

The Hughes Report: Avoiding harm through hearing our patients

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Main text

The Hughes Report outlines options for redress for people harmed by valproate and pelvic mesh in England,[1] building on the findings and recommendations of the Independent Medicines and Medical Devices Safety Review chaired by Baroness Cumberlege.[2] Both reports make for harrowing reading. The Hughes Report estimates that 14,000 children have been harmed from exposure to valproate while in their mother's womb since 1973, and that at least 10,000 women have been harmed due to insertion of pelvic mesh for the treatment of stress urinary incontinence or prolapse since 1998. And these figures are just for England.

Beside the numbers, the two reports include quotes from women with epilepsy or bipolar disorder who now have disabled children, often describing guilt from unknowingly taken a teratogenic drug during their pregnancy, and women left in debilitating pain from pelvic mesh, who were unable to work, have a sex life or enjoy everyday activities. The report makes ten recommendations relating to appropriate redress for those harmed. We highlight two cross-cutting issues and how practice needs to change.

Inequalities in healthcare quality and safety

Socioeconomic, racial and ethnic inequalities in healthcare are receiving increased attention.[3] The Hughes Report brings another area of inequality to the forefront: sex. Those who received unsafe care were biologically female. There is lack of research into suitable treatments, adverse effects and responses to patient safety among women. Pregnant and lactating women continue to be excluded from clinical trials, even post-marketing, and it is not compulsory for research findings to be reported by sex or gender.[4] The issues around valproate and vaginal mesh could have been mitigated, or even avoided, by giving female health research greater priority. Hughes' call for more research in this area risks getting lost in the recommendations on redress unless researchers and funders take note.

Besides sex, there are additional intersectional inequalities. For example, a French investigation found valproate to be more commonly prescribed to women receiving social security, suggesting those from more deprived backgrounds may be disproportionately affected.[5] A US study identified a decrease in mesh use among white and African American women but not among Hispanic women following a 2011 safety alert.[6] Even among 571 respondents to the Hughes' survey of people harmed,[1] 96% described themselves as white in

a country in which 81% report white ethnicity.[7] It's unlikely that mesh and valproate were used less in people of other ethnicities, which suggests some people may have had less opportunity to contribute or felt less likely to be heard even in a supportive context. Hughes' tenth recommendation points out that the redress scheme needs to be widely communicated and clinicians need to play a role in recruiting the most vulnerable.

Listening and hearing all patients

Underpinning the entire Hughes Report is the stark reality that women were simply not heard. Hughes suggests epistemic injustice as a key factor. Epistemic injustice describes how a person's knowledge is denied, undervalued or undermined as a result of power structures that value some people's experiences more than others.[8] In the case of valproate and pelvic mesh, women's knowledge was undervalued and ignored. First, women were not heard when making treatment choices, often including lack of meaningful informed consent. Second, they were dismissed or overruled when reporting serious adverse effects to their healthcare providers. Finally, when trying to raise the issues more widely, harm was compounded by adversarial and burdensome complaints processes.[9] In contrast, restorative approaches to redress, as well as being co-designed with those affected, are relational in nature. Features include active participation, respectful dialogue, truthfulness, empowerment, and storytelling.[9] For those, who wish to tell their stories, this may need to be orally rather than in writing. While the quotes in the Hughes Report tell part of the experiences of those affected, "*a story read is nothing like a story told and heard.*"[10] A story told orally includes the storyteller's voice, face and body language, and facilitates sensing their emotions. From the storyteller's point of view, seeing their listeners give them respect and time also tells them their lived experience matters.[10]

A call to action

While the Hughes Report's call for redress is primarily aimed at the English government, the actions needed are much wider - both for those already harmed and to make sure history is not repeated with other drugs or procedures.

Before treatments become mainstream, there needs to be clear research on their safety for females. Healthcare professionals need to listen and truly hear their patients' preferences and experiences. At treatment initiation, this includes establishing "what matters to you",[11] using evidence-based decision aids for shared decision making,[12] and ensuring patients are able to give genuine informed consent. When patients report adverse effects, they should be heard with compassion, and given credibility while reflecting on the dangers of epistemic injustice.[4] Following medical harm, any solutions must be co-designed with individuals affected, from all backgrounds. Without hearing our patients, there won't be a solution.

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