

Equality & Health Impact Assessment for

(Medical Devices Policy and Procedure)

Part 1

Please answer all questions:-

1.	For service change, provide the title of the Project Outline Document or Business Case and Reference Number	
2.	Name of Clinical Board / Corporate Directorate and title of lead member of staff, including contact details	Health Protection and Screening Services Fu-Meng Khaw, Executive Medical Director Meng.khaw@wales.nhs.uk
3.	Objectives of strategy/ policy/ plan/ procedure/ service	The Medical Devices Policy and Procedure is aimed at defining how medical devices are introduced, deployed and monitored in Public Health Wales in accordance with guidance from the regulator, the Medicines and Healthcare products Regulatory Agency (MHRA)
4.	Evidence and background information considered. For example <ul style="list-style-type: none"> • population data • staff and service users data, as applicable • needs assessment • engagement and involvement findings • research • good practice guidelines • participant knowledge 	The MHRA guidance on managing medical devices: Safeguarding public health (publishing.service.gov.uk)

	<ul style="list-style-type: none"> • list of stakeholders and how stakeholders have engaged in the development stages • comments from those involved in the designing and development stages <p>Population pyramids are available from Public Health Wales Observatory and the 'Shaping Our Future Wellbeing' Strategy provides an overview of health need.</p>	
5.	<p>Who will be affected by the strategy/ policy/ plan/ procedure/ service</p> <p>Consider staff as well as the population that the project/change may affect to different degrees.</p>	<p>All staff in Public Health Wales that use, manage or quality assure medical devices in the organisation. Medical devices are deployed in teams across the organisation. Beneficiaries of medical devices include patients, participants and members of staff.</p>

Part 2- Equality and Welsh language

6. EQIA / How will the strategy, policy, plan, procedure and/or service impact on people?

Questions in this section relate to the impact on people on the basis of their 'protected characteristics'.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps	Action taken by Directorate. Make reference to where the mitigation is included in the document, as appropriate This column is to be updated in future reviews	Recommendations for improvement/ mitigation/ identified gaps or opportunities
6.1 Age For most purposes, the main categories are: <ul style="list-style-type: none"> • under 18; • between 18 and 65; and • over 65 	There is no identifiable impact.		
6.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term	The deployment of some medical devices may be restricted in use for people with specific disabilities.	The deployment of medical devices will take into account persons with disabilities and adjustments made to ensure the device can be used safely either by	This will be built in to the training policy.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps	Action taken by Directorate. Make reference to where the mitigation is included in the document, as appropriate This column is to be updated in future reviews	Recommendations for improvement/ mitigation/ identified gaps or opportunities
medical conditions such as diabetes		taking adjustments and additional training.	
6.3 People of different genders: Consider men, women, people undergoing gender reassignment NB Gender-reassignment is anyone who proposes to, starts, is going through or who has completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender	There is no identifiable impact.		
6.4 People who are married or who have a civil partner.	There is no identifiable impact.		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps	Action taken by Directorate. Make reference to where the mitigation is included in the document, as appropriate This column is to be updated in future reviews	Recommendations for improvement/ mitigation/ identified gaps or opportunities
6.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding.	Some medical devices may be harmful to pregnant women.	The deployment of medical devices is risk-assessed for use and users.	
6.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies/travellers, migrant workers	There is no identifiable impact.		
6.7 People with a religion or belief or with no religion or belief.	There is no identifiable impact.		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps	Action taken by Directorate. Make reference to where the mitigation is included in the document, as appropriate This column is to be updated in future reviews	Recommendations for improvement/ mitigation/ identified gaps or opportunities
The term 'religion' includes a religious or philosophical belief			
6.8 People who are attracted to other people of: <ul style="list-style-type: none"> the opposite sex (heterosexual); the same sex (lesbian or gay); both sexes (bisexual) 	There is no identifiable impact.		
6.9 People according to their income related group: Consider people on low income, economically inactive, unemployed/workless, people who are unable to work due to ill-health	There is no identifiable impact.		
6.10 People according to where they live:	There is no identifiable impact.		

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Consider people living in areas known to exhibit poor economic and/or health indicators, people unable to access services and facilities			
6.11 Consider any other groups and risk factors relevant to this strategy, policy, plan, procedure and/or service	There is no identifiable impact.		
6.12 Welsh Language			
There are 2 key considerations to be made during the development of a policy, project, programme, service to ensure there are no adverse effects and/or a positive or increased positive effect on: (please note these will continue to be reviewed to ensure Public Health Wales fulfils their duties to comply with one or more standards outlined within the Welsh Language Standards (No 7) Regulations 2018)			
Opportunities for persons to use the Welsh language	There is no identifiable impact.		
Treating the Welsh language no less	There is no identifiable impact.		

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favourably than the English language			

Part 3 – Health

Questions in this section relate to the impact on the health and wellbeing outcomes of the population **and** specific population groups who could be more impacted than others by a policy/project/proposal.

The part of the assessment identifies;

- which specific groups in the population could be impacted more (inequalities)
- what those potential impacts could be across the wider determinants of health framework?
- Potential gaps, opportunities to maximise positive H&WB outcomes
- Recommendations/mitigation to be considered by the decision makers

7. Identification of specific population groups

Use the WHIASU Population Groups checklist as a reference to identify the population groups who could be more impacted than others by a policy/project/proposal. The check list can be found on the PHW Integrated EqHIA guidance pages (requires link to PHW Intranet pages for additional information and resources)

The groups listed have been identified as more susceptible to poorer health and wellbeing outcomes (health inequalities) and therefore it is important to consider them in a HIA assessment. In a HIA, the groups identified, as

more sensitive to potential impacts will depend on the characteristics of the local population, the context, and the nature of the proposal itself.

7.1 Groups identified	Rational/explanation
None in addition to those in previous section.	

Assessment

Complete the wider determinants framework table below providing rational/evidence where appropriate:

1. Consider how the proposal could impact on the population and specific population groups identified above (positive/negative) for each of the wider determinants (the bullets under each determinant are there as a guide)
2. Record any unintended consequences (negative impacts) and/or gaps identified
3. Record any positive impacts or missed opportunities to maximise positive health and wellbeing outcomes
4. identify and record mitigation/recommendations where appropriate

Please note you may find that not all determinants are relevant to the project/plan however recording N/A is not acceptable a rational or evidence should be explained/referenced

Wider determinant for consideration	Positive impacts or additional opportunities	Unintended consequences or gaps	Population groups affected	Mitigation/recommendations
7.2 Lifestyles <ul style="list-style-type: none"> • Diet/nutrition/breastfeeding • Physical activity • Use of alcohol, cigarettes, e-cigarettes • Use of substances, non-prescribed drugs, abuse of prescription medication • Social media use • Sexual activity • Risk-taking activity i.e. gambling, addictive behaviour 	There is no identifiable impact.			

7.3 Social and community influences on health <ul style="list-style-type: none"> • Adverse childhood experiences • Citizen power and influence • Community cohesion, identity, local pride • Community resilience • Domestic violence • Family relationships • Language, cultural and spirituality • Neighbourliness • Social exclusion i.e. homelessness • Parenting and infant attachment • Peer pressure • Racism • Sense of belonging • Social isolation/loneliness • Social capital/support/networks • Third sector & volunteering 	There is no identifiable impact.			
7.4 Mental Wellbeing <ul style="list-style-type: none"> • Does this proposal support sense of control? • Does it enable participation in community and economic life? • Does it impact on emotional wellbeing and resilience? 	There is no identifiable impact.			
7.5 Living/ environmental conditions affecting health <ul style="list-style-type: none"> • Air quality • Attractiveness/access/availability/quality of area, green and blue space, natural space. • Health & safety, community, individual, public/private space • Housing, quality/tenure/indoor environment • Light/noise/odours, pollution • Quality & safety of play areas (formal/informal) 	The use of medical devices may have an impact on carbon emissions.		Population-wide	Consideration under the NHS decarbonization strategy.

<ul style="list-style-type: none"> • Road safety • Urban/rural built & natural environment • Waste and recycling • Water quality 				
7.6 Economic conditions affecting health <ul style="list-style-type: none"> • Unemployment • Income, poverty (incl. food and fuel) • Economic inactivity • Personal and household debt • Type of employment i.e. permanent/temp, full/part time • Workplace conditions i.e. environment culture, H&S 	There is no identifiable impact.			
7.7 Access and quality of services <ul style="list-style-type: none"> • Careers advice • Education and training • Information technology, internet access, digital services • Leisure services • Medical and health services • Other caring services i.e. social care; Third Sector, youth services, child care • Public amenities i.e. village halls, libraries, community hub • Shops and commercial services • Transport including parking, public transport, active travel 	There is no identifiable impact.			
7.8 Macro-economic, environmental and sustainability factors <ul style="list-style-type: none"> • Biodiversity • Climate change/carbon reduction/flooding/heatwave • Cost of living i.e. food, rent, transport and house prices • Economic development including trade • Government policies i.e. Sustainable Development principle (integration; 	The use of medical devices may have an impact on carbon emissions.		Population-wide	Consideration under the NHS decarbonization strategy.

collaboration; involvement; long term thinking; and prevention) • Gross Domestic Product • Regeneration				
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Stage 3

Summary of key findings and actions Please answer question 8.1 following the completion of the EHIA and complete the action plan

Key findings: Impacts/gaps/opportunities	Actions (what is needed and who needs to do) to address the identified mitigation and recommendations	Lead		
<p>The range of medical devices used in PHW is wide, ranging from Breast Imaging equipment to first aid kits.</p> <p>The medical devices policy and procedure ensures that the deployment of medical devices in PHW is safe, monitored and governed in accordance with the MHRA guidance. The equalities impact is considered to be minimal as medical devices are deployed equally across all population groups. There may be impact of users with</p>	<p>The risk assessment of medical devices should take into account disability and pregnancy.</p>	<p>Medical Devices Safety Officer and Local MDSOs</p>		

certain characteristics, but these are risk-assessed on a case by case basis.				
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Alternatively, if appropriate, please explain the steps taken to consult with and consider the differential impact of the changes on the various protected characteristic groups (part 2) or any specific identified population groups (part 3).