World Health Organization

POLICY BRIEF

FOR MANUFACTURERS OF MEDICAL DEVICES INCLUDING IVDS

Implementation of post-market surveillance in cervical cancer programmes

Summary

World Health Organization (WHO) recommends that the health care programmes actively contribute to post-market surveillance of the medical devices they are using. Post-market surveillance provides insight into potential quality, safety and performance issues with the medical devices so manufacturers can re-evaluate the risk/benefit profile and take action when necessary. Although users have no official responsibility for post-market surveillance, most of the information on the experience with the actual use of medical devices comes from users.

Background

WHO guidance on post-market surveillance of medical devices, including in vitro diagnostic medical devices (IVDs), provides an overview of proactive and reactive measures to collect information on the safety, quality and performance of medical devices used within cervical cancer programmes *(1)*. When implemented correctly, post-market surveillance allows manufacturers to correct and prevent recurrence of issues that may lead to harm. Besides manufacturers of medical devices, and other economic operators in the supply chain, WHO's guidance addresses the role of health care workers, and gives an overview of the market surveillance activities that are the responsibility of national regulatory authorities (NRAs).

Although medical devices are designed, developed, manufactured and distributed on the global market after thorough validation and verification, there might be questions that cannot be fully answered in the pre-market phase or problems that only arise once medical devices are being used in the real world.

Internationally recognized standards such as International Organization for Standardization (ISO) standards for medical devices place emphasis on the importance of post-market surveillance. There are ISO standards on quality management systems for medical devices, risk management for medical devices and clinical investigation for medical devices that include requirements for post-market surveillance, as well as a standalone standard on post-market surveillance for manufacturers of medical devices *(2, 3, 4, 5)*.

Post-market surveillance – conducted by manufacturers and other economic operators

Post-market surveillance is a set of activities conducted by manufacturers of medical devices and other economic operators (distributors, importers, authorized representatives) to detect, investigate and act on any data/information made available to them on quality, safety or performance of their medical device. Post-market surveillance is a crucial tool to ensure that medical devices continue to be safe and perform as intended, and to consider necessary actions to maintain an optimal benefit-risk balance. The outcome of the analysis of post-market surveillance data can also indicate opportunities to improve the medical device. Feedback from users and patients/clients on the safety, quality and performance of medical devices, including IVDs, is the basis for post-market surveillance. Feedback is evaluated by the manufacturer to establish if it constitutes an incident that should be reported to the NRA, and if action should be taken to reduce risk to patients, users and other people.

Specific implementation considerations for cervical cancer programmes

The manufacturers that supply medical devices or IVDs for cervical cancer programmes, shall be required to have a system in place for post-market surveillance. Programme implementers should include this requirement in their purchase arrangements with manufacturers and other economic operators.

Cervical cancer programme implementers will play a role in post-market surveillance. As the feedback on the medical device comes primarily from users (laboratory staff, biomedical engineers, physicians, gynaecologists, etc), they must be aware of the importance of timely feedback on quality, safety and performance of medical devices, including IVDs, that they use. In addition, patients/clients should be encouraged to provide feedback. WHO guidance provides information on the kind of feedback that should be reported, and on how this could be done, see **Table 1**.

Table 1.
Product problems that might be reported as feedback for medical devices used in cervical cancer programmes

Type of device	Type of problem
• Vaginal speculae • HPV virological technologies • Colposcopes • Thermal ablation units • Cryotherapy units • Electrosurgical unit (ESU) for large loop excision of the transformation zone (LLETZ), also known as loop electrosurgical excision procedure (LEEP) • Devices for collecting and processing specimens for cytology and histopathology, and devices for surgical resection	• Patient-device interaction • Manufacturing, packaging or shipping • Chemical • Material integrity • Mechanical • Optical • Calibration • Output (e.g. false negative, false positive) • Temperature • Computer software • Connection • Communication or transmission • Infusion or flow • Activation, positioning or separation • Electrical/electronic property • Protective measure • Compatibility • Contamination/decontamination • Environmental compatibility • Installation-related • Labelling, instructions for use (IFU) or training • Human-device interface • Use of device

How to report user feedback on medical devices?

Users can use the WHO user feedback form or equivalent to notify the manufacturer. If it is not feasible for users to provide feedback directly to the manufacturer, it can be provided to the local distributor or agent, or the NRA, who will forward the feedback on to the manufacturer, see **Table 2**.

Table 2.
Activities to be conducted by users

Type of device	How	Data source
Detect issues	Conduct physical inspection of incoming devices: • check for manufacturing, packaging or shipping problems, including defective or damaged devices/components/packaging materials (e.g. sterility), missing components • check for any evidence of tampering of labels and/or packaging (e.g. falsification) and • check for problems with labelling, including IFU; and/or need for training	• Inventory records • Certificate of analysis issued by manufacturer
	Conduct calibration and maintenance as per IFU	Maintenance records
	Observe clinical procedures	Clinical patient records
	Use clinical judgement to identify misdiagnosis or ineffective treatment	Clinical patient records
	Allow patients/clients to provide their feedback	Interviews
	Review cervical cancer registries and population-based cancer registries for misdiagnosis	Registry data
	If IVD: • conduct QC to detect nonconforming product (out of specification results) and • participate in EQA to detect nonconforming results (incorrect status)	• EQA and QC reports • Data from LIMS
Document feedback	Gather supporting information: • product details (serial number/lot number, model number/product code, etc.) • take a photograph of labelling, if possible • note when and where you received the device • describe how you stored the device until you used it • describe exactly what happened, and include photographs, if relevant	• Product labelling • UDI on device • Clinical patient records • Data from LIMS
	Fill in standardized form to report feedback	Feedback form in local language
Provide feedback	Send feedback directly, or via the local economic operator, to the manufacturer	Contact details on labelling
Act on advice from manufacturers and from authorities	Quarantine affected devices and/or retain samples of affected devices but continue services as usual unless otherwise instructed	
	Act on instructions issued by manufacturers which detail field safety corrective actions	Manufacturer-issued FSNs or letters
	Act on NRA letters to users or WHO information notices for users of medical devices	NRA-issued or WHO-issued notices

Note: EQA – external quality assessment; FSN – field safety notice; IFU – instructions for use; LIMS – laboratory information management system; NRA – national regulatory authority; QC – quality control; UDI – unique device identification system.

Special considerations for users of HPV virological technologies

Users should place emphasis on providing feedback for any output problem, that is incorrect, inadequate or imprecise results or readings which led or might have led to misdiagnosis, delayed or inappropriate treatment. Participation in EQA schemes may detect nonconforming product where the results don't agree with the EQA providers reference result. Similarly, internal and external QC materials may be used to monitor for out of specification results.

Key WHO publications on medical devices for cervical cancer programmes

- Introduction and scale-up of HPV virological testing for screening within a comprehensive cervical cancer prevention and control programme: a WHO step-by-step guide. Geneva: World Health Organization; 2020. ISBN 978-92-4-001516-6.
- Guide for establishing a pathology laboratory in the context of cancer control. Geneva: World Health Organization; 2019. ISBN 978 92 4 151693 8.
- WHO technical guidance and specifications of medical devices for screening and treatment of precancerous lesions in the prevention of cervical cancer. Geneva: World Health Organization; 2020. ISBN 978 92 4 999263 0.
- WHO/IAEA technical specifications for radiotherapy equipment in cancer treatment. Geneva: World Health Organization; 2020.

What is the role of the NRA?

Market surveillance is undertaken by the NRAs, using a risk-based approach. It is their responsibility to ensure that necessary checks and balances are made on the ongoing safety, quality and performance of medical devices, through review of documentary evidence or on-site inspection or physical inspection/testing. Regulators also receive reports on certain categories of incidents (adverse events and product problems), monitor the actions taken by manufacturers, and take their own actions where necessary.

To date, very few low- and middle-income countries implement market surveillance due to capacity and lack of implementation of legislative frameworks. This only heightens the need for device manufacturers to conduct post-market surveillance in less well-regulated markets.

What is the role of the WHO?

WHO will provide support to users to enable them to give feedback to manufacturers. WHO will support NRAs who wish to extend their capacities to implement market surveillance activities. For WHO listed medical devices, WHO reserves the right to conduct follow-up inspections to ensure that adequate actions are taken regarding post-market surveillance data analysis and that the necessary corrective actions/preventive actions have been implemented.

Where do I find information on current product safety, quality or performance issues?

- For members of the International Medical Device Regulators Forum
- WHO recommended medical devices including IVDs