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ORIGINAL RESEARCH ARTICLE

Health technology assessment of an automated unit-dose drug distribution system in a high-specialization national referral hospital of the Italian National Health Service

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ABSTRACT

Introduction: Automated unit-dose (UD) medication distribution systems are increasingly recognized as enabling technologies for safer, more efficient, and traceable drug administration in hospitals. Closed-loop UD systems integrate electronic prescribing, automated dispensing, and bedside barcode scanning to ensure full traceability throughout the medication process. This study evaluated the clinical effectiveness, organizational impact, and cost-effectiveness of a closed-loop UD system implemented at a 930-bed national referral hospital in Northern Italy, compared with the previous ward-stock system.

Methods: A convergent mixed-methods mini-Health Technology Assessment combined administrative, clinical, and financial data (2018–2021) with literature evidence and 18 semi-structured staff interviews. Outcomes included medication administration errors (MAEs), adverse drug reactions (ADRs), and preventable hospitalizations. Cost-effectiveness was assessed from the Italian National Health Service perspective, and qualitative findings were analyzed using framework analysis.

Results: Based on literature-derived parameters, the model suggests a reduction in MAE rate from 10.6% to 5.0%, preventing an estimated 57,247 errors, 4,294 ADRs, and 42 hospitalizations per year. These outcomes were associated with net annual savings of €1.32 million and an ICER of €48.67 per error avoided. The model also indicated that around 34,000 nursing hours could be reallocated to direct patient care, while qualitative evidence highlighted improved staff satisfaction and medication traceability. Sensitivity analyses confirmed economic robustness in 95% of simulations.

Conclusions: Implementation of a closed-loop UD system enhances medication safety, workflow efficiency, and cost-effectiveness, supporting its scalability as a strategic innovation aligned with institutional goals for quality and sustainability.

Keywords: Automation hospital pharmacy, Cost-effectiveness, Drug administration errors, Drug distribution systems, Health technology assessment, Unit-dose distribution

Introduction

Pharmaceutical supply chains within hospitals need to evolve from labour-intensive, manually documented workflows to highly digitized, interoperable ecosystems that prioritize patient safety and fiscal stewardship, with a specific focus on traceability. Given the constant worldwide increase in pharmaceutical spending, top management must have direct access to this data. Among emerging innovations, automated unit-dose (UD) distribution, defined as the dispensing of single, machine-readable medication units synchronized with electronic prescribing and administration, is probably the most significant. By providing granular traceability, UD bridges the gap between electronic prescription intent and bedside administration, thereby reducing latent error pathways, systemic vulnerabilities that, if unaddressed, can align and lead to patient harm, as described in the Swiss-cheese model of system failure (1).

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Contemporary UD implementations typically take the form of either product-oriented architecture, where unique identifiers are attached to each dose at the central pharmacy, or patient-oriented architectures, in which robotics assembles daily therapy strips customized for individual patients (2). Systematic review evidence indicates that both automated and unit-dose dispensing systems outperform ward-stock models in reducing medication errors, though real-world outcomes may differ depending on clinical culture, digital maturity, and implementation resources (3).

ASST Papa Giovanni XXIII (PG23) is a high-specialization national referral hospital within the Italian National Health Service, located in the Lombardy region of northern Italy, and comprising 930 inpatient beds. In 2012, the institution launched a hybrid automated UD program that combines centralized singularization with traditional management of packaged drugs. A pragmatic, longitudinal implementation strategy was adopted, progressively extending the unit-dose system across all inpatient wards until full hospital-wide coverage was achieved by 2017. The performance analysis focused on the 2018-2021 period, excluding 2020.

More than a decade later, there remains a lack of comprehensive evaluations that quantify the multidimensional return on this investment. The present study addresses this gap by conducting a comprehensive HTA spanning technological, clinical, organizational, and economic domains. This integrated infrastructure constitutes a closed-loop medication system, where electronic prescribing, centralized unit-dose preparation, automated ward dispensing, and bedside barcode scanning are fully connected to ensure end-to-end traceability and medication safety.

Methods

Study design and governance

A convergent mixed-methods mini-HTA was conducted using the Danish Centre for Health Technology Assessment (DACEHTA) framework and reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards (4). The evaluation combined quantitative data analysis with qualitative insights derived from in-depth interviews with 18 clinical Key Opinion Leaders. These included 5 prescribers, 8 nurses, 2 hospital pharmacists, 1 IT specialist, and 2 external pharmacists, purposely selected for their direct involvement in the unit-dose system. The interviews were structured around the "Organization" domain of the Mini-HTA framework and explored workflow organization, usability, and perceived impact on medication safety. Each session was audio-recorded, transcribed verbatim, and analyzed using framework analysis. Coding was performed by one researcher and validated through multidisciplinary team discussions to ensure interpretative consistency. Thematic saturation was reached by the completion of the 18 interviews. Reporting followed the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines to enhance transparency and rigour. Ethical approval was not required, as all data were anonymized and derived from routinely collected administrative sources.

The study population comprised all adult inpatients admitted to ASST Papa Giovanni XXIII between 2018 and 2021 in wards where the automated unit-dose (UD) medication distribution system was fully operational. Pediatric, intensive care, and emergency departments, as well as outpatient and day-hospital units, were excluded because UD workflows were not technically compatible. Each *medication administration episode* was defined as a single act of drug delivery to a patient, documented in the electronic medication administration record and aggregated at the ward level for analysis.

A quasi-experimental pre-post design was adopted, comparing the conventional ward-stock model (baseline 2017) with the UD system (post-implementation 2018-2021). The year 2020 was excluded to minimize confounding due to COVID-19-related operational disruptions.

Potential confounders, including variations in case mix and workload, were mitigated by excluding the pandemic year and by triangulating administrative data with qualitative evidence from staff interviews. To ensure temporal comparability, annual event rates were standardized to total medication administrations for each year, and trend stability was verified through sensitivity checks excluding partial-implementation quarters. The exclusion of high-complexity wards reflected the absence of UD-compatible workflows and was not expected to introduce systematic bias in evaluating system performance.

In 2018, a total of 1,185,703 medication administration events were managed through the UD system, representing 36.16% of the hospital's overall 3,279,002 drug administration episodes. This proportion reflects specific contextual and operational constraints:

1. **Care setting:** The UD system is currently implemented exclusively in inpatient wards. Outpatient and day-hospital services are managed through traditional drug distribution workflows and are not included in the scope of the UD infrastructure.
2. **Clinical scope:** Key departments such as the Emergency Department, Pediatrics, and Intensive Care Units are currently excluded from the UD workflow.
3. **Pharmaceutical form:** Not all intravenous preparations are included in the UD protocol, particularly those intended for continuous infusion. Other non-standard formulations (e.g., ointments or topical salves) are also excluded.
4. **Drug selection criteria:** Inclusion in the UD catalogue is restricted to drugs listed on an annually updated "high utilization" formulary, as defined by each ward's medical leadership.

Additionally, the system does not include non-substitutable or variable-dose medications or those with unpredictable dosing regimens, further limiting its scope. However, this selective approach ensures optimal system performance and safety for standardized medication workflows.

Setting, technology and comparators

The evaluated intervention consists of an integrated automated UD distribution system designed to enhance traceability, safety, and inventory control across inpatient wards.

The technological infrastructure includes: (i) a high-throughput external singularization facility equipped with 2D data matrix printing for blister-pack identification; (ii) a network of 21 ward-based dispensing cabinets currently active for unit-dose distribution, forming part of a broader infrastructure gradually scalable across the hospital; (iii) an interoperability layer (middleware) ensuring real-time reconciliation between electronic prescribing and actual drug availability; and (iv) point-of-care barcode scanning devices used to support medication administration aligned with the "five rights" principle—right patient, right drug, right dose, right route, and right time, as established by Hughes and Blegen (2008) (5) and endorsed by the US Institute of Medicine (now National Academy of Medicine) as a core safety framework in medication management.

The comparator was the pre-existing ward-stock model, which relied on bulk drug storage within wards, typically in secure cupboards and paper-based or manual recording of drug administrations. During the comparator period, when the pre-existing ward-stock model was in use, electronic prescribing systems were not fully operational, and no structured traceability tools were implemented at the point of administration.

Analytical framework and endpoints

Building on the DACEHTA mini-HTA framework, four evaluative dimensions were operationalized:

- Technological – interoperability evaluation, comparison with alternative technology, and potential performance scalability.
- Clinical – absolute and relative changes in MAE rate, ADR incidence, and medication-related mortality (exploratory).
- Organizational – staff time allocation, work-as-imagined versus work-as-done analysis and training requirements.
- Economic – cost-effectiveness analysis.

Data sources, modeling assumptions and statistical analysis

Administrative data sources included annual hospital discharges (n = 40,562), aggregated drug administration records (unit-dose and conventional), and pharmacy invoice archives from 2018 to 2021. While the precise number of drug administrations was not detailed, the model used hospital-wide extracts to capture overall medication handling volume over time.

Literature-derived clinical parameters included medication administration error (MAE) rates of 10.6% under conventional conditions and 5.0% with unit-dose systems, as reported by Cousein et al. (6). Baseline rates were based on that study because the technological maturity and workflow organization at the time of system implementation were comparable to those described in the French setting, representing an intermediate stage of digitalization before full automation. ADR progression from MAEs was assumed in 7.5% of cases (7), with an associated mean increase in hospital stay of 1.7 days per ADR event.

Costing parameters were based on 2024 Italian DRG reimbursement rates (mean €4,236 per inpatient episode) and an amortization period from 2015 to 2020 for capital investments amounting to 2.786 million euros. The cost structure incorporated both capital expenditures (hardware, installation, and validation) and operating expenditures (maintenance, software licensing, consumables, and staff training), derived from hospital accounting records using a micro-costing approach. All costs were expressed in 2024 euros. Given the model's time horizon of ≤4 years, neither costs nor effects were discounted.

TABLE 1 - Data sources and key modelling assumptions

Parameter	Unit-dose system	Traditional system	Source
Medication administration error rate (%)	5.00%	10.60%	(6)
Proportion of medication errors resulting in an adverse drug reaction (ADR) (%)	7.50%		(7)
Mean cost per avoided hospitalisation	€4,236		(15)
Annual cost of the unit-dose system (2015–2020 total)	€2,786,000	€0	(11)

Deterministic sensitivity analyses were performed by varying key model parameters within plausible ranges to test the robustness of the results. The analysis included variations in the reduction of medication administration errors (MAE), the unit cost of adverse drug reactions (ADR), and the mean inpatient DRG cost. Probabilistic uncertainty was assessed through Monte Carlo sampling (6,000 iterations), where parameter values were drawn from beta distributions for error rates and gamma distributions for cost variables. Consistent with recommended practices in health economic modelling, cost parameters were modeled using gamma distributions, which accommodate positive skew and non-negativity inherent to healthcare expenditure data (8).

Results

Technological performance

The automated unit-dose distribution system demonstrated a mean technical uptime of over 99.3%, with recorded downtime occurring almost exclusively during scheduled preventive maintenance. This result is in line with the availability benchmarks for hospital-grade medical automation equipment.

While not formally assessed, the implementation of automated dispensing infrastructure supported the standardization of device authentication and access protocols, aligned with the guiding principles of cybersecurity frameworks such as the National Institute of Standards and Technology Cybersecurity Framework NIST CSF (9).

Clinical effectiveness

Enhancing medication safety remains a primary objective of hospital-based pharmaceutical systems. The unit-dose

approach adopted at ASST Papa Giovanni XXIII contributed to this goal by introducing a structured, traceable workflow that supported compliance with the "five rights" principle of safe medication administration. In 2018, over 1,185,703 individual administrations, representing 36.16% of total drug episodes, were managed through the barcode-assisted dispensing infrastructure, ensuring system-level control and traceability across wards.

Although the original HTA assessment did not include direct clinical endpoints, qualitative insights collected from frontline nurses and pharmacists suggested a perceived reduction in high-risk medication errors, including wrong-drug and omission events. These improvements were most evident in units with higher complexity and full integration of digital tools.

This interpretation aligns with existing literature (10), which has demonstrated that the adoption of computerized physician order entry systems significantly reduces preventable medication-related harm in hospital settings.

Organizational impact

The implementation of the unit-dose closed-loop system yielded tangible organizational improvements. Nursing drug-preparation time was estimated to decrease by a median of 21% (IQR 18-25%), corresponding to ~34,000 nursing hours reallocated annually to direct patient care, as documented in the HTA report developed by the internal multidisciplinary team (11).

In parallel, pharmaceutical waste due to expired medications was reduced by 67%, generating annualized savings of approximately €112,000. This was primarily attributed to real-time inventory tracking and the adoption of automated stock rotation workflows within the dispensing infrastructure.

Qualitative findings from 18 semi-structured interviews with clinical staff, including nurses, pharmacists, and physicians, highlighted increased stock traceability, improved visibility of medication availability at the point of care, and enhanced confidence in system-generated decision support. A minority of respondents reported ergonomic issues related to barcode scanner handling, though these concerns did not appear to hinder system adoption or satisfaction. These themes were consistently identified across professional groups and reflected the key categories emerging from the framework analysis.

Economic evaluation

The cost-effectiveness analysis was conducted from the perspective of the Italian National Health Service (SSN), over a four-year time horizon (2018-2021), without discounting and was conducted as a cost-effectiveness analysis (CEA), comparing the unit-dose UD closed-loop system to the traditional ward-stock drug distribution model. The primary outcome was the incremental cost per MAE avoided.

Baseline clinical event rates were parameterized using published estimates, with MAE incidence set at 10.6% for conventional systems and 5.0% for unit-dose dispensing (6).

By applying these rates to administrative records capturing an estimated 1,022,268 annual drug administrations, the model estimated 57,247 MAEs avoided per year.

A 7.5% MAE-to-ADR (7) progression probability was applied to estimate 4,294 avoided ADRs annually. Direct medical costs of ADRs were derived from recent Italian DRG reimbursement tariffs, ranging from €266 (minor) to €1,035 (severe), resulting in a projected annual cost avoidance of €1.14M - €4.44 M.

Additionally, hospitalization reductions due to preventing severe ADRs were modelled using national estimates of preventable ADR-related admissions. Assuming a mean length-of-stay extension of 1.7 days per ADR, the UD system was associated with 42 hospitalizations avoided and €176,000 in inpatient cost savings per year.

Total capital investment amounted to €2.786 million, amortized over five years (2015-2020). This yielded an incremental cost-effectiveness ratio (ICER) of €48.67 per MAE avoided, well within acceptable value-for-money thresholds in hospital pharmacy interventions.

Sensitivity analyses

Deterministic sensitivity analyses were conducted by varying key parameters within plausible ranges: MAE reduction (±30%), ADR unit costs (baseline €266-1,035, each varied by

TABLE 2 - Base-case economic results comparing the closed-loop unit-dose (UD) and ward-stock models. All values are expressed in 2024 euros (Italian National Health Service perspective)

Outcome/Parameter	Estimated annual reduction/avoidance	Unit cost (€)	Annual economic benefit (€)	Source/Notes
Medication administrations (per structure)	1,022,268	–	–	(11)
Medication administration errors avoided	57,247	–	–	Model-derived (based on (6))
Adverse drug reactions (ADRs) avoided	4,294	Min: €266.40 Max: €1,035.00	Min: €1,143,795 Max: €4,443,799	(7); Italian DRG tariffs
ADR-related hospitalizations avoided	42	€4,236.32 (per admission)	€176,031.88	(15)
Incremental cost-effectiveness ratio (ICER)	–	–	€48.67 per MAE avoided	*Calculated value (model-derived)*

±50%), and mean inpatient DRG cost (€4,236 ± 50%). Across all scenarios, the unit-dose system remained cost-effective, with ICERs ranging from €37.44 (optimistic) to €69.52 (pessimistic) per MAE avoided. A scenario analysis on preventable ADR-related hospitalizations confirmed robustness, with inpatient cost savings between €88,000 and €264,000 depending on hospitalization rate and DRG mix.

Probabilistic uncertainty was assessed using Monte Carlo simulations, with cost inputs modelled using gamma distributions and event probabilities via beta distributions. The mean ICER from probabilistic simulations was €49.2 per MAE avoided (95% credible interval: €35.2 - €72.9). The cost-effectiveness acceptability curve (CEAC) showed a >95% probability of cost-effectiveness at a willingness-to-pay threshold of €100 per MAE avoided.

Overall, the model demonstrated consistent dominance across deterministic and probabilistic analyses, reinforcing the economic robustness of the unit-dose closed-loop system.

Conclusions

Interpretation of findings

Our findings suggest that the integration of automated unit-dose technology within a high-specialization national referral hospital in Italy can lead to concurrent improvements in medication safety, workflow efficiency, and economic performance. The reduction in medication administration errors is consistent with international evidence, including a Finnish university hospital study showing a decrease from 3.2% to 1.7% (12) after introducing unit-dose dispensing, and a Dutch study reporting a reduction from 19.5% to 15.8% (13) after the introduction of unit-dose dispensing systems, demonstrating a significant improvement in medication safety.

Mechanisms of benefit

In addition to standardizing mechanical dose control, the unit-dose system fosters a culture of clinical accountability by aligning electronic prescribing with traceable, patient-specific dose dispensing. This integration narrows the so-called "last 100 centimetres" of the medication-use process, where many latent errors typically occur. Furthermore, the estimated reduction in nursing preparation time underscores the opportunity cost inherent to manual workflows, suggesting potential for meaningful workforce reallocation.

Contextualization within literature

Recent European evidence from the Netherlands showed that UD implementation was associated with a significant reduction in medication administration errors and a cost-effectiveness ratio of €17.69 per avoided error (14). These findings support the economic sustainability of automated unit-dose systems and align with the present evaluation, which extends this evidence to the Italian healthcare setting through a broader mini-HTA framework.

Strengths and limitations

This evaluation has several strengths, including a mixed-methods design, the use of three years of longitudinal administrative data (2018-2021), and comprehensive sensitivity analyses to address parameter uncertainty. Limitations include the quasi-experimental pre-post design, potential residual confounding, and reliance on literature-based assumptions for clinical parameters such as ADR progression. Although the unit-dose system was implemented across all inpatient wards, intensive care, emergency, and pediatric units were excluded due to distinct medication-use processes, which may have introduced selection bias. Transferability of findings may also depend on contextual factors such as digital maturity, implementation phase, and the degree of workflow compatibility with unit-dose traceability systems. Deterministic sensitivity analyses addressed uncertainty in MAE, ADR, and hospitalization cost parameters, tested separately to avoid compounding effects. Parameter ranges (±30% and ±50%) align with standard practice, while potential interdependencies were captured within the probabilistic analysis.

Policy Implications

The adoption of an automated UD system at ASST Papa Giovanni XXIII was associated with measurable improvements

TABLE 3 - Deterministic sensitivity analyses of key parameters. MAE reduction tested at ±30%; ADR unit costs varied by ±50%; inpatient DRG costs varied by ±50%

Parameter	Range tested	BASE CASE	Outcome metric	Low scenario	High scenario	Interpretation
MAE reduction	±30%	€48.66/MAE avoided	Cost per MAE avoided (€)	€37.44	€69.52	Remained cost-effective across the tested range
ADR unit cost	±50%	€266 (minor)-€1,035 (severe)	Total ADR-related costs avoided (€)	€0.57-€2.22M	€1.72-€6.67M	Savings scaled proportionally with unit cost assumptions.
Preventable ADR-related hospitalization costs	±50%	€4,236	Total inpatient cost savings (€)	€88,000	€264,000	Savings remained substantial under pessimistic assumptions.

*ADR unit costs represent the baseline DRG range (€266-1,035), each varied by ±50% to capture tariff uncertainty.

in medication safety, nursing efficiency, and drug traceability, alongside demonstrable economic value under real-world Italian conditions.

These findings support the role of UD as a strategic enabler for modern hospital pharmacy services.

To maximize impact, policymakers should consider a phased implementation, prioritizing high-risk wards, supported by structured change management and real-time monitoring tools.

Attention to training and ergonomic usability will be essential to ensure sustainability. Future evaluations should employ quasi-experimental methods such as interrupted time-series designs and integrate patient-reported outcomes to capture broader system effects.

While further validation is needed across diverse healthcare settings, the evidence positions the UD model as a scalable and cost-effective innovation that aligns with quality, safety, and operational efficiency objectives.

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