Risk management regarding the use of medical equipment

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Patient safety is a key dimension of the quality of medical care.

It is a term that includes actions aimed at eliminating, reducing and mitigating the avoidable adverse outcomes generated as a consequence of the care process, as well as promoting those practices that have resulted.

It involves all health professionals and of course includes the patient.

Who regulates the quality of medical services in Romania ?

Autoritatea Naţională de Management al Calităţii în Sănătate (ANMCS)/

National Authority for Quality Management in Health

The purpose of ANMCS is to ensure and continuously improve the quality of health services and patient safety,
by standardizing and evaluating health services and accrediting health units.

Who regulates the quality of **medical equipment** in Romania ?

Agentia Nationala a Medicamentului si a Dispozitivelor Medicale din Romania/National Agency for Medicines and Medical Devices in Romania

- maintaining a high level of performance and safety of medical devices in use in healthcare networks throughout the country, regardless of the nature of their ownership;
- the evaluation with the maximum exigency of the technical-medical units providing services in the field of medical devices, so that the services of prosthesis of any kind and those of repair-maintenance of the medical devices are carried out at the optimum level of quality and competence;
- elaboration of specific technical procedures in the field of medical devices;

Medical devices are used

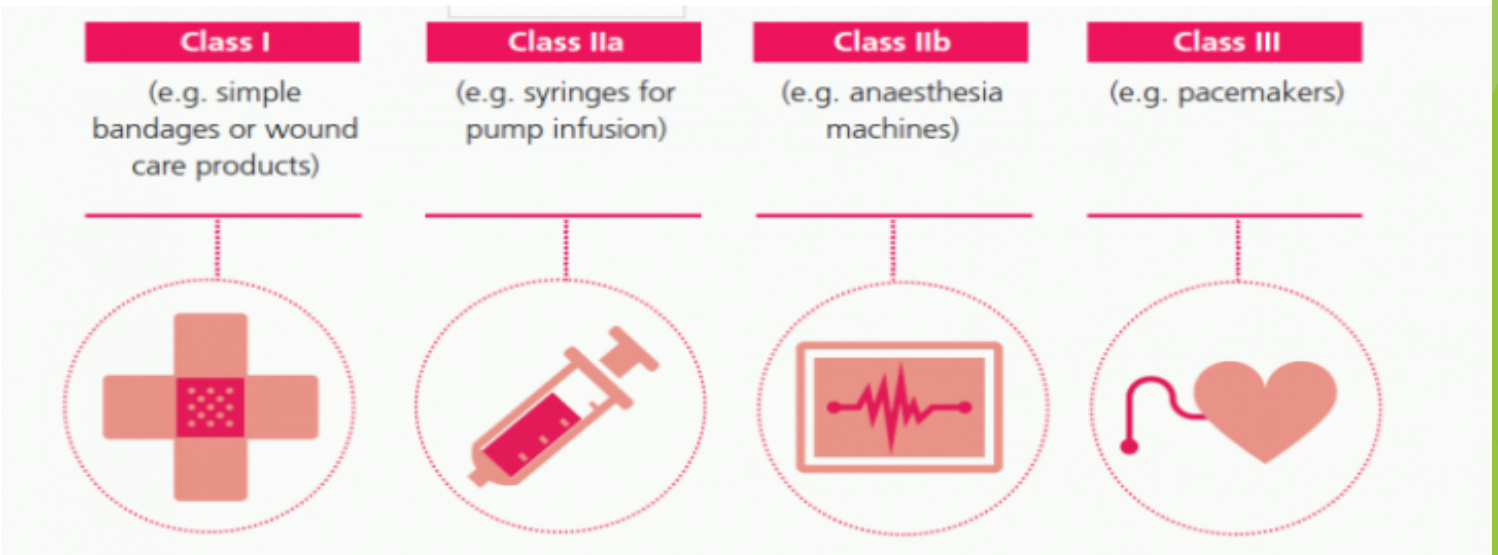
- for diagnosis
- for treatment

The World Health Organization (WHO) in accordance with ANMCS have made quality assurance in the use of medical devices a strategic objective

Modern technology produces an overwhelming abundance of medical devices at a rate that soon makes the latest device outdated.

At European level, there are concerns regarding the medical devices and the diagnostic ones regarding:

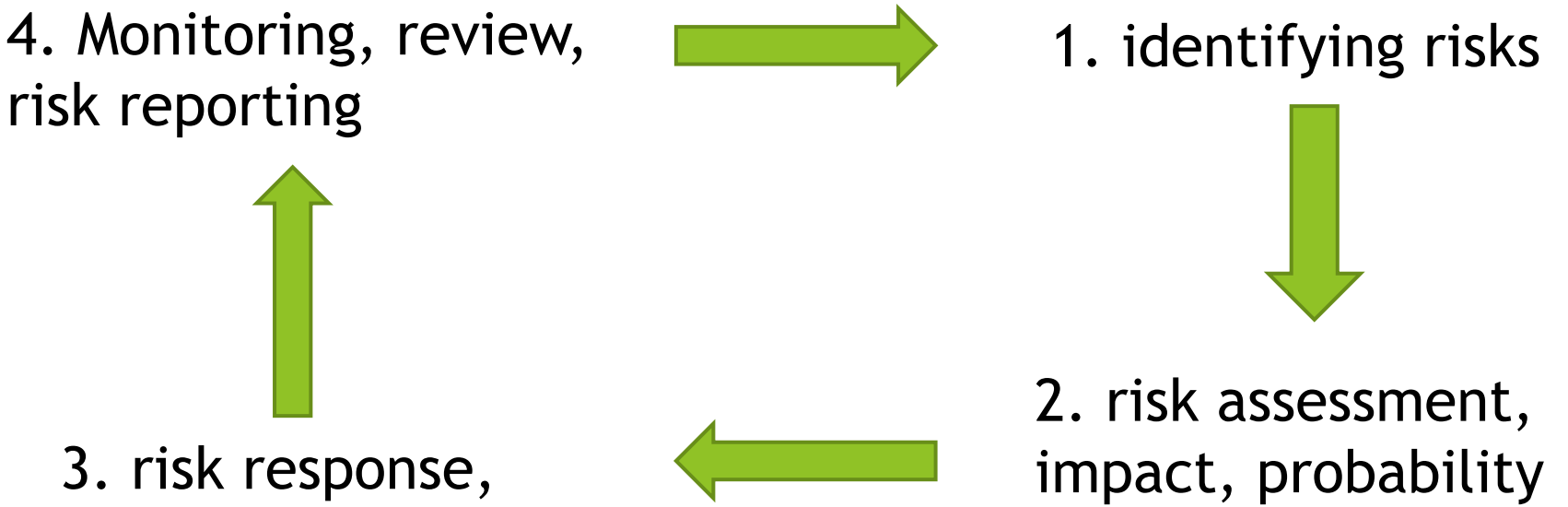
- improving the quality, safety and reliability of medical devices;
- enhancing transparency regarding consumer information;
- increasing the vigilance and supervision of the market for sale, marketing



Medical devices are effective when considered in the broader context of the comprehensive health care package needed to meet public health needs:

- prevention
- clinical care (investigation, diagnosis, treatment and management, monitoring and rehabilitation)
- access to adequate health care.

Risk management processes



1. Risk assessment

Assume-

- evaluation of the probability-impact binomial for each risk
- clear differentiation of inherent risks from residual risks
- prioritizing risks
- the risk must be evaluated from the perspective of a combination between the probability that it will happen and the impact that its materialization will have

Particularities of risk assessment

The purpose of the evaluation
- establishing the risk hierarchy based on risk tolerance

Risk assessment must be based on
- ✓ objective evidence,
- ✓ to take into account all those affected by the risk
- ✓ to distinguish between risk exposure and risk tolerance

Risk assessment is carried out through

- evaluation of the probability of materialization of the identified risk
- assessing the impact on the objectives in case the risk would materialize
- risk exposure assessment = product of probability and impact

Probability

= determining the chances of occurrence of risk

Example

- out of 200 lots produced from a supplier it was found that in 18 cases there were deficiencies / defects

The risk of non-compliant supply has a probability of materialization of 9%

The impact

The assessment of the impact on the objectives in the event of risk materialization can be quantitative and qualitative

example
the impact produced by the risk of hiring inadequate personnel
- deterioration of the working climate (qualitative)
-XXX lei / year lost budgetary effort (quantitative)
-xx hours delay in carrying out tasks (quantitative)

Exercise

Is the failure of the blood pressure monitoring equipment in a dental office a risk?

- of course

or

- is not

Why? argument

Risk response / control

The goal

- transforming uncertainty into an advantage for unity, limiting the level of threats and benefiting from the advantages

Risk response strategies

-acceptare / tolerance
-tratare / attenuation / mitigation
-elimination
- transfer

The best way to get rid of a problem is to solve it-
Brendan Francis

Risk monitoring, review and reporting

The process of monitoring, updating risks must

-It will be done at least annually
- to communicate to the management
-to analyze causes and mechanisms of correction

Medical devices can be classified as risk dependent

- Availability
- Accessibility
- Appropriateness/ Matching
- Affordability

These four components allow the selection of appropriate medical devices purchased in a rational way, to meet the needs and to ensure that they are used as effectively as possible to improve the health of patients.

- A medical device must be appropriate to the context or framework in which it is intended.
- Context in this regard refers to the connection of the correct medical device to the corresponding health need to maximize its effectiveness.
- However, almost all devices in developing countries have been designed for industrial use.
- Up to three quarters of these devices do not work in the new settings and remain unused.

The factors contributing to this are:

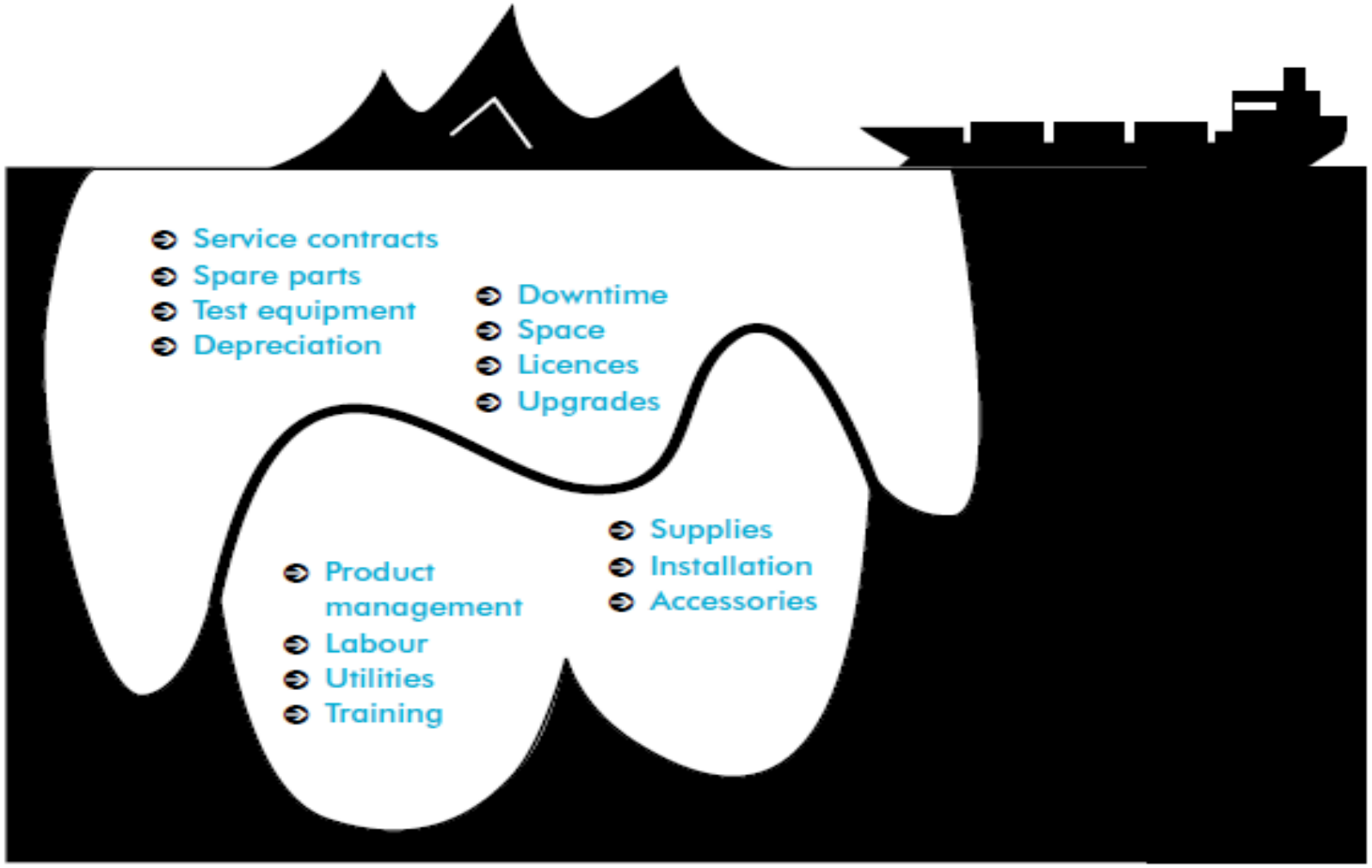
- Lack of needs assessment,
- proper design,
- robust infrastructure,
- spare parts
- spare parts when devices fail, consumables and lack of information for purchases and maintenance,
- untrained user personnel
- lack of a medical device management system.

The concept of appropriate medicine

- For example, the abundance of high-tech medical devices, actively marketed in high-income countries, may mean that medical devices are chosen and used based on factors other than clinical and public health need.

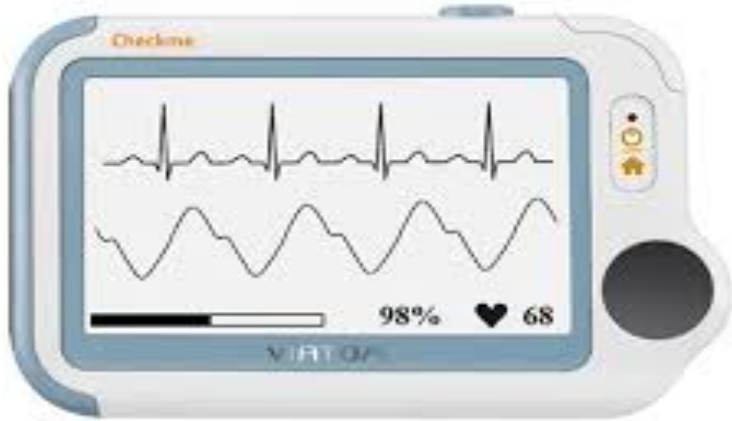
- In low-income countries, medical devices may be available but not adapted to be used effectively in the local context; for example, they cannot withstand heat and dust or may not work because electricity is insufficient.

Figure 5.1 The hidden costs of medical devices



Source: Adapted from Cheng *(41)*.

- For a hospital or clinic in the process of deciding which device to buy, an important factor is to know how safe and effective a particular device is in actual use.
- Post-market surveillance is a way of tracking the safety and effectiveness of a device.
- Manufacturers are obliged to engage in market surveillance for all introduced medical devices.
- The regulatory authorities ask the manufacturers to present the unexpected safety or use problems detected by the surveillance system.
- However, there are several shortcomings of the post-market surveillance systems and the reporting of adverse events for medical devices.



Problems

- The lack of standardization is clearly a barrier to the use of medical devices.

- The World Bank has estimated that over 50% of medical equipment in developing countries is not maintained and is out of order: "Developing countries could make higher returns on their investments in health services if they pay more attention ensuring adequate recurring budgets would give the importance of training operators and staff and introducing good practice management. “

Thank you for your attention!