

RISK OF PERSONNEL EXPOSURE TO HAZARDOUS DRUGS IN ROBOTIC COMPOUNDING

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BACKGROUND AND SIGNIFICANCE

Continuous occupational exposure to hazardous drugs (HD) poses significant risks to healthcare personnel. Robotic compounding systems have been introduced in pharmacies to enhance patient and staff safety. These systems operate within enclosed ISO Class 5 environments with negative pressure, which effectively minimizing personnel exposure to HD during critical operations. However, there is a concern that surfaces in the compounding area may get contaminated, potentially exposing hospital personnel to these hazardous substances.

AIM AND OBJECTIVES

The primary objective of this study is to evaluate the risk of occupational exposure to HD when utilizing robotic compounding systems for the preparation of antineoplastic sterile medications. Specifically, we aim to assess the levels of HDs present on the surfaces of ready-to-use preparations and on the gloves worn by personnel involved in the compounding process.

MATERIALS AND METHODS

This study was conducted over a period of three days during routine production at KIRO Oncology (Kiro Grifols, Mondragon, Spain). Each day, we collected wipe samples from the surfaces of 20 HD preparations and from the gloves of the operator engaged in the compounding process using Cytoxlab sampling kits (CYTOXLab, Geneva, Switzerland). Our analysis included the detection and quantification of 25 anticancer molecules commonly used in hospital pharmacies.

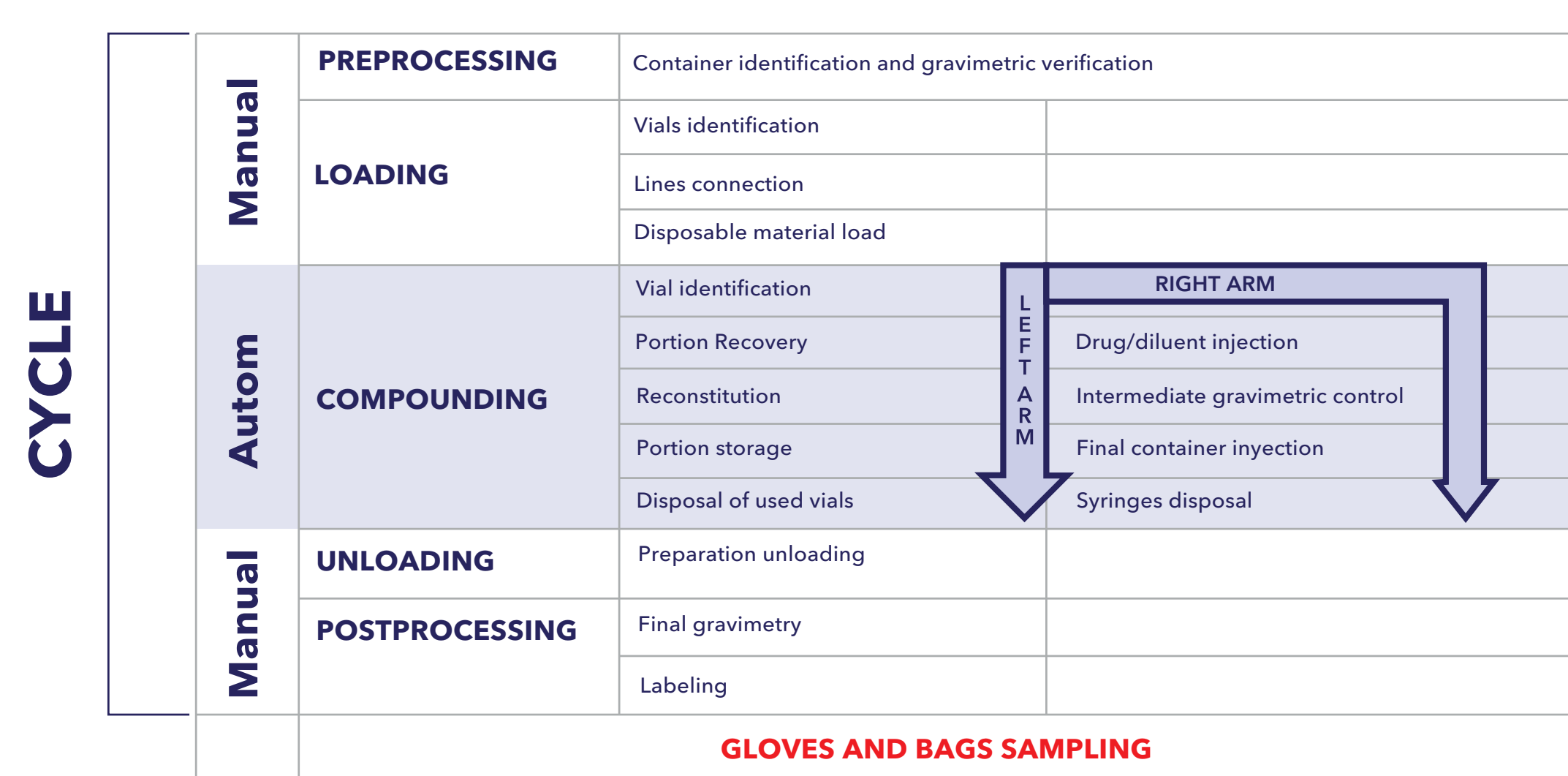


Figure 1. Compounding process and sampling.

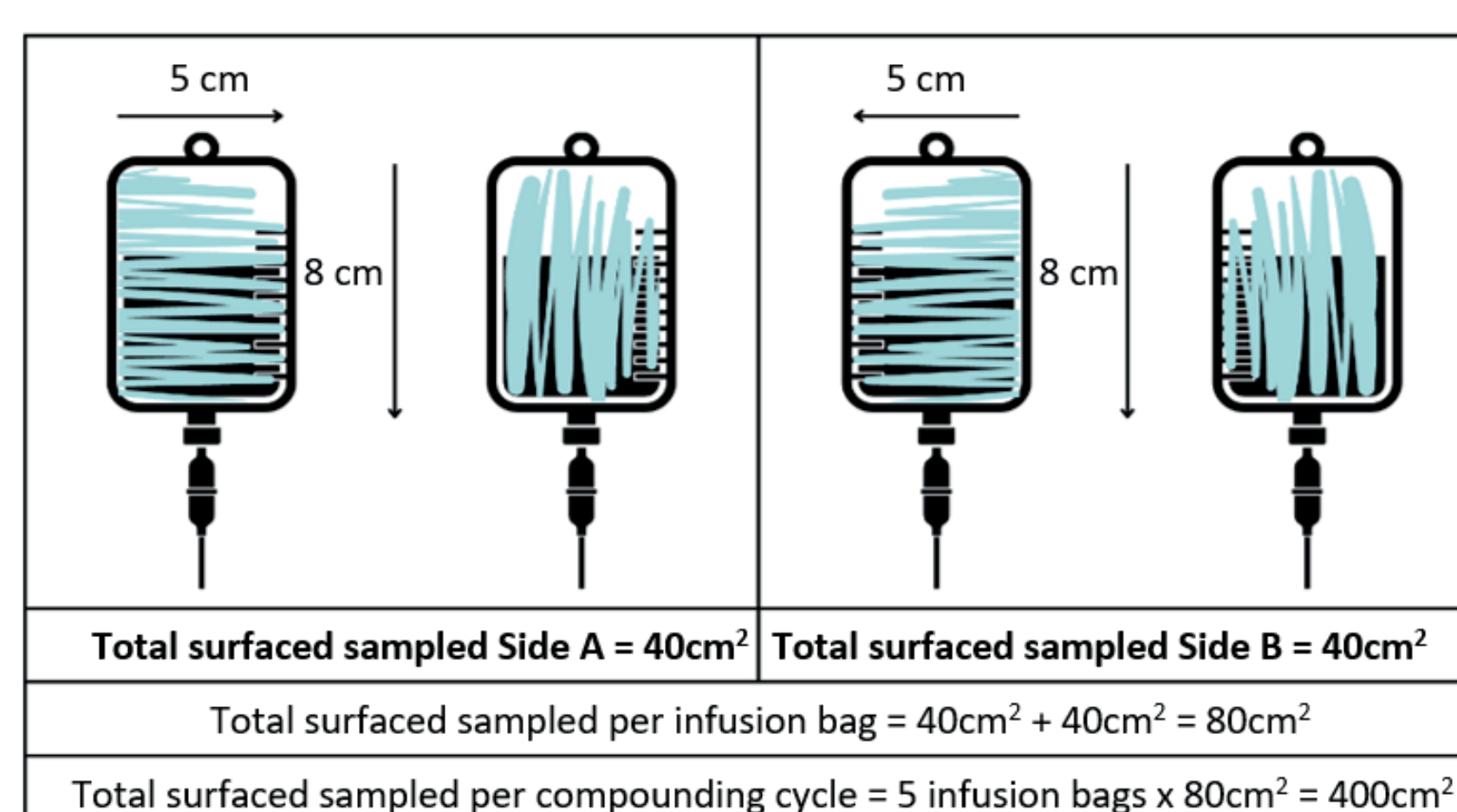


Figure 2. Horizontal and vertical wiping of the compounded preparation.

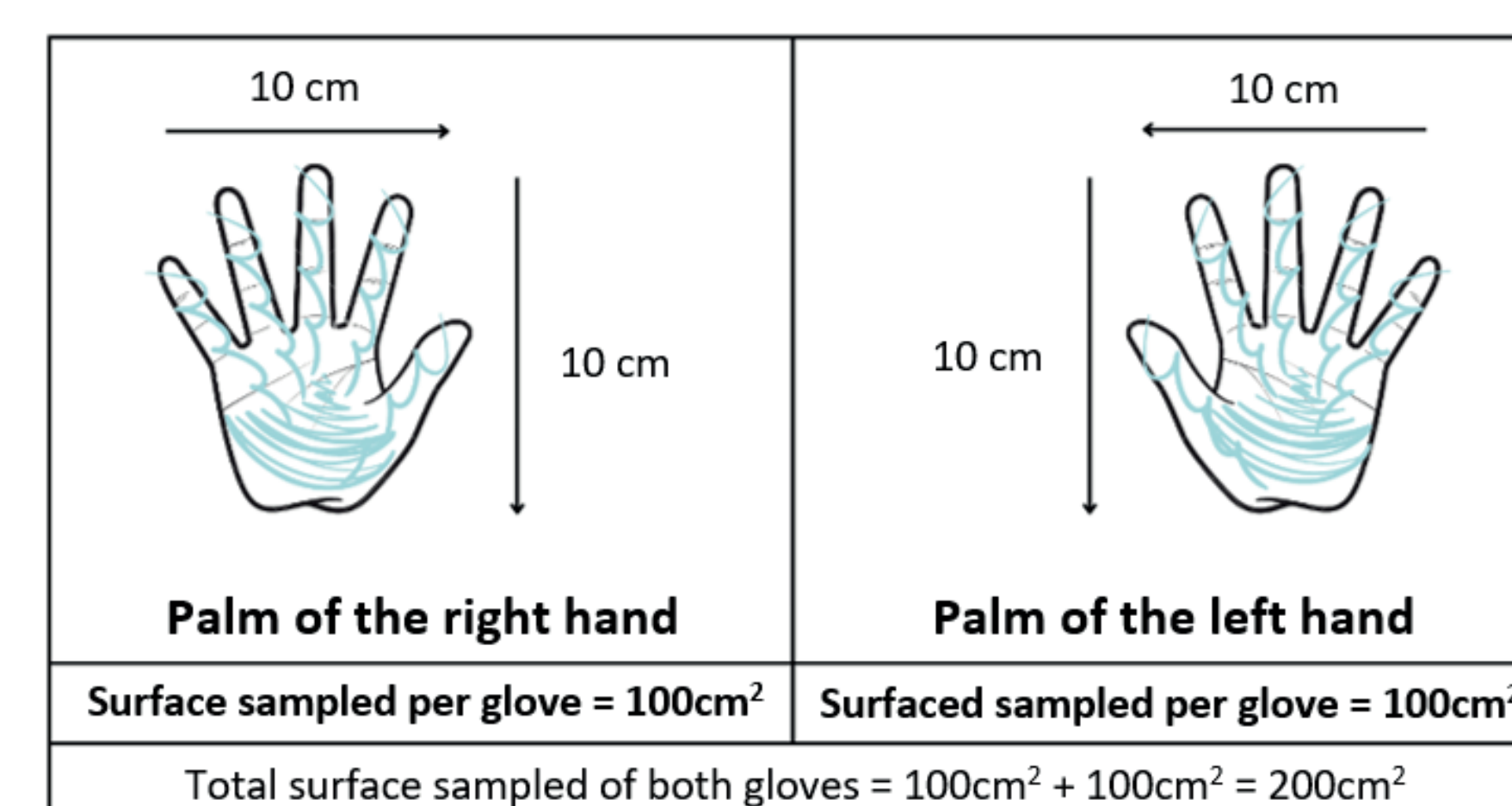


Figure 3. Horizontal and vertical wipe sampling of the gloves.

RESULTS

Throughout the study, 19 different drugs were compounded by the robot, including 5-Fluorouracil, Bevacizumab, Carboplatin, Cisplatin, Cyclophosphamide, Docetaxel, Doxorubicin, Eribulin, Etoposide, Gemcitabine, Irinotecan, Nivolumab, Oxaliplatin, Paclitaxel, Panitumumab, Pembrolizumab, Pemetrexed, Trastuzumab, and Vinorelbine. We observed only a negligible amount of Gemcitabine, which fell below the quantification limit ($<0.005 \text{ ng/cm}^2$), on the surfaces of 2 out of the 20 bags and on 2 of the operator's gloves.

CONCLUSION AND IMPLICATIONS

The results of this study demonstrate that levels of HD surface contamination in robotic compounding are exceedingly low and, in most cases, undetectable. Occupational exposure to HD remains consistently below 0.1 ng/cm^2 , a threshold deemed "safe" according to certain studies. This finding assures the safety of the compounding personnel and other hospital staff members involved in cancer treatment.

KEYWORDS

Antineoplastic drugs; environmental contamination; occupational exposure; robotic system.

