

# TRACEABILITY AND SAFETY IN THE PREPARATION OF CYTOTOXIC DRUGS

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## BACKGROUND

The constantly growing incidence of cancer and long-term treatment are leading to an increasing number of cytotoxic preparations in hospital pharmacies. Quality standards of cytotoxic preparations are essential to assure treatment efficiency and limit iatrogenic toxicity

**Purpose:** Establish a quality control that ensure traceability and safety in the preparation of cytostatic drugs as well as ensure consistency between prescription and product made to minimize errors such as the administration of defective chemotherapies.

## MATERIAL Y METHODS

Gravimetric method for the qualitative and quantitative control of cytostatic drugs is computer-aided in all stages. It consists in three weighings: just before the injection of cytotoxic drugs, weigh the dose of cytotoxic drug, and weigh of the bags containing solutions and drugs just after the injection of the cytotoxic drug. This weight depends on the volume injected and the density of the cytotoxic solution. The volume depends on the prescribed dose of the cytotoxic drug and its concentration. For each active ingredient, the value of density is collected from the supplier beforehand.

It allows the comparison between the exact amount of the drug added to the mixture and with the amount of the drug prescribed, the qualitative control by uniquely identifying products used by data-matrix codes and the traceability of batch used and finally, the control of all the process.

Descriptive retrospective observational study between october 2014 - august 2015. We calculated the following indicators: degree of coverage (%) of technological qualitative control and rate of defective preparations (DP) intercepted (DP x 1000 preparations).

## RESULTS

During this period 6420 preparations have been prepared. Quantitative control coverage was 82.3% (5347 preparations) and qualitative control coverage was 83.4% (5352 preparations). 347 errors have been detected: 61(0.9%) by gravimetry and 286 (4.5%) by qualitative control. Global Error rates intercepted were 11.4 DP x 1000 preparations by gravimetry and 53.4 DP x 1000 preparations by data-matrix reading.

## CONCLUSION

This method improves the quality and safety because it allows correcting errors in the preparation of antineoplastic real-time so it prevents reach the patient and avoids us having to repeat or discard defective preparations and economic losses. It is necessary to learn this system because keeps full traceability and really assess the intercepted errors.