# Medical devices in Morocco: what guarantees of quality and safety ?

GRP-112

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## OBJECTIVES

Nowadays, all over the world, many medical devices, initially considered as non-risk or low risk, have been proved to be extremely dangerous to human health, as evidenced by the latest scandal of PIP implants.

This study aims to report the experience of Mohammed V Military Teaching Hospital of Rabat in evaluating the quality and safety of medical devices and to analyse elements that can compromise the quality of these products in our country.

## METHODS

It's a 30-month prospective study (January 2010 - June 2012) during which we collected claims relating to the quality of medical devices at our hospital, in normal conditions of acquisition, dispensing and use. We also analysed the processes of placing on the market medical devices, the systems governing their use in hospitals and the main Moroccan rules regulating them.

## RESULTS

30 claims were collected. They concerned: catheters (40%), surgical drapes (20%), gloves (17%) and other medical devices (23%). 47% of their defects were discovered before they were used in patients, 13% presented a risk of incident and 40% caused an incident in patients.
The process of marketing a medical device, ensuring its quality and safety, must satisfy several checks regarding the design, manufacture, import, sale purchase and use, before Ministry of Health certification can be obtained.

**Table 1 : Types of collected claims**

| MEDICAL DEVICES | TYPES OF CLAIM |
|---|---|
| **Catheters** | - urinary catheters: too flexible or too rigid, balloon hernia;<br>- haemodialysis catheters: thrombogenic, insufficient blood flow;<br>- infusors tubes: tube bending. |
| **Surgical drapes** | low impermeability, a blue tint was released in the operating field. |
| **Gloves** | - clean gloves: poorly talc-powdered, low impermeability, break easily;<br>- sterile gloves: poor resistance, difficult unpacking in sterile conditions. |
| **Others** | - trocars: mandrel hard to remove, difficult screwing and unscrewing;<br>- needles: difficult handling, nonconformity of the tip;<br>- sticking plaster: poor adhesion. |

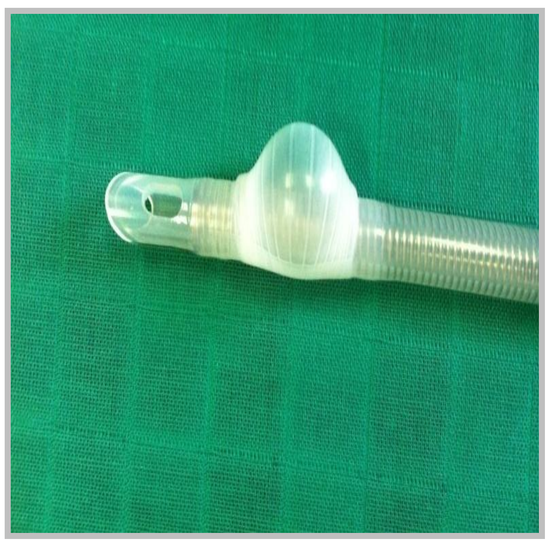

**Figure 1** : Endotracheal Tube with an asymmetrically inflated balloon

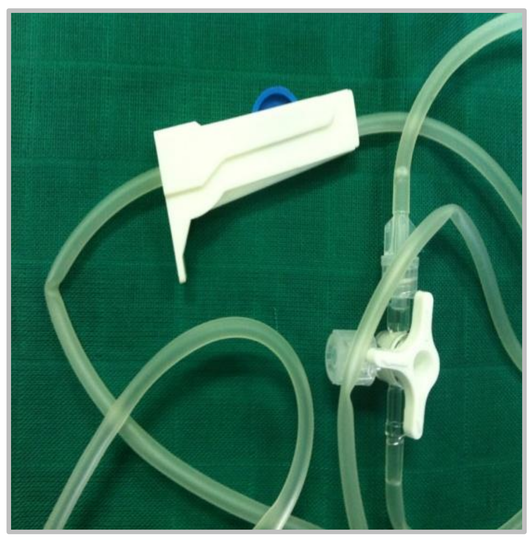

**Figure 2** : Perfusor tube bending preventing solutes passage

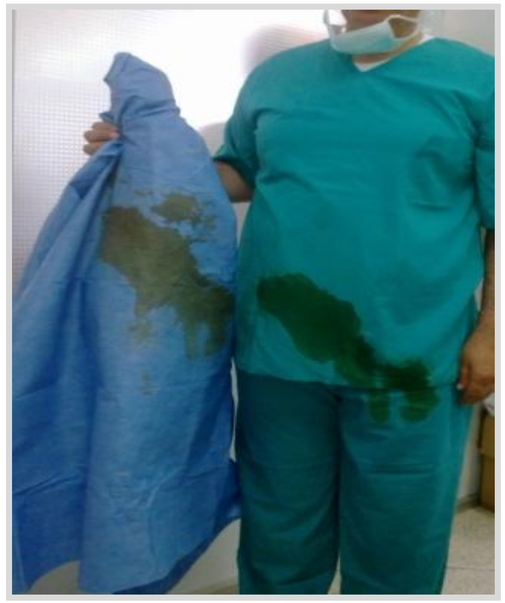

**Figure 3** : Surgical gowns with waterproofing default

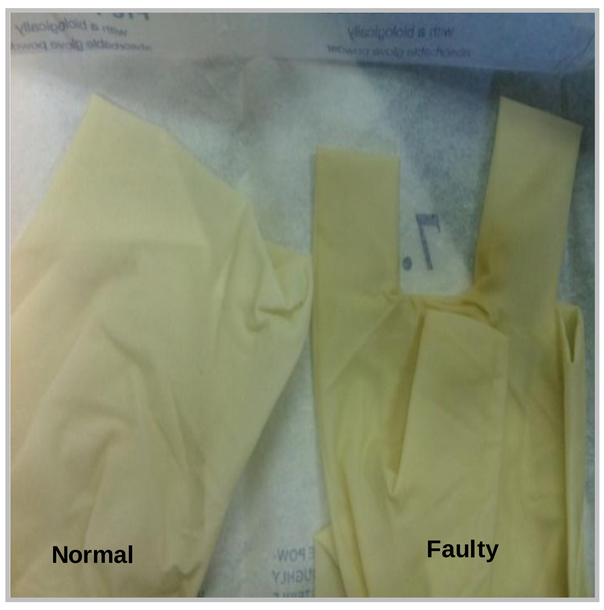


**Figure 4** : Surgical gloves with a change in hue

**Table 2 : Main Steps of marketing a medical device and applied controls**

| STAGE | GUARANTEE OF QUALITY AND SAFETY | DETAILS |
|---|---|---|
| **Conception** | Trials - clinical trials | Physico-chemical tests, clinical trials... |
| **Manufacturing** | Controls | Raw materials, semi-finished products, finished products |
| **Marketing circuit (import, sale)** | Technical and administrative controls | Registration, accreditation, certification... |
| **Purchase / acquisition** | - Mastery of the nomenclature;<br>- elaboration of the specifications sheet;<br>- technical analysis. | Compliance with the specified technical requirements |
| **Use** | Technical mastery and vigilance | Monitoring the "post-marketing" quality and safety |

**Table 3 : Main failings observed in medical devices circuit**

| STAGES | FAILINGS |
|---|---|
| **Before marketing** | - No double-blind / placebo trials ;<br>- efficiency evaluation is often operator-dependent ;<br>- predominant "engineer culture " whose objective is to improve the technical performance. The processes are not mainly focused on the patient ;<br>- indications are those claimed by the manufacturer, unlike drugs for which therapeutic indications are validated ;<br>- marketing approval on a simple homologation, instead of a mandatory marketing authorization by a national authority. |
| **Importation and marketing** | - Morocco imports from several countries, which applied requirements and repositories are often different. This generates an additional constraint for the application of control standards ;<br>- in the absence of means of control and technical analysis necessary for the review of registration files, the guarantees held in the country of origin are applicable and sufficient to obtain the registration attestation ;<br>- registration national authorities can not, because of insufficient technical and personnel resources, process all registration applications within a timeframe compatible with the urgency characterizing some product categories, necessary for patients care ;<br>- several medical devices, often belonging to class III, escape the registration procedures (cardiac endoprosthesis...). |
| **Acquisition by public hospitals** | - The new public procurement code recommend to make homogeneous lists for the acquisition of medical devices, and requires a simple documentation instead of a sample for technical compliance analysis;<br>- the lack of an uniform common nomenclature (several different proposals for the same item) ;<br>- selection of retained items is based on the interpretation of the users in charge of the technical analysis. |
| **Use in patient** | Several medical devices do not include a technical leaflet despite the presence of an icon on the labeling of these articles recommending consulting the leaflet. The use of these medical devices, in a context of uncertainty, is not optimal. |

## COMMENTS

Despite the measures and precautions taken when placing medical devices on the market and despite the provisions laid down in new legislation on medical devices, we find that in hospital practice, several medical devices present quality defects which can seriously compromise patients safety and quality of their therapeutic management.

If we consider, for several reasons which can be cultural, technical or personal, that hospital practitioners do not routinely report every adverse effects related to the use of defective or of poor quality medical devices, we can easily imagine the real scale of the problem and the eminence of the risk to any patient using a poorly controlled medical device will be used.

Moroccan industrial production of medical devices is negligible compared to imports. The majority of this production, whose raw material is totally imported, is sold in Morocco.

Unlike pharmaceutical companies that are large, and often multinational companies, manufacturers of medical devices are often small companies, more numerous.

The analysis of medical devices circuit revealed that all steps present risks of "non-quality". These risks can be classified into two main categories :

- risks related to the nature of medical devices compared to drugs ;
-risks related to failure and / or lack of controls.

The legal arsenal regulating medical devices must be constantly updated for a permanent adaptation, reflecting the rapid development of health technologies.

## CONCLUSION

Claims concerned several categories of medical devices. Abnormalities detected compromise the quality and the safety of our patient care. Checks must take place at all levels of the distribution chain to avoid these risks.