

CHECK AGAINST DELIVERY

## PRESS CONFERENCE SPEECH 8 JULY 2020

Good morning.

1. The people of Britain have every reason to be proud of their NHS.

Its response to the pandemic has demonstrated the exceptional care and bravery of staff, but this does not mean that the healthcare system is free from faults.

2. We have reviewed three interventions which have caused avoidable harm to thousands of people. We revealed how the healthcare system in its entirety does not work for some patients. If this Government and the Healthcare system ignores our Review, and another intervention damages people at such a scale, the Government and the Healthcare System will not and should not be forgiven.
3. We have called our report “First Do No Harm”.

Why?

Because it is a well known phrase. Those working in healthcare recognise it as the starting point for good quality care. That should be not only for doctors but for the whole of the system.

**Too often we believe it has not.**

4. Jeremy Hunt, then the Secretary of State, commissioned our Review and asked us to look at three medical interventions.
5. **Sodium valproate**, an effective medication for epilepsy. But still today this medication causes harm to unborn children when their mother, unaware of the risks, takes it when she is pregnant.

**Pelvic mesh**, used to treat pelvic organ prolapse and urinary incontinence.

Many women have suffered terrible complications following their mesh surgery.

**Primodos**, a hormone pregnancy test taken by women between the 1950s and the late 1970s, associated with damage to children, and those children now adults, are still needing care and support

6. At the start of the Review - 2 and a half years ago, - we realised we had to find out first-hand from women and their families, what impact these medications and devices had, had on them.
7. Travelling across the UK we met over 700 women and their families. They made a lasting impression on us.

Their experiences were harrowing. They told us of lives that had been damaged, families under immense strain, relationships destroyed, careers broken, and as a result financial ruin, with no income , , many lost their homes, and faced their children being taken into care.

They spoke of the most intimate details not only about their lives, but about their bodies.

They spoke with such dignity and courage. Above all I want to thank them.

8. Women told us that when pregnant and controlling their epilepsy with Sodium Valproate, they were never told that their unborn baby could be seriously damaged. They did not know that the chances were one in two – one in two damaged babies - what a tragedy.
9. We met women who told us that they were given two little pills called Primodos to confirm whether they were pregnant. Many went on to lose their babies or to give birth to babies who were damaged. Now in their 70s parents still carry the guilt that taking these two pills may have caused this irreparable loss or harm. They agonise as to who will care for their disabled offspring when they no longer can.'
10. We met women whose lives have been turned upside down by mesh. Many were healthy and active but they were offered a quick fix for their incontinence or prolapse. An operation they thought would cure them has ruined their lives. They have lost their independence, their careers, life partners, sex life, even their ability to go for a walk. Their relentless physical pain is like razors inside their body. They feel helpless, alone, and ignored. Some have suicidal thoughts.
11. Among those we met, and many more who contacted us by email and phone we heard common themes. These themes arose from patients' experiences and they are in Chapter 2 of our report. I urge you to read them.
12. I and members of the Review team have conducted many reviews and we all agree – we have never encountered anything like this,  
  
the intensity of suffering,  
  
the fact that it has lasted for decades. And the sheer scale. This is not a story of a few isolated incidents. No one knows the exact numbers affected by mesh, Primodos and sodium valproate but it is in the thousands. Tens of thousands.
13. As if the physical, developmental and emotional harm weren't enough, these families have had to fight to be listened to and to be taken seriously.
14. They organised themselves into groups and have battled for years. I want to thank the patient groups. Their expertise, courage and tenacity is truly remarkable and they have helped us throughout. I want to stress our Review was set up because these people **refused to give up.**
15. In our research we have been astonished how the healthcare system  
  
–which includes the NHS, private providers, the regulators and professional bodies, manufacturers, and policymakers

– is disjointed, siloed, unresponsive and defensive. It does not adequately recognise that patients are its sole purpose. It has failed to listen to their concerns.

16. Over the past two years we have found ourselves in the position of recommending, encouraging and urging the system to take action that should have been taken long ago.
17. Innovation in medical care has done wonderful things and saved many lives. But innovation without pre-market testing, post-marketing surveillance and long-term monitoring is quite **simply dangerous**.
18. The fact is that the healthcare system does not know the scale of the problems we were asked to investigate. **It is flying blind**.
19. The healthcare system fails to acknowledge when things go wrong. it fears blame and litigation - mistakes are perpetuated through a culture of denial, a resistance to no-blame learning, and an absence of accountability.
20. There are times when manufacturers fail to acknowledge that their product is causing harm. They fail to recognise their obligation to contribute towards help for patient who have suffered harm.
21. In the face of all this we have found that patients are exposed to risks when they do not need to be.
22. I now want to briefly explain our conclusions on each of the three interventions we looked at.

#### *Primodos*

23. In our view Primodos continued to be given as a pregnancy test for years longer than it should. In the face of growing concerns it should have ceased to be available from 1967. A non-invasive alternative was available by then, and the concerns that were being expressed should have led to action by the regulator. It continued to be given to women for years longer. While there is disagreement between experts about whether Primodos caused birth defects, the fact remains that thousands of women and unborn children were exposed to a risk that was acknowledged at the time. That should not have happened. This is not a case of us judging the actions of the past by the standards of today. This was discussed at the time, but not acted upon. **The system failed**.

#### *Sodium valproate*

24. Sodium valproate has been licensed in the UK since 1972. It was known from the very beginning that it is harmful to unborn children. No one disputes that.  
  
Yet, even today, hundreds of women who are taking valproate become pregnant without being aware of the risks.
25. These women and their children have been let down by the healthcare system. **Health professionals** do not inform them of the risks, **regulators** have not done enough to make

them do so, and **no one is tracing those affected**. There is simply a **woeful lack of support and help**.

### *Pelvic mesh*

26. Women with mesh complications have suffered terribly. We were so appalled by this suffering that in July 2018 we said that mesh for the treatment of Stress Urinary Incontinence must be halted immediately. We set conditions that had to be met before these operations could continue. Today, two years later, they have not been met.

27. Twenty years after mesh started to be used in the pelvis we still don't know its long-term risks or complication rate. The same is true for mesh removals.

There is still no consensus on how to treat these complications and what type of procedures are best.

28. We have said that if the conditions for lifting the pause are ever met and the pause is lifted, then mesh should only be considered after all the other surgical and non-surgical options have been considered. And women must be able to make a fully informed decision about a mesh implant in the full knowledge of all the risks.

29. On this basis, we expect that the number of pelvic mesh procedures in the future will be tiny. Gone are the days when women in their tens of thousands had mesh implanted and were told it was the gold standard.

30. I want to conclude by summarising the nine major recommendations we are making. Taken together, these recommendations are **wide ranging and radical**.

31. The system's response – or lack of it – has added to people's suffering and pain. It needs to **acknowledge** what has gone so badly wrong.

32. So **our first recommendation** is that the Government must immediately issue a fulsome apology on behalf of the healthcare system to the families affected by Primodos, sodium valproate and pelvic mesh.

33. Next the patient voice needs to be strengthened. Patients know when something has gone wrong. Their experience must no longer be ignored.

34. We don't need another re-organisation of the NHS.

We don't need another regulatory body

But we **do** need a new voice, with statutory powers, to encourage the system to do what needs to be done.

We need a person of standing who sits outside the healthcare system and who is accountable to Parliament through the Health and Social Care Select Committee.

35. So **our second recommendation** is that a Patient Safety Commissioner is appointed. This person will be the patients' port of call, the listener, the advocate, who holds the system to account, monitors trends, and above all demands action.

This is the golden thread, tying the disjointed system together in the interests of those who matter most. The patients.

The state and manufacturers have a moral responsibility to provide *ex gratia* payments to those who have experienced avoidable damage from the interventions we have reviewed.

36. We **are therefore recommending** that separate schemes should be set up for Hormone Pregnancy Tests, valproate and pelvic mesh to meet the cost of providing additional care and support to those who have experienced avoidable harm and are eligible to claim.

Patients have waited far too long for redress. These schemes must be set up at speed.

37. Beyond these three specific schemes - for the future, we need a new way of dealing with redress, a way to resolve disputes between patients and the healthcare system. It is not right that the only option for people who have been harmed is to attempt to go to court.
38. So **our fourth recommendation** is the establishment of a Redress Agency. Rather than blaming individuals, its decisions will be based on whether there has been avoidable harm. The support it provides should be both non-monetary and financial.
39. The costs of running the Redress Agency should be met by contributions from manufacturers and the state, but it must be situated outside the current organisations and it must be independent.
40. Those who have been harmed deserve better care and support. We **are therefore recommending** the establishment of two types of **specialist centres** – one for mesh, and another for those affected by medications taken during pregnancy. They will be located regionally. As well as meeting clinical needs, these centres should act as a one stop shop, able to signpost and refer patients to other services.
41. A regulator must work both for patients and with them. This hasn't been the case in the past. **We are recommending that** the regulator of medicines and medical devices, the MHRA, is overhauled. It needs to change and radically improve the way that concerns about medicines and devices are detected and acted upon. The regulation of devices in particular needs urgent change. The MHRA needs to engage more with patients and track how medicines and devices improve - or fail to improve - patients' health and quality of life. It needs to raise public awareness of its role and it needs to ensure that patients have a core role in its work.
42. Earlier on I described the system as flying blind – every successful organisation knows that good data is essential. Detecting concerns over medical devices, tracking patient outcomes and acting swiftly to prevent harm, is impossible without good data. Currently no one knows the number of patients implanted with pelvic mesh, their surgeon, the mesh product used, or the outcomes.
43. **We are recommending** that a central database should collect these details, including retrospective details. We asked the Secretary of State to make the collection of this information mandatory and he has agreed. The database will be linked to registries to research and audit outcomes in terms of both device safety and the patient's experience.

44. There is no central register of clinicians' financial and non-financial interests. We are concerned by doctors who have financial and other links with manufacturers
45. So our 8<sup>th</sup> **recommendation is that** the register of the General Medical Council (GMC) should be expanded to include a list of financial and non-pecuniary interests for all doctors. **The public has a right to know.**
46. Likewise, manufacturers must should report payments made to teaching hospitals, research institutions and individual clinicians under a new law similar to the similar to the Physician Payments Sunshine Act in the US.
47. We hope this Government, and all those bodies that comprise the healthcare system, will take heed of what we have to say, and that our recommendations will be implemented with determination and urgency.

That leads me to **our final recommendation** which is about implementation. We want the Government to immediately set up a **task force** to implement this Review's recommendations. Its first task **should be a timeline** for implementation.

48. Innovation and technology will bring exciting change. There is potential to do so much good, but we must ensure the risks of increasingly complex healthcare are understood - where the system is not sure of the risks it must say so. Had it done so in the case of our three interventions, I have no doubt that much anguish, suffering and many ruined lives could have been avoided.
49. Our recommendations will improve the lives of people who have been harmed and make the system safer in the future. This report must not be left on a shelf to gather dust. Implementation needs to be approached with a new urgency and determination, founded on the guiding principle that our healthcare system .....must .....first .....do no harm.

Thank you.