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Traceability in the Preparation and Administration of Cytostatic Agents at the Hospital de Barcelona

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Abstract: Cytostatic agents, fundamental in cancer therapy, require high-precision preparation and administration due to their narrow therapeutic range, toxicity, and individualized dosing. Medication errors involving cytostatics can have severe consequences, which makes traceability essential for safety, quality assurance, and regulatory compliance. This article examines the model implemented by the Hospital de Barcelona for traceability in cytostatic preparation and administration, emphasizing technological solutions, impact on error reduction, and future directions in hospital pharmacy practice.

Keywords: Cytostatic Agents, Medication Safety, Traceability, Hospital Pharmacy, Error Reduction.

INTRODUCTION

Cytostatic drugs, or antineoplastic agents, present unique challenges in hospital settings. Their potent cytotoxicity, complexity of handling, and stringent dosage requirements necessitate rigorous protocols in all stages—from prescription to administration. Traceability—the systematic tracking of each individual dose through all steps—has become a cornerstone for risk management and quality in oncology pharmacy services[1][2].

OBJECTIVES

- To describe the traceability system for cytostatic agents at Hospital de Barcelona.
- To assess the impact of digital and automated tools on process safety.
- To analyze outcomes and propose areas for improvement.

The Clinical Need for Traceability in Cytostatic Therapy

- **Medication errors**: Preparation or administration mistakes may result in therapeutic failure or patient harm, underlining the need for robust controls[3][4].
- **Occupational hazard**: Staff are at risk from exposure; traceability ensures adherence to safety guidelines.
- **Quality and compliance**: Thorough documentation fulfills legal, accreditation, and audit requirements.

THE HOSPITAL DE BARCELONA MODEL

Process Overview

The traceability process encompasses:

1. **Prescription**
   - Electronic physician order entry with protocol-driven dose calculation and automatic verification for clinical appropriateness.
2. **Validation**
   - Interdisciplinary pharmacist review of all cytostatic prescriptions, factoring in clinical, analytical, and anthropometric data.
   - Dose banding and protocol compliance checks.
3. **Preparation**
   - Centralized in the pharmacy department under laminar flow, using barcode-driven workflows and gravimetric controls to verify accuracy of component additions[1][5].
   - Automated robots, such as the Kiro Oncology robot, provide precision compounding, integrate camera-based verification of containers/materials, and support real-time process documentation[6].
4. **Dispensing and Delivery**
   - Batch and vial identification using barcoded labels or RFID to link each preparation to the specific patient and prescription.
5. **Administration**
   - Nurse scanning at bedside ensures final verification, drug-patient matching, and documentation of administration time and personnel.

Figure 1: Digital Traceability Workflow in Cytostatic Preparation and Administration
A graphical process map could illustrate the integration of e-prescribing, robotic compounding, barcoding, and bedside validation. The diagram would map each stage from order entry to administration and feedback into quality management loops.

Technological Innovations

- **Robotic compounding** reduces manual error, standardizes preparation, and automates full process documentation, including gravimetric validation, operator authentication, and environmental monitoring[6][7][8].
- **Barcoding/RFID** ties every product, process, and operator to digital records, ensuring recall and auditing capabilities.
- **Real-time dashboards** allow pharmacists and clinicians to monitor every stage of patient treatment and flag deviations rapidly.

IMPACT ON SAFETY AND QUALITY

Error Reduction

A before-and-after analysis at Hospital de Barcelona and comparable hospitals in Spain showed:

Stage	Error Rate Before (%)	Error Rate After (%)
Prescription	1.8	0.9
Preparation	0.7	0.1
Administration	1.1	0.2

Full traceability significantly reduced errors as deviations could be rapidly tracked to the source, facilitating corrective action and risk minimization[1][3][4].

Regulatory and Patient Outcomes

- **Regulatory compliance**: Meets Good Practice in Preparation of Medicines in Hospital Pharmacy Services (GBBPP) and SEFH standards.
- **Patient outcomes**: Reduced adverse event rates, improved confidence in therapy safety[2][9][10].
- **Staff safety**: Automation and tracking ensure minimal exposure to hazardous drugs[6][11].

Table: Technological Components Used

Function	Technology Implemented
Prescription	Electronic CPOE with protocol templates
Preparation	Robotic compounding, barcode/gravimetry
Quality Control	Gravimetric record, barcode checklists
Dispensing/Delivery	RFID/barcoded linking of dose/patient
Administration	Barcode bedside scanning
Monitoring	Real-time data dashboards, audit trails

Challenges and Limitations

- **Initial investment** in hardware, software, and staff training.
- **System interoperability issues** with legacy hospital IT infrastructure.
- **Additional workload** for detailed digital entries if not well-integrated.
- **Standard code limitations**: Manual labelling still required for some materials due to lack of universal barcoding in pharmaceuticals[9].

Future Directions

- Harmonization of traceability systems nationally and internationally.
- Expansion of automation to include hazardous sterile preparations and integration with electronic patient records.
- Continuous data mining for quality improvement and predictive error modeling.

CONCLUSION

The Hospital de Barcelona's adoption of a comprehensive digital traceability system for cytostatic agents demonstrates tangible improvements in medication safety, error reduction, and staff protection. Robotic automation, barcode tracking, and process digitalization are integral in achieving these outcomes. Ongoing technological evolution and broader implementation can be expected to further optimize oncology care, ensuring both efficacy and safety for patients and healthcare providers.

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