

## Surgical Mesh

Sarah Wollaston Chair, Health and Social Care Committee, Chair, Liaison Committee (Commons)

I pay tribute to the many women, including those in my constituency, who have come forward to discuss deeply personal and painful accounts of serious complications following mesh surgery, sometimes with life-changing and lifelong consequences for them and their families. I also thank Emma Hardy who, as always, has set out the background to the issue so eloquently. She has been such a campaigner on behalf of victims, and I really thank her for what she is doing. I will not repeat much of the background that she set out, but I will highlight a few points to which I hope the Minister will respond in her closing remarks. As we have heard, NHS Digital has published a review of patients who have undergone urogynaecological procedures for prolapse or stress urinary incontinence, including those where mesh, tape or equivalents were used. However, as the hon. Lady pointed out, the review does not cover all procedures, nor does it include the men who have been affected. We know that 100,516 women underwent these procedures between 2008 and 2016, of which 27,016 cases involved mesh for prolapse. Although the numbers are falling, I am afraid that this is just a snapshot.

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Sarah Wollaston Chair, Health and Social Care Committee, Chair, Liaison Committee (Commons)

I was about to come to that very point. Crucially, many of the women I have met have been treated in the private sector. In this House, we should be concerned about all our constituents, not only those who are treated in the NHS. Of course, it is the NHS that often then bears the burden of managing complications, but we must have a much more accurate picture. I support the call from the Royal College of Obstetricians and Gynaecologists and from the British Society of Urogynaecology for mandatory prospective data collection, using the BSU's database. That is a well-established method of collecting outcome data. Retrospective snapshots are no substitute for collecting data as we go forward or, most importantly, for being able to track it in the long term. Although the majority of complications that happen after 30 days happen in the first year, many of the women I have met developed complications far later than that. I particularly want to emphasise to the Minister how important it is that we have access to shared databases not just here in the UK, but across Europe. Will the Minister tell us whether the Government will be seeking for us to remain part of the European Database on Medical Devices "EUDAMED" so that we not only get an accurate picture of what is happening here in the UK, where our population is smaller, but can compare our data with the whole European Union? That brings me to the wider point about Brexit that is highlighted in the report of the Select Committee on Health on the implications of Brexit on medicines, devices and substances of human origin: the issue of access to clinical trials. It is encouraging that the Government have stated that they wish to remain a part of the European Medicines Agency or to have associate membership, but there are all sorts of aspects to forward clinical research on which it is essential that the

Government campaign. They must campaign not just to maintain regulatory alignment and harmonisation, but to ensure that we can remain part of all research mechanisms and mechanisms for ensuring that we have the earliest possible awareness of any complications—not just from drugs but, as this situation has shown, from medical devices. I hope that the Minister will further outline the Government’s intention in that regard.

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Sarah Wollaston Chair, Health and Social Care Committee, Chair, Liaison Committee (Commons)

My right hon. and learned Friend is absolutely right, and his point applies not only to medical devices. When it comes to relatively rare conditions, we need to look at the widest possible population base in order to detect any complications. It is also important to use the widest possible population base when detecting rare complications. I thank him for highlighting that.

If we are to have informed consent for women, it has to be based on high-quality, balanced and evidence-based information, and that has been lacking. We also need to be clear that if a medical device is altered in any way, it must be part of a clinical trial. That was entirely lacking in this situation. The types of device, including the size and thickness, were changed without anyone properly recording or following up on those changes. That has to be the key lesson for the future.

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Sarah Wollaston Chair, Health and Social Care Committee, Chair, Liaison Committee (Commons)

I absolutely agree. It strikes me that there has been a kind of wild west out there, with representatives saying, “Why don’t you try this one? This is probably going to be better without organisations setting up clinical trials from the start so that we could compare different devices, and without women giving properly informed consent that a different kind of device would be used. Lessons have to be learned not just for mesh surgery, but for other medical devices. Just because something sounds like it might be better, it does not mean to say that there will not be serious complications. Those complications may also happen at a late stage. We need databases such as EUDAMED so that we have access to the widest possible population base and clear device tracking.

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Sarah Wollaston Chair, Health and Social Care Committee, Chair, Liaison Committee (Commons)

I do agree. As I say, informed consent is essential, and that was lacking in very many cases. There are cavalier attitudes and assumptions that medical devices are somehow safer than medicines, but we know that that is simply not the case. We have to rigorously make sure that devices are all part of clinical trials, with long-term follow-up and tracking. Perhaps the Minister could update us on how we are getting on with the barcoding of devices, which clearly makes them over time. One of the tragedies is that many women are completely unaware that they have even had mesh inserted at all. That, again, has to be a lesson that we learn for the future about accurate documentation. I hope that the Minister will comment on whether there are plans to introduce compensation for victims. As I said, many of the women I have met have had profound, life-changing injuries, and many are entitled to compensation.

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Sarah Wollaston Chair, Health and Social Care Committee, Chair, Liaison Committee (Commons)

I thank the hon. Lady for making that point. Yes, absolutely: the scars have been profound not only in physical terms but in the impact on how people feel about themselves. There is a great impact not only on them but on their families and their relationships. On access to services, while we all welcome a tertiary service being set up for victims of urogynaecological mesh, there is concern about current waiting times for those who wish to have a referral to a tertiary centre, and about access to investigations, which need to be timely. When women come forward to report deeply personal and distressing experiences, it is important that they can be seen as rapidly as possible. I hope that the Minister will comment on that.