The importance of implementing a continuous cycle of improvement for medical devices.

Roles for various stakeholders

Robert Geertsma, Arjan van Drongelen
Robert.Geertsma@RIVM.nl
RIVM – National Institute for Public Health and the Environment

Governmental Agency since 1909

RIVM Act: Scientific Independency

Main commissioning:
• Ministries:
  – Health, Welfare and Sport
  – Infrastructure and the Environment
  – Economic Affairs
  – Social Affairs and Employment
• Inspectorates
• EU, UN

Medical Devices one of the strategic focus areas
Important requirements for medical devices

Design (Medical Device Directive, Essential Requirement 2)
1. eliminate or reduce risks as far as possible
2. take adequate protection measures
3. inform users of the residual risks

Risk management (EN ISO 14971)
- continuous, ongoing, iterative process
- set of repeatable steps
- throughout the entire life cycle

Post marketing and vigilance
- active collection of data
- Risk management, CAPA and FSCA

+ Interaction between above components !!
The concept of a Continuous Cycle of Improvement (CCI) for Medical Devices

- Design and user information of medical device
- Risk management activities
- Post-market surveillance

PMS important cornerstone
PMS in Medical Device Directive (MDD)

● Annex II:
an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:
[...]

● Annex X (Clinical evaluation)
  – Update clinical evaluation with PMS data
Reality check in practice

- Multiple studies assessing technical documents performed by RIVM
  - Annex II
  - Devices for clinical study
  - Over-the-counter devices
  - CCI
  - IVDs for self testing
  - Class III
  - POC-devices
  - MoM-hip implants
  - Blood glucose meters
  - Silicone Breast Implants
  - ...
CCI in practice, with focus on PMS

PMS & Vigilance

● An adequate PMS procedure:
  – active collection and review of experiences and
  – the use of multiple sources of information and

● An adequate vigilance procedure shall consider:
  – incidents/complaints and recalls and
  – notification duty to competent authorities and

● Both PMS & Vigilance:
  – Part of a complete cycle of continuous improvement: lessons learnt will be fed back in risk analysis, and may lead to e.g. changes in the product, intended use and labelling or instructions for use.
CCI in practice (Annex II devices, 2005)

File assessments RIVM
- PMS often passive/reactive
- Little connection to risk management/CAPA

From: RIVM report 265011003: 2005
CCI in practice (CCI study, various devices, 2009)

CCI implemented, but often in infancy; issues:
- Device modifications and risk analysis update - not tuned
- Procedural implementation PMCF not yet established
- Risk management and CAPA underexposed in procedures.
- The quality of PMS and vigilance procedures to be improved.

Further implementation of CCI necessary to optimise safety of patients, users and other persons

CCC in practice: SBI (2016)

File assessments RIVM
PMS more often (pro)active instead of only passive
Better connection to risk management/CAPA than before
However, also shortcomings ...

New: Criteria for action & check if decision on action was taken
Point-of-care diagnostics
Studies on use of devices

- Hospital
- General practitioners
- Nursing homes

Outcome relevant for PMS: When a device failure occurs, the actions taken are often limited to repeating the test. In such cases, hardly any of the respondents contact the manufacturer.

! Users should contact manufacturer
! Manufacturers should approach users actively
Conclusions reality check in practice:

- Implementation of PMS could AND should be improved
  - Wide variety of manufacturers and products assessed
  - Outcomes similar

- PMS has to and is going to become more important in EU

- Better and uniform understanding of PMS is needed, so guidance or standards is desirable
Initiatial proposal and negotiations on new Medical Device Regulation (MDR) and PMS

● European Commission: initial proposal contained limited requirements for PMS

● Dutch delegation took initiative and got support from many Member States

● RIVM reports played a role in thinking about PMS

● Council proposal: PMS much more detailed.
PMS and legislation; MDR

Final text - PMS related requirements in multiple places, e.g.:

- Definition of PMS, PMS-data added to definition of clinical data
- Person responsible for regulatory compliance: also PMS
- Monitoring of NBs by authorities includes PMS activities
- Specification for what to use as PMS data
- Periodic safety update report
- Electronic system for vigilance and PMS

Manufacturers should play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices in order to update their technical documentation and cooperate with the national competent authorities [...]. To this end manufacturers should establish a comprehensive post-market surveillance (PMS) system, set up under the quality management system and based on a PMS plan. Relevant data [...] should be used to update any relevant part of technical documentations, such as those relating to risk assessment and clinical evaluation, and should also serve the purpose of transparency.
PMS in MDR

- Definition of PMS

‘post market surveillance’ means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a **systematic** procedure to **proactively** collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to **immediately** apply any necessary corrective or preventive actions;

PMS also mentioned in definition of clinical data
PMS in MDR

- PMS explicitly mentioned in article on responsibilities of manufacturers.
- Person responsible for regulatory compliance: also PMS
- Monitoring of NBs by authorities includes PMS activities

Chapter VII Post-market surveillance, vigilance and market surveillance

SECTION 1 POST-MARKET SURVEILLANCE
PMS in MDR

- Relevant data on the quality, performance and safety of a device throughout its entire lifetime, to draw the necessary conclusions...

- PMS data used to:
  - Update benefit/risk ratio, risk management, design, IFU, labelling
  - Update clinical evaluation
  - Update summary of safety and clinical performance
  - Identify need for CAPA
  - Improve the usability, performance and safety of the device
  - Contribute to the post-market surveillance of other devices
  - Trend analysis and reporting, significant increase to be reported to authorities
PMS in MDR

- Post market surveillance plan, part of technical documentation
  - Specific for a device

- PMS report
  - Class I
  - Data, analysis and actions (if needed)

- Periodic safety update report (PSUR)
  - The conclusion of the benefit risk determination;
  - the main findings of PMCF-report
  - the volume of sales and an estimate of the use of the device
  - Class IIb an III: annually, Class IIa: every two years
PMS and standardization – ongoing progress

- ISO TC 210, technical committee responsible for
  - ISO 13485 Quality Management System: recent revision and related Handbook containing more explicit links to PMS
  - ISO 14971 Risk Management: Currently ongoing revision is explaining more information on and links to PMS
  - ISO/TR AWI 20416 Post Market Surveillance: approved work item; work has started – guidance on how to perform PMS
Conclusions:

● PMS requirements strengthened in MDR compared to MDD

● PMS links to several other important elements, e.g. risk management, quality management and clinical data.

● Together the new requirements, and the revised standardisation documents explicitly including PMS will stimulate the implementation of a Continuous Cycle of Improvement for medical devices.
Recommendations

● For manufacturers:
  – Start thinking about your current system for & use of PMS
  – Do you obtain sufficient information about safety and performance? If not: improve your system
● For users:
  – Provide more feedback to manufacturers, do your part
● For standard/guidance developers:
  – TR on PMS, PMS in risk management and PMS in quality management to be developed in liaison
● For Regulators:
  – Include requirements for PMS in your regulatory system
Thank you!