21st Congress of the EAHP
Vienna, Austria - 16-18 March, 2016
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**Abstract Number:** PP-037

# RISK OF MICROBIAL CONTAMINATION OF PHARMACY STERILE PREPARATIONS: A RISK-BASED DECISION MATRIX

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## OBJECTIVES

**Background:** In order to adapt Spanish regulations in accordance with the principles set out in the European Resolution CM/ResAP(2011)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies, a guideline on pharmacy sterile preparations at hospital pharmacies (GPSP) was published by the Ministry of Health in June 2014. The guideline includes a risk-based decision matrix to determine potential risk of microbial contamination of pharmacy sterile preparations (PSPs) and set beyond-use dates (BUDs). According to GPSP requirements, if recommended BUD limits are exceeded, each batch of PSP must be tested for sterility.

**Purpose:** To determine risk of microbial contamination of pharmacy sterile preparations according to current recommendations and to adapt beyond-use dates.

## METHODS

Risk of microbial contamination was determined for PSPs prepared in a grade C environment at our pharmacy during 2014. No batch was tested for sterility.

PSPs were classified by dosage form. A database was created to evaluate the 6 risk-based decision matrix criteria: preparation process, route of administration, drug safety profile, units per batch, microbial contamination susceptibility and distribution. According to the determined risk, GPSP recommended BUD was set for each preparation and compared with the previous defined storage requirements.

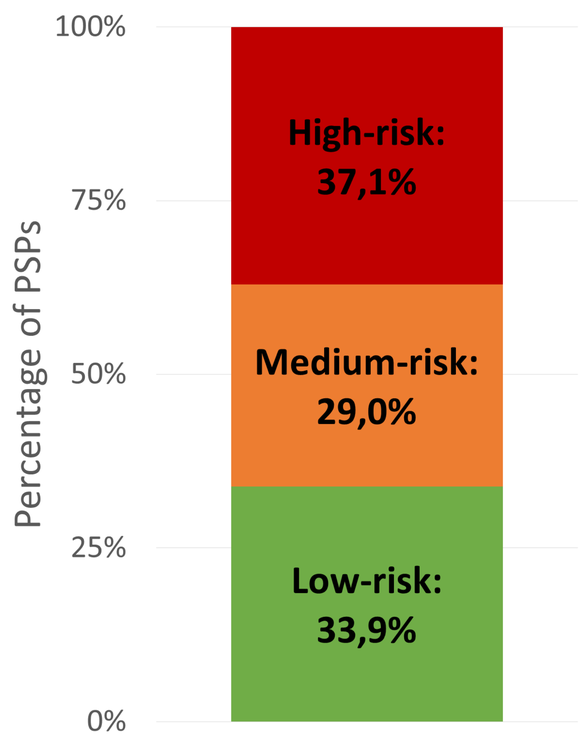
## RESULTS

Sixty-two PSPs were evaluated (Table 1.). According to the risk-based decision matrix we obtained: 21 (33,9%) low-risk (most individualized intravenous solutions, subcutaneous preparations), 18 (29,0%) medium-risk (standardized intravenous solutions, intravitreal injections) and 23 (37,1%) high-risk PSPs (ophthalmic solutions, PSPs prepared from nonsterile components) (Graph 1.).

**Table 1.** PSPs classified by dosage form

| Pharmacy sterile preparation | N=62 | Risk of microbial contamination |
|---|---|---|
| Individualized intravenous solutions | 18 | Low-risk (15) |
| | | Medium-risk (3) |
| Standardized intravenous solutions | 11 | Medium-risk (11) |
| Subcutaneous preparations | 6 | Low-risk (6) |
| PSPs prepared from nonsterile components that are terminally sterilized | 8 | High-risk (8) |
| Ophthalmic preparations | 15 | High-risk (15) |
| Syringes for intravitreal injection | 4 | Medium-risk (4) |

**Graph 1**. Risk of microbial contamination of PSPs




When comparing GPSP recommended BUDs and storage conditions with the previous defined BUDs, 21 (100%) low-risk and 14 (77,8%) medium-risk PSPs meet GPSP recommendations. Beyond-use dates of 4 (22,2%) medium-risk preparations have been shortened to comply with GPSP recommendations. In order to establish an extended BUD for 23 (100%) high-risk PSPs, each batch must be tested for sterility.

## CONCLUSIONS

The GPSP proposed risk-based decision matrix is a useful tool to determine potential risk of microbial contamination of PSPs. Compliance with GPSP contributes to increase sterile compounding quality and protect the health of patients.

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