



valproatevictims@gmail.com

www.pharmaconsent.org

<https://www.facebook.com/groups/justiceforfacskids/>

Principles of Patient Safety Consultation

Submitted response to Patient Safety Commissioner England and Wales

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Susan Cole

Bozena Michalowska

Principle 1:

Leaders have a responsibility to lead by example to inspire a just and learning culture of patient safety and quality improvement. They aim to keep people safe, support continuity of care, and foster a culture of compassion, listening, and restorative practice.

Response:

Individuals affected by valproate, we have experienced decades of compassion and listening—expected attributes of anyone in public service. While families often receive sympathy from doctors, this alone does not help us progress. What we truly need is not just compassion, but concrete action to address the harm done.

The idea that leaders should lead by example is clear; good leaders naturally inspire and emphasise patient safety, quality care, and compassion. These principles are fundamental to the National Health Service and should not be questioned. What requires clarification is the concept of "restorative practice."

Restorative practice is not just an approach but a structured method for resolving conflicts and repairing harm. It involves holding those responsible accountable, facilitating reparation, and fostering dialogue among all parties affected. This process emphasises healing and understanding, moving beyond blame toward resolution.

For those impacted by valproate, restorative practice offers a meaningful way forward, emphasising accountability, repair, and genuine progress in addressing past harms

Principle 2:

Leaders put the patient at the heart of all their work, with patient partnerships as the default at all levels of the organization. They work collaboratively with patients to identify risks and deliver person-centered care. Leaders ensure that the patient voice is central to fully informed consent and shared decision-making.

Response:

The historical paternalism in the NHS has led to preventable tragedies, such as with Valproate, Mesh, and Allergan breast implants. These incidents underscore the need for truly patient-centred care, where patient voices are not only heard but acted upon. Had patients' concerns been taken seriously earlier, much harm could have been avoided.

The question now is whether patient-centred care should remain a guiding principle or be formalised into rules and laws to ensure accountability. While the Montgomery v Lanarkshire ruling of 2015 sets a legal precedent for fully informed consent, principles alone are not enough to safeguard patients in the future.

Regarding Valproate, mothers with hidden disabilities were often marginalised, further silencing their voices. Clear communication of risks is essential for informed decision-making, especially when it involves complex statistics. Many women were told of a "1-2%" risk of spina bifida, but clearer communication about the tenfold increase in risk would have led to different choices. Risk statistics should be presented simply, cautiously, and widely, ensuring patients can make informed decisions. When new risks emerge, prescriptions should be paused quickly, and alternative treatments offered without delay.

Principle 3:

Patients are treated with fairness, respect, equality, and dignity. Leaders incorporate the views of all and proactively seek meaningful feedback from patients, families, and staff. Feedback is acted on to embed equality of voice.

Combined Response:

This principle highlights the importance of proactive feedback mechanisms, but feedback often seems to be sought after decisions are made. A more effective term might be "continuous engagement," involving patients throughout every stage, from planning to evaluation. Continuous engagement ensures that patients' voices are heard in real time, promoting a more responsive and inclusive care environment. However, the key question is whether this should remain a principle or be formalized into rules with clear mechanisms for implementation.

Patients and campaigners have often found their voices diluted, heard but not acted upon. Sitting at the table with decision-makers, like the MHRA, allowed some input but limited discussions about past harms. Effective engagement should include a range of stakeholders who can influence real change, ensuring an inclusive and transparent process. Valproate Victims and other groups have proposed models for patient engagement that prevent tokenism and ensure a democratic approach. Structured outreach programs that actively seek underrepresented voices could further improve this process, allowing all stakeholders to feel that their concerns are genuinely addressed.

Principle 4:

Health inequalities and their drivers are identified and acted upon at every stage of healthcare design and delivery.

Combined Response:

Addressing health inequalities requires prioritising continuous data collection and engaging with affected communities to co-create solutions. Ongoing independent analysis of health data is essential for identifying disparities and crafting strategies to improve equity. Patients, especially informal groups, often act as the “canary in the coalmine,” noticing adverse effects that researchers might miss. Collaborating with these groups could enhance early warning systems for risks.

Beyond data collection, equity demands broader approaches, including the use of social science, historical research, and even the arts to raise awareness. The Wellcome Trust effectively uses creative mediums to highlight health issues, and similar methods could support reconciliation and awareness in healthcare. Furthermore, the healthcare system's two-tier structure, with many doctors using private care, widens the gap between patient experiences and medical understanding. A holistic approach is necessary, where not only evidence-based medicine but also qualitative research guide healthcare design, ensuring prompt action when risks emerge, based upon the Precautionary Principle.

Principle 5:

Targeted and coordinated action is directed to mitigate patient safety risks. Leaders escalate new and existing risks to healthcare commissioners and regulators. Staff are supported to proactively identify risks, hazards, and improvements.

Combined Response:

The principle lacks urgency by not addressing the need to escalate risks "promptly." Delays in responding to alarms raised by patients, doctors, and surgeons—such as in the cases of valproate, mesh, and metal-on-metal implants—caused unnecessary harm. Leaders, commissioners, and regulators must act swiftly and transparently when risks are identified. Protecting commercial interests should never take precedence over patient safety, and this principle should advocate for public reporting mechanisms on how risks are managed and escalated.

Additionally, frontline healthcare workers' voices should be heard directly in consultations. For example, during the valproate consultations, the involvement of an epilepsy nurse provided vital insights that improved protocols. Frontline staff, who have a unique and neutral perspective, are essential in identifying risks early and should be empowered to escalate these concerns without delay. The system must ensure they are included in decision-making processes that impact patient safety.

Principle 6:

Leaders create a culture where there is honest, respectful, and open dialogue, with candour as the default position. This ensures a continuous improvement cycle and prevents avoidable harm due to a cover-up culture.

Combined Response:

This principle must clarify that a shift from a blame culture to one of learning is crucial. Blame-oriented approaches, such as those seen in the metal-on-metal implant scandal, often deter professionals from reporting safety concerns due to fear of retribution. Promoting a no-blame culture would encourage healthcare professionals to report issues openly, allowing quicker identification and resolution of risks.

However, in practice, even with a no-blame approach, individuals may hesitate to admit mistakes, fearing reputational damage. This has led to destroyed records, obfuscated communication, and institutional cliques protecting each other. To combat this, regular, independent inspections—such as those by the CQC—should be conducted and well-funded. While fostering a learning culture is important, it often requires legislation to enforce. Safeguarding all patients should be a priority, similar to how safeguarding children has become a legal mandate.

Principle 7:

Leaders use and provide information and data of all types to drive their work, ensuring good-quality data captures the needs of all patients, including those from underrepresented groups. All staff are supported to pass on information relevant to the improvement of patient care, and best practices are shared widely.

Response:

no comment other than strongly agree

Missing principles

The first principle references restorative practice. This principle should be clearly defined and stand alone, serving as the cornerstone of a redress scheme. By doing so, it would not only uphold the other principles but also translate them into concrete and actionable steps, ensuring they are fully realized and impactful in practice.

There is no reference to ethical leadership or behaviour in any of the draft principles. Sound ethics must be the foundation of the draft principles and are essential for maintaining the integrity of all the other principles and the health care system as a whole. Leaders must demonstrate unwavering commitment to ethical standards, acting in the best interests of patients, staff, and the community and be held accountable for upholding these standards.

Other comments

The principles outlined are self-evident and should be consistently at the forefront of the minds of leaders, professionals, stakeholders, and regulators. However, the critical challenge lies in ensuring these principles are not just aspirational but actively enforced and embedded into practice.

Implementation of a redress scheme based on these principles

To make these principles meaningful and actionable, it is essential to develop robust mechanisms for enforcement. One effective approach would be the implementation of a redress scheme explicitly grounded in these principles. Such a scheme would ensure that when deviations occur resulting in harm, they are addressed swiftly and transparently, holding all parties accountable to the standards set forth. This will not only encourage adherence to the principles but also create a culture of accountability and continuous improvement.

Audits and prevention

Regular audits, public reporting, and independent reviews should be integrated into the enforcement process to maintain transparency and trust among all stakeholders.

Ultimately, by anchoring the redress scheme in these principles and ensuring their rigorous enforcement, we can transform these foundational values from mere statements of intent into tangible protections that safeguard patients and uphold the integrity of the healthcare system.

Delays

There needs to be a recognition of the many years of delay that are caused by an ineffective safety system. Delays in providing redress create further harm. As years pass by the effect is increased in magnitude and we therefore propose that a year zero date is set when the harm was first recognised by the patient whether that involves a causative effect or just a concern. Offenders benefit from time passing by as it reduces their exposure to blame, victims or defendants always lose out.