WELSH HEALTH CIRCULAR

Llywodraeth Cymru Welsh Government

Issue Date: 08 August 2023

STATUS: ACTION

CATEGORY: QUALITY & SAFETY

Title: Consent to Examination or Treatment - update

Date of Expiry / Review: 8 August 2028

This Welsh Health Circular replaces WHC/2017/036 issued on 24 July 2017, which is retired with immediate effect.

For Action by:

All Health Boards and NHS Trusts in Wales

Action required by: With immediate effect

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Enclosure(s): The documents referred to in this WHC can be found at the various links shown as these are the most up to date versions.

About this Welsh Health Circular

1. This Welsh Health Circular replaces WHC/2017/036. It sets consent in the context of the framework of the Duty of Quality that is now in place in Wales. It also brings together in one place links to materials, guidance, and training information developed and promoted by the NHS Wales Welsh Risk Pool, to support NHS organisations in Wales to approach the taking of consent consistently and robustly. It is the Welsh Government's clear expectation that these materials will be used by NHS organisation to improve the consent process.

The importance of informed consent

- 2. Having to give consent to an examination or treatment is likely to be something most of us will have to do during our lifetimes and understanding the risks and benefits of the treatment being proposed is a fundamental part of that process. Shared, open decision-making between professionals and their patients, families and carers plays a vital part in the consent process. Patients place a huge amount of trust in their healthcare professionals and in turn should expect clear and honest information about the risks, benefits and alternatives to the proposed treatment or intervention options, so they can make up their own minds in an informed way. Each patient has a right to be listened to and given information, time, and support to make their decision.
- 3. Informed consent is a legal requirement. However, it is also a fundamental component in the provision of high-quality, person-centred care and in achieving good outcomes for patients as envisaged by the **Duty of Quality** which now applies to all NHS bodies in Wales and to Welsh Ministers.

Duty of Quality Statutory Guidance (gov.wales)

4. Thanks to the All-Wales Consent to Examination and Treatment Team and national collborative group led by the Welsh Risk Pool, a significant amount of work to improve consent-taking processes has already taken place in Wales, and this is described below. Even so, litigation associated with failings in the consent process continues to be a regular feature of claims experienced in the NHS in Wales. Somewhere between 15% and 25% of all claims received in relation to clinical negligence involve allegations relating to the consent to treatment process. Between £10m and £20m is paid out annually in relation to claims where consent to treatment is a contributory factor. This seems to suggest that even more can be done in this area to improve the process.

Previous work

5. The Welsh Government published an updated **Guide to Consent for Examination or Treatment** in 2017 which sets out the current legal position and is still of relevance. The guidance was updated following the landmark judgment in Montgomery v Lanarkshire Health Board, which redeclared the legal framework for informed consent in the UK and

demanded the involvement of a fully informed patient in a process of shred decision-making

Welsh Government Guide to Consent for Examination or Treatment - July 2017

- 6. The issue of informed consent was also a theme included in the report of the Independent Medicines and Medical Devices Review (*First Do No Harm*, known as the Cumberlege Report).
- 7. In 2018, the National Consent to Examination & Treatment Group updated the Model Policy for Consent to Examination or Treatment and all-Wales Consent Forms, which are now in use in all NHS organisations in Wales.

Welsh Risk Pool Model Policy for Consent to Examination or Treatment

All Wales Consent Forms

8. Providing patients with high quality procedure specific patient information as part of the consent process is crucial. With a view to achieving a consistent national approach to the use of patient information leaflets used during the consent process, the Welsh Risk Pool placed a requirement in 2020 on NHS organisations in Wales to use **EIDO or professionally recognised patient information leaflets** during the consent process.

<u>EIDO Healthcare Download Centre (Patient Information Leaflets) - NHS</u> Wales Shared Services Partnership

Recent work

- 9. Best practice in this area needs to be continuously developed and enhanced and so on 3 March 2023, the Minister for Health and Social Service formally launched a **Wales-specific consent e-learning package** developed by the Welsh Risk Pool in partnership with The Sound Doctor. The new package is accessible and engaging, translating the legal position into clinical practice using real-life examples.
- 10. It has been installed onto the NHS Electronic Staff Record (ESR) and Learning@Wales (nhs.wales) platforms and is accessible to all NHS Wales staff. We expect health bodies in Wales to ensure their staff utilise this important resource and embed it into their practice. We would encourage staff to undertake the training once in each revalidation cycle. In addition to this e-learning package, the All-Wales Consent to Examination and Treatment Team will continue to organise additional, focussed, training and webinars. The use of peer review of clinical notes to ascertain the standard of consent taking in place, and where improvements may be needed, is also highly recommended and is a method of achieving strong assurance in the Welsh Risk Pool assessment programme.

Future work

11. Digital platforms/technologies now exist to evidence and support the consent process. The current national pilot, led by the Welsh Risk Pool in conjunction with partner organisations, is considering the challenges in terms of integration with other patient information systems, the required workflow, necessary investment in hardware and infrastructure. In due course, it is therefore expected that consent for examination and treatment will be digitised and available to patients through the NHS Wales App. We do not yet have a timeframe for the implementation of digital consent, however, we will look to implement it as soon as is practical.

<u>Action</u>

12. Health Boards need to have quality assurance mechanisms in place to ensure the continuous monitoring, review and improvement of the consent policy into practice. In addition, the NHS executive quality assurance function will be assessing these quality control and assurance mechanisms as part of their core responsibilities in future.