

National Assembly for Wales / Cynulliad Cenedlaethol Cymru
Health and Social Care Committee / Y Pwyllgor Iechyd a Gofal
Cymdeithasol

Legislative Consent Memorandum: Medical Innovation Bill /
Memorandwm Cydsyniad Deddfwriaethol: Y Bil Arloesi Meddygol
Evidence from Patients Association – MIB 02 / Tystiolaeth gan
Cymdeithas Cleifion – MIB 02

29th December 2014

The Patients Association response to the:

National Assembly for Wales (**Cynulliad Cenedlaethol Cymru**):
Health and Social Care Committee (Y Pwyllgor Iechyd a Gofal Cymdeithasol)

*Evidence gathering on: **The Medical Innovation Bill***

The Patients Association is an independent national health and social care charity established over 50 years ago and has a long history of campaigning to ensure that the voice of patients is heard within the Health and Social care system. We achieve this through research, campaigns to support patients' rights, lobbying Government to address healthcare issues affecting patients and speaking up for patients and carers.

The Patients Association also provides an advisory national Helpline service to over 7000 patients each year who raise concerns about their experiences with healthcare providers. The nature of these enquiries cover issues such as poor care (particularly of elderly people in hospital), delayed or cancelled operations and problems with the complaints services.

This offers us a wealth of information, with a database currently consisting of well over 40,000 cases, spanning many years and giving us a unique insight into the diverse nature of concerns raised by patients themselves. In order to make the best use of this information, the Patients Association provides data analysis and statistical research to detect emerging trends and patterns, and any concerns can be targeted towards improving patient care.

The Patients Association welcomes the opportunity to contribute to the National Assembly for Wales's inquiry on the Medical Innovation Bill. We hope that our insights and expert advice are able to help shape the health and social care landscape for the benefit of patients.

- 1.1 The Patients Association supports any innovation that saves lives and provides better outcomes for patients; who deserve access to high quality, safe care. While medical innovations are important to provide the highest quality of healthcare possible, the Patients Association would like to highlight a number of key points which should be emphasised in the discussions regarding the implementation of the Medical Innovation Bill.
- 1.2 As an organisation that represents patients and their carers, we strongly believe that the underlying motivation behind the Medical Innovation Bill should be to improve patient care, interventions, experience and outcome. Ensuring the safety and dignity of all patients at all times, it is important that the proposals put forward for the Bill are not driven by commercial, financial or staffing interests. Any diversion of focus away from the interests of the patient is likely to compromise the quality, safety and dignity of the patient. It is essential that doctors only offer treatments which are believed by both doctor and patient on reasonable grounds to be in their best interests, and to offer a reasonable prospect of doing more good than harm.
- 2.1 The Patients Association would like to stress the importance of informed patient consent. In all cases, prior consent must be sought from the patients concerned, with the risks and benefits of procedures associated clearly communicated to patients and/or their relatives. Patients must be involved in the decision making process and be fully informed of any risks and benefits of the treatment. Patients and their relatives need this information in a clear unambiguous way so that they may make an informed decision. This is particularly important when they are offered innovative and untried treatments.
- 2.2 A significant number of calls to our confidential Helpline are made by patients and their relatives concerned about matters relating to consent. A substantial proportion of callers seek access to their medical records in order to make a complaint, very often regarding a misdiagnosis.
- 2.3 Furthermore, it is vital that due consideration is given to patients that may have communication difficulties due to language barriers or cognitive issues. We are also particularly concerned about patients in especially vulnerable situations, including frail and elderly people seeking medical attention. Every attempt must be made to discuss the treatment with the patient and the next of kin or other individuals identified by the patient. Many such patients are not aware of their rights and entitlements.
- 3.1 While the NHS Constitution grants these rights to all patients, in our experience, the NHS Constitution is poorly promoted within the NHS both to

patients and NHS employees. For these patients, it is vital that consent is clearly communicated and that they are made aware of the risks, benefits and implications of the treatments involved.

- 3.2 The Patients Association advocates for a patients' right to complain if they are not satisfied with the medical care received. We receive many calls to our Helpline from people asking how to complain and it is important to note that people who are not offered the chance of medical innovation may want to complain about unfairness.
- 4.1 The Patients Association accepts that the possibility of litigation may, on occasions, deter doctors from innovation. While we do not have any direct evidence or experience of a lack of clarity for doctors in carrying out innovations, we do have ample evidence as gathered from our Helpline to suggest that there is often a lack of effective communication between healthcare professionals and patients, resulting in gaps in the way the patient is involved and engaged in their care and how care is provided. Based on this, we believe there is a need to ensure clarity and clear guidelines about the circumstances under which innovation can be applied and the process to be carried out to avoid any ambiguity.
- 4.2 We believe that it is vital to ensure that staff will speak out when they witness poor care or unacceptable practices that puts patients at risk. The Patients Association would like to stress the importance of creating a culture of learning, clarity in procedures and ensuring the competence of doctors in order to avoid any unnecessary risks to the patient. It is also crucial to highlight the importance of clear communication channels to ensure that the patient is actively involved and empowered to make the appropriate decisions.
- 5.1 We support the aspiration to encourage 'responsible innovation' in medical treatments. However, we see challenges in ensuring a consistent and uniform application of the Bill. The Patients Association would like to emphasise the importance of innovative medical procedures applied consistently across clinical conditions, patient groups and geographical areas to avoid variations in the quality of care.
- 5.2 In our view the decisions regarding innovation should always be for the benefit of the patient and not driven by systems, staff or other considerations. These decisions should be consistent across the patient groups and clinical conditions and should have a clear audit trail. Every doctor carrying out medical innovation should be appropriately trained in doing so with adequate peer supervision. In addition we would like to see the responsibility applied to the multi-disciplinary teams rather than just one person, as in our experience, poor patient care is due to a lack of coordinated team effort. It is vital that the

Duty of Candour is applied in such situations and members of the team must feel able to speak out if there are concerns about patient care, innovation and inappropriate procedures or treatments.

- 6.1 The Patients Association welcomes the acknowledgement that a 'proper process' must be undertaken before a decision to carry out innovative treatment can be reached. These are positive steps as accountability and transparency are prominent themes for patients calling our Helpline. However we do have concerns about the process itself if it only involves the doctor and the patient as we are not convinced that the conversations or decisions made in such situations would be at equal level. The patient may feel obliged to agree to the clinician's decision due to a feeling that the doctor "must be right".
- 6.2 This is particularly true for patients who are frail and elderly or are in vulnerable situations due to their clinical condition. Indeed, we are strongly in favour of stringent measures to ensure clear accountability for decisions, both during and after the treatment has taken place. We also feel that there should be a clear definition of what constitutes accountability in such circumstances. The bill in its current form does not provide this clarity.
- 6.3 In addition the accountability should extend to the multidisciplinary teams involved in care of patients to avoid any gaps or misunderstandings during and after the procedure. This could take the form of a signed consensus from the team to clearly document and demonstrate that the patient's clinical and non-clinical needs have been considered and the resulting decision would benefit the patient in the short term as well as in the long term. It is positive to see clause 1(7) drawing particular attention to discussing the relevant treatment with the patient. The needs, desires and concerns of the patient should be of paramount importance throughout the process. As mentioned above, due consideration must be given to the patient's ability to understand and consent before making any decisions about the care and treatment. We hear many cases where patients and their carers have either not been involved in the decisions or have not been given adequate and meaningful information to ensure informed consent.

Conclusion

The Patients Association does see the merit of medical innovation and is wholeheartedly in favour of new procedures that enhance healthcare and improve outcomes for patients. However, as advocates for patients' experiences, we are mindful of the undesired consequences to patients due to a lack of robust governance and scrutiny. It is essential therefore, that any change to medical practice is implemented with the patients' best interests at heart. It is vital that the safety and dignity of every patient is assured in all circumstances. This is particularly important as the issues here are likely to affect people when at their most vulnerable.

As things stand at the moment, the Patients Association would oppose this Bill. The Patients Association would like to see a wide ranging public debate that would allow the profile of this issue to be raised. Only in this way can the views of all interested parties including the public, practitioners and pharmaceutical companies be taken into account. Without this, the Patients Association would be concerned that medicine would be moving into grey areas where issues such as responsibility, accountability, understanding and outcomes become blurred.