AIMS For a better birth...

A short analysis on First Do No Harm, the Independent Medicines and Medical Devices Safety Review chaired by Baroness Cumberlege, July 2020

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www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

Introduction

> 'This report deals in the shame felt by women and the currency of silence. It deals in misogyny, in paternalism, in arrogance and in the imbalances of power – both individual and systemic.' Kate Jarman, Health and Care Women Leaders Network, 14/7/20.

The review is 'about people who have suffered avoidable harm' specifically the use of two medications and one medical device. It examined Primodos which was a hormone pregnancy test (HPT) used between

the 1950s and 1978; Sodium Valproate which is an anti-epileptic drug taken by women during pregnancy and pelvic mesh implants used for treating vaginal prolapse, the latter two are still used today. The HPT and Sodium Valproate are known to be teratogenic, i.e. capable of causing malformation of the embryo.

The review found that the healthcare system, which in this definition means the NHS, private providers, the regulators and professional bodies, pharmaceutical and device manufacturers and policymakers, *'is disjointed, siloed, unresponsive and defensive. It does not recognise that patients are its raison d'etre'* and that *'the system is not good enough at spotting trends in practice and outcomes that give rise to safety concerns'*.

The review document is very long (268 pages), detailed and complex - so for the purposes of this article I will highlight areas which are relevant to the maternity services and those who are pregnant or intend to be. For a quick read you will find that Chapter 1 is a summary of findings and recommendations and Chapter 2 considers the overarching themes found; other chapters consider the detail and implementation of the recommendations. Chapter 6 considers the role of public inquiries.

The new 'AIMS Guide to Resolution After Birth' describes in detail the issues surrounding complaining about care. This review serves as a stark reminder that it certainly isn't easy to**complain** and be heard. The review clearly states that improvements must take place in relation to**informed consent**, again a constant theme in the new series of AIMS Guides. Together with these issues and many others, AIMS looks forward to hearing how the recommendations from the review will be taken forward.

Patient involvement

In setting the review in place, it had been recognised that legitimate concerns of patients, families and campaigners had not been heard, not just for a year, a decade, but for 40 years. The patients' concerns, which make harrowing reading, were *'dismissed, overlooked, and ignored for far too long'* (1.10). There is a list in 1.12 of the review highlighting the sixteen common themes found by the teams, amongst them*'the lack of information to make informed choices'*, **'***the struggle to be heard***'** and *'not being believed'* – words often heard in relation to the maternity services.

Descriptions of the clinicians include '*defensive*', '*dismissive*' and '*arrogant***'** (2.3) and patients spoke of being **'***gaslighted***'** – a really serious accusation which means 'to manipulate (a person) by psychological means into questioning his or her own sanity.' Oxford English Dictionary (P17 ref).

Consent and Risk

> 'It is the patient's right to be told whatever information they need and in a manner that they understand – not what the reasonable clinician chooses to say – to make a decision on whether or not to proceed with a particular procedure or medication.' (2.14)

Some women did not know they had had mesh inserted, some who agreed to full removal were never told that not all of it had been removed. Some women were never told of the effect their medication for

epilepsy **could** have on their unborn children. Some women were given the HPT pills from their GPs' desk drawers – samples from drug companies – no prescription.

The new series of AIMS Guides highlights the complexity of reporting complaints, giving consent and understanding risk. The review examines the general level of dissatisfaction with all the bodies who receive complaints and recommends more changes to the system. The review recommends that *'More thought needs to be given to help patients conceptualise risk.'* (2.21) There is mention of the GMC recommendation that every patient conversation with a clinician about consent will be documented with both parties' views being noted, perhaps with the use of audio or video (2.24).

The review is recommending the appointment of a Patient Safety Commissioner to champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices, and a new independent 'Redress Agency' for those harmed by medicines and medical devices.

Medications and Devices

The frightening bigger picture found by this review is that it is not just the three chosen subjects, but there is another long list patients have been complaining about for years, including Essure (a contraceptive device), Roaccutane (a treatment for severe acne that can cause birth defects if used in pregnancy), Poly Implant Prostheses (PIP) breast implants, cervical cancer vaccination, in utero exposure to hormones, Valproate use in children and other mesh procedures.

The review highlights major flaws in innovation in medical care – lost opportunities to learn the efficacy of products, and a lack of comprehensive pre- and post-market testing and long term monitoring. The Medicines and Healthcare products Regulatory Agency (MHRA) does not have the same high profile as similar agencies in other countries, but it will have to change post-Brexit, as it will be the UK's standalone medicines and medical devices regulator, taking over from the EU regulatory function. It needs far more robust surveillance post-marketing of medicine and devices, but unbelievably they are not involved in the pre-market development of medical devices.

The system doesn't know what works and what doesn't (1.16)

- The system doesn't know how many women were treated with the mesh, how many were cured and how many had life-changing conditions because of the mesh.
- The system doesn't know how many women took Sodium Valproate who then went on to become pregnant. It is a very effective treatment for managing epilepsy BUT it is known to be a teratogenic medication. It doesn't know where children/adults affected by Sodium Valproate are or how many there are.
- The system doesn't know how to ensure women who take Sodium Valproate are monitored, advised and aware of the Pregnancy Prevention Programme.
- The system doesn't know how many women took a HPT, how many miscarriages were caused,

> how many children may have been malformed, or how many are still alive.

The review heard that '*crucial research evidence that should help to shine a light on what are safe and effective interventions is neither prioritised nor funded*' and importantly, they heard that research funded by manufacturers '*never sees the light of day because it is negative or inconclusive*' (1.22).

The vital information for AIMS and the people we care about is that:

> ' ….the system is not safe enough for those taking medications in pregnancy or being treated using new devices and techniques.' '……. we have heard nothing that would lead us to believe that things are different for other surgical procedures and devices or other medications.' (1.23)

This means that the healthcare system is not robust and safe enough and healthcare providers are not informed well enough, to know **fully** about the safety of **any** medication or procedure used in a pregnancy.

Duty of Candour is also discussed in the AIMS Guide to Resolution After Birth; it is the requirement for health and social care professionals and to be open and honest with patients if things go wrong, but the review found that there is still a '*persistent culture of reluctance to speak out*'. During the pandemic, there have been disturbing headlines such as '*Coronavirus: NHS whistleblowers 'threatened with job loss' for speaking out on PPE*'. (Independent 15 May 2020)

Conflicts of interest have the potential to arise in the complex financial links between drugs and medical device companies AND doctors, hospitals and other health organisations and private practice. Currently there is **no centrally mandated register** for healthcare professions to hold information about actual and potential conflicts of interest. This applies in maternity services as well as anywhere else in healthcare.

The Royal College of Obstetricians and Gynaecologists (RCOG) has highlighted an issue that '*the same procedure may be carried out by both accredited sub-specialists and by those who have done general training and developed an interest in specific interventions who, necessarily, will not have the same level of skill.*' (2.57) Patients have no access to any information which will tell them the competencies of their doctor.

Most importantly there appears to be no requirement to declare conflict of interest when doctors sit as experts on working groups, advisory committees or to agree guidelines. For example, the review found that clinical members of such groups were being paid by pharmaceutical companies. The review says that reliance on voluntary, self-declaration of conflict of interest must cease.

Guidelines

Guidelines are advisory. All AIMS information states this but we have a long-held belief that often guidelines are, on one hand, out of date and on the other not followed when they do have good evidenced-based information. The healthcare system has a responsibility to ensure common practice is in

line with recommendations, but the review found this does not always follow, despite it being a requirement in annual appraisals, clinical audit and monitoring quality. An additional comment was in relation to Fitness to Practice investigations where guidance has not been followed *'appropriately'* (2.70). In the maternity services, AIMS often finds staff slavishly following guidance to the detriment of their clients but not reporting out of date or inappropriate guidance to their Trust.

Databases

Despite all the information in patients' individual records, 'they' still don't know who has what! This is in relation to medical devices, such as the mesh, and to those women of child-bearing age who are taking Sodium Valproate. The review has called for a more complex system, including evaluation of long term outcomes and patient safety. (See above Medications and Devices.)

Patient Safety

Risk profiles for medicines used in pregnancy and identifying teratogens

The risk of teratogenicity has meant women are largely excluded from clinical trials; as a result, only a handful of medicines are licensed for use in pregnancy and the safety profiles of newer medicines in pregnancy are initially unknown. Indeed, the whole pharmaceutical and devices regulatory systems have been criticised as being sub-optimal for women1'2'3. There are moves to change this nationally and internationally. (2.122)

The review found that all the professional and systems regulators including the MHRA, NICE, Care Quality Commission, NHS England and NHS Improvement and the Department of Health and Social Care worked only within their own remits – there were no effective linkages between them and no oversight of the system as a whole. The review supports much of the work being done by these bodies, but highlights their failures, hence their call for a new Patient Safety Commissioner – independent, proactive, having statutory authority, accountable to Parliament directly. Read Theme 12: Patient safety – doing it better starting P55, for an in-depth insight into the plan. It cannot be worse than we have now.

Challenges for healthcare professionals

- Listen to the patients and clients, listen carefully. Show that you've heard.
- If you are responsible for the maternal postnatal check at 6-8 weeks and your client has a pelvic floor disorder, search for evidence-based nonsurgical options, including that of specialist physiotherapy.
- If you have a patient to whom you are prescribing Sodium Valproate, check if she is of child-bearing age and ask her if it is possible she could get pregnant.
- Are you up-to-date with any alerts about a pharmaceutical drug, medical device, treatment or procedure you are prescribing or recommending?

If you are a birth worker, help your clients to be aware of these issues.

A lesson for us all

Anecdotal patients' evidence is too often disregarded. Evidence-based medicine is all very well and should be used when it is available. However anecdotal evidence should always be listened to and not dismissed and as this review shows, it may be the only evidence we have on side effects and issues. The pharmaceutical industry must not be allowed to dominate the evidence base, and independent research needs to be undertaken, along with long term review.

Conclusions

The review is comprehensive in explaining the history of pregnancy testing with Primodos, Sodium Valproate use in pregnancy and pelvic mesh and the regulatory background of how we have got to where we are today – it is worth the long read, although much of it is heart-rending and may leave you feeling angry and upset.

There is a systematic problem within healthcare provision and it needs everyone – clinicians, other professionals and managers - to face up to this truth and for pregnant women and people to understand the implications.

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1 John Naish 'The everyday medicines that make women ill because they have only been tested on MEN' Daily Mail 5 November 2012

2 Amy Westerveldt 'The medical research gender gap: how excluding women from clinical trials is hurting our health' The Guardian 30 April 2015

3 Simon Crompton 'Why the drugs don't work for women and what to do about it' The Times 2 July 2019. (ref P53)