# HAZARD VULNERABILITY ANALYSIS (HVA): EVALUATION OF RISK IN EXPERIMENTAL ONCOLOGICAL DRUGS COMPOUNDING

5PSQ-024

L01- ANTINEOPLASTIC AGENTS

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## BACKGROUND AND IMPORTANCE

Oncological drugs used in clinical trials are often characterized by:

- low therapeutic index;
- unknown toxicity;
- dosage to be personalized on patient;
- assignment of number kit/placebo to specific patient;
- associations with other drugs not known in consolidated clinical practice

All these elements can contribute to the occurrence of potential **ERRORS.**

## AIM AND OBJECTIVES

To use **HVA - *Hazard Vulnerability Analysis*** in order to classify, into **HIGH, MEDIUM, LOW RISK,** experimental protocols that provide for chemiotherapic drugs compounding.
For protocols classified as high risk, outline **STANDARD PROCEDURES** to minimize risks.

## MATERIALS AND METHODS

For each experimental protocol currently active at our hospital, we calculated the percentage risk (***R%***) using the formula:

$$R\% = \frac{P}{3} * \left[\frac{(MA+MI)}{18}\right] * 100$$

- **R% < 30%** LOW RISK
- **30% ≤ R% ≤ 60%** MEDIUM RISK
- **R% > 60%** HIGH RISK

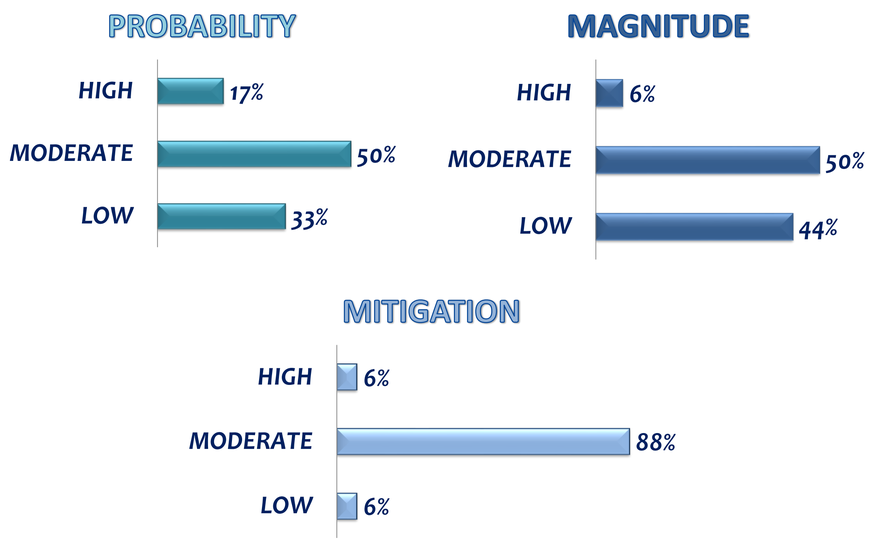
■ WHAT IS **P- PROBABILITY**?
Possibility that an event will occur.
We have calculated **number of preparation-phases.**

■ WHAT IS **MA - MAGNITUDE**?
All factors that increase the risk. It evaluates human impact, property impact and business impact.
We have calculated **carcinogenicity, storage time of preparation** and **chemical incompatibility between drugs and medical devices.**

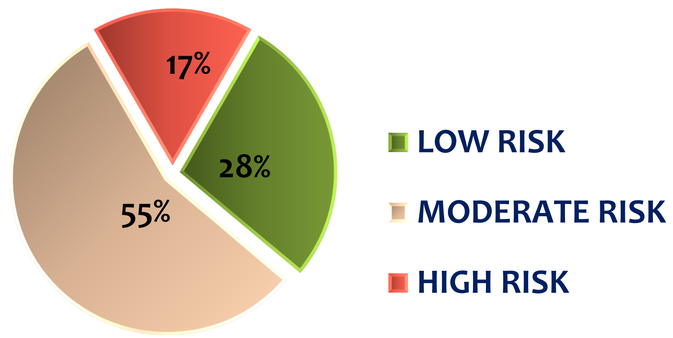
■ WHAT IS **MI- MITIGATION**?
All factors that may reduce the magnitude of the impact.
We have calculated the **drug dosage, chemical-physical preparation stability, possible use of safety-devices.**

## RESULTS

Among 35 active clinical-trials analyzed, **18** require chemiotherapic drugs **compounding**. For each of the 18 protocols, was calculated:




By applying the formula to calculate **R%**, it was found that:




***Classification of protocols according to R%***

## CONCLUSION AND RELEVANCE

Clinical protocols classified as "high risk" have been monitored, and **standard procedures** have been outlined to minimize the risks; for example:

- procedures for managing vial accidental breaking;
- cold chain control for prepared drugs;
- use of software to calculate drug dosage based on body surface;
- others.

These procedures are aimed at all personnel involved in preparation phase, including the hospital pharmacist. Hospital pharmacist is coordinates whole process, deals with **risk management** and ensures **personnel/patients safety.**

eahp european association of hospital pharmacists

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