they had undergone full removal of mesh, but later discovered they had only had a partial removal. The review will give women the opportunity to set out their concerns and to have their records reviewed by an independent panel of clinicians. The findings will be discussed with individual women and this is intended to promote mutual understanding.

The review will initially be offered to women who attended meetings that the First Minister and I held in November 2019. However, after careful evaluation, consideration will be given to offering a review based on a similar model, to a broader group of women with concerns relating to use of transvaginal mesh.

Mesh Fund

Last year, the Scottish Government established a £1 million fund to help women who have experienced transvaginal mesh complications. This opened for applications on 1 July 2020 and successful applicants receive a one-off payment of £1,000 to help towards the costs associated with emotional or practical support. The views of

women were key to our approach and I hope this fund goes some way to helping women affected. Over 400 applications have been received to date.

Public Inquiry

I have given careful consideration to the calls for a public inquiry. Indeed, I recognise this was one of the requests made by the petitioners in 2014 and I do understand why many feel that this course of action is justified. However, in light of of the actions already taken by the Scottish Government and, mindful of the comprehensive investigation conducted in the course of the Independent Medicines and Medical Devices Safety Review (IMMDS), I do not believe that a further inquiry is now warranted. In reaching this conclusion I am in agreement with Baroness Cumberledge and the reasoning detailed in her IMMDS Review. I do not think a public inquiry conducted now will add materially to our knowledge or understanding of the issues and may in reality duplicate work already completed by the Baroness and her inquiry team.

In conclusion, I hope that I have demonstrated my determination to ensure that the women affected by transvaginal mesh complications are listened to, and decisive action is taken. By establishing a new national specialist service, and through co-design, we intend to provide care for women of the highest quality. We will work to build trust and confidence and we will ensure the skills of our surgeons are recognised. For women who feel they cannot use our service and whose concerns cannot be reconciled, we will offer alternative pathways for care. I also hope that, through the case record review, we can bring better understanding and a degree of resolution for women with particular and important concerns. Finally, we have acted to help alleviate financial hardship.

Taken together, I hope the Committee will agree that the package of measures and series of initiatives I have set out here is both comprehensive and coherent. This will improve the quality of care and services, not only for women harmed by transvaginal mesh but, by influencing the health service more generally, all patients will benefit. This will be the enduring legacy of the tireless, dignified and commendable campaigning by the women harmed by transvaginal mesh and the support given to them by your committee.

I am copying this letter to the Health and Sport Committee.

Jeane Freeman