Improving Medical Device Information and Data for NHS Scotland

Equality Impact Assessment (EQIA) Results

Scottish Government
Riaghaltas na h-Alba

EQUALITY IMPACT ASSESSMENT - RESULTS

Title of Policy: Improving Medical Device Information and Data for NHS Scotland

Summary of aims and desired outcomes of Policy: Aims to improve patient safety in the context of medical device use in Scotland by improving the available information and system wide data on medical devices

Directorate: Division: Team: Chief Medical Officer: Chief Medical Officer Policy Division: Medical Devices and Legislation Unit
Executive summary

The SG Medical Devices and Legislation Unit (MDLU) are working to develop policy that will improve patient safety in the context of medical device use in Scotland by improving the information and system wide data on medical devices.

The key aim of this policy is to improve patient safety by improving the traceability of medical devices and equipment through manufacture to implantation in the patient, and in the longer term to improve the linkage of medical devices to patient outcomes.

An Equality Impact Assessment (EQIA) was carried out to assess impacts of this policy direction on people in Scotland in terms of:

- eliminating unlawful discrimination, harassment, victimisation;
- removing or minimising any barriers and/or disadvantages;
- taking steps which assist with promoting equality and meeting people's different needs;
- encouraging participation; and
- fostering good relations, tackling prejudice and promoting understanding.

The evidence base for the following protected characteristics was reviewed and assessed: age, disability, sex, pregnancy and maternity, gender reassignment, sexual orientation, race, religion and belief, and marriage and civil partnership.

In addition, the EQIA considers wider socio-economic factors, including those living in poverty or low income households and remote and rural communities (including islands).

Background

Traceability of devices, patient safety, and determining real world clinical outcomes in the use of medical devices has been a long term issue and formed key recommendations in Baroness Cumberlege's Independent Review of Medicines and Medical Devices (the Cumberlege Review).

The SG MDLU recognises that improving the available information and system wide data on medical devices will be fundamental to both improving patient safety and helping patients make informed choices about their treatment and care.

With these aims in mind, the MDLU is developing its inaugural Medical Devices Strategy. As part of this, an NHS Scotland Scan for Safety Programme was established, aligned with the aims of Realistic Medicine, to take a Once for Scotland approach to electronic point of care data capture using world-wide data standards. This Programme will enable rapid electronic traceability, improve the ability to use data to expand our knowledge of medical device outcomes and improve the information available to patients on their medical device.

In addition, this approach will prepare for legislative changes (under the Medicines and Healthcare products Regulatory Agency (MHRA) Medical Devices Regulations and Medicines and Medical Devices Act 2021) which will mandate and place statutory duties on all NHS Boards to collect core medical device data as described here.

The Scope of the EQIA

The evidence base used to inform this EQIA was drawn from a broad range of sources, including existing national and international resources relating to the use of track and trace systems and Unique Device Identification (UDI) in healthcare.

In developing this EQIA, exploratory Patient Involvement Workshops were undertaken in partnership with Glasgow Centre for Inclusive Living (GCIL) to consider patient requirements and maintain a person-centred focus. A literature review of existing work, including a review undertaken by Health Improvement Scotland (HIS) and work undertaken for the

Scottish Government Data Strategy and UK Medical Device Information System (UK MDIS), was also taken into consideration.

Key Findings

The evidence reviewed suggests that a system wide approach to electronically capturing medical device data, enabled by the Scan for Safety programme in Scotland should have a significant positive impact on all patients, their families, and carers, by improving patient safety and improving the patient experience of those receiving an implantable medical device.

The implementation of Scan for Safety methodology has the potential to improve the evidence base relating to the use of implantable devices in people with various protected characteristics, including pregnancy, sexual orientation and gender identity or transgender people, which will meet the needs of the Public Sector Equality Duty (PSED) by seeking to advance equality and eliminate unlawful discrimination.

However, the EQIA and exploratory patient involvement work have identified some considerations that must be taken into account as this policy progresses to ensure that any potential inequalities are addressed and mitigated. The key themes identified were:

Accessibility and inclusivity of public communications. The Scottish Government is committed to producing clear and accessible public communications, meaning that all public communications should be clear, easy to understand and unambiguous in their meaning. As this policy develops appropriate measures will be required to ensure that any public communications, including information provided to patients on the medical devices being used in their care, can meet the needs of those with additional accessibility requirements, such as requiring translations or easy read formats. Communicating with patients using a range of appropriate, accessible, and inclusive means and methods, both digital and physical, will help to ensure that patients have the information they require and in a format that is appropriate to their requirements.

Digital exclusion. Certain groups such as older people, disabled people, lower income people, and those living in rural communities are more likely to experience digital exclusion, and it can take many forms including lack of internet access, lack of IT literacy, lack of accessibility modifications including alternative languages, and lack of device/charging facilities due to low income. As this policy develops it

will be important to work closely with groups most likely to be impacted by digital exclusion to mitigate the potential impacts of digital exclusion both with regards to any digital systems implemented as a result of policy, or when taking part in patient engagement sessions. Communications and information in non-digital formats will be important to reduce discrimination against these groups.

Lower income barriers. Evidence indicates that accessibility of information, health literacy, language barriers and digital exclusion are potentially issues for low income households. It will be important to engage directly with these communities if further patient involvement work is progressed, for example by advertising engagement sessions outside of digital barriers, such as in GP surgeries, supermarkets and local cafes or community centres.

Trust regarding the gathering and storage of medical data. The Scottish Government is developing Scotland's first Data Strategy for health and social care, due for publication in early 2023. The Data Strategy aims to empower the use of quality data to drive high quality service delivery, bringing services together and improving the experience of the individual and their treatment. The findings from recent extensive public consultation work in relation to the Data Strategy illustrates that, while most patients can see the benefits that improved medical data can bring to health care services**,** certain groups, for example older people, people from minority ethnic backgrounds, and transgender people are more likely to have concerns regarding institutions gathering and storing their medical data. The MDLU will develop any future policy regarding medical device data for NHS Scotland in line with the SG Data Strategy once published.

Accessibility and inclusivity of any future public engagement. Both physical, digital, and cultural barriers can be considered with regards to future public engagement. Access points will be important for people who rely on information in alternative formats such as Easy Read, BSL, Braille, translations, and audio/visual formats. A range of access points for information will also be important for people who are more likely to be digitally excluded and/or without regular access to mainstream and digital media.

Recommendations and Conclusion

There is currently no evidence to suggest this policy would have a direct negative impact on any of the protected characteristics or socio-economic considerations. It is expected that the policy will have a positive impact on all patients by improving patient safety and improving data collection, which has the potential to enable the addressing of data gaps and improve research.

The potential for unintended discrimination, particularly in regards to accessibility requirements and digital exclusion, will be kept under review as this policy progresses so mitigations can be put in place where necessary and practical.