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

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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 chemotherapic 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:

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

- 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 chemotherapic drugs compounding. For each of the 18 protocols, was calculated:

**PROBABILITY**

- HIGH: 17%
- MODERATE: 50%
- LOW: 33%

**MAGNITUDE**

- HIGH: 4%
- MODERATE: 68%
- LOW: 28%

**MITIGATION**

- HIGH: 85%
- MODERATE: 48%
- LOW: 6%

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

- LOW RISK: 55%
- MODERATE RISK: 25%
- HIGH RISK: 17%

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.