HOPA
Hematology/Oncology Pharmacy Association

Pharmacists Optimizing Cancer Care®

Intravenous Cancer Drug Waste Issue Brief

In 2024, national healthcare expenditure (NHE) grew by 7.2%, reaching $5.3 trillion and accounted for 18% of the Gross Domestic Product (GDP). The projected average growth in NHE (5.8 %) is expected to outpace GDP (4.3 %) over the next 10 years.[1] It is estimated the US healthcare system wastes approximately 25% of what is spent on healthcare annually.[2] Specifically looking at drug waste associated with intravenous (IV) cancer therapies, it is estimated the amount of discarded or leftover after compounding costs the US healthcare system almost $3 billion annually.[3] As an uncontrolled cost, drug waste is harmful to patients and health-systems' financial sustainability.

Contributing Factors

In May 2017, HOPA hosted a policy summit, Drug Waste in the Treatment of Cancer, to identify factors contributing to drug waste with IV cancer therapies and rationale approaches to ameliorate the issues. Centered in the discussion were the following factors that directly attribute to waste:

1) *Lack of clarity associated with the problem* – Not all healthcare providers or institutions use available tools to report discarded medications, thus resulting in incomplete data and an underestimate of the true cost of discarded drugs. The simplicity of current tools does not accurately describe the variability in economic value of individual drug waste.
2) *Antiquated prescribing practices* – Dosing of cancer drugs are often calculated based on a patient's body size and is therefore individualized and highly variable relative to medication vials sizes. As a result, the amount of leftover drug can be as high as 33%.[3]
3) *Limited variation of drug product packaging and sizes* – Many drugs are available in a limited quantity of strengths and are most often provided only as single dose vials (SDV), which restricts the ability to select products matching a patient's prescribed dose. In circumstances where it is permissible to use leftover drug, it must be used within a few hours for subsequent patients, which is not always feasible.
4) *Lack of drugs supplied as a multi-dose vial (MDV)* – Unlike SDVs, MDVs contain a preservative and, unless otherwise specified by the manufacturer, allow for a maximum of a 28-day expiration once the vial is punctured. Meaning, multiple patients can be dosed, and waste is minimized or eliminated.
5) *Optional use of closed-system drug transfer devices (CSTD) in compounding* – CSTDs are proven to minimize occupational exposure to hazardous drugs. In addition, limited data demonstrates CSTDs limit the contamination of vial contents; thus, potentially allowing CSTDs to extend beyond-use dating for SDVs.
6) *Lack of harmonization among regulatory policies governing sterile compounding* – From the drug approval process through drug compounding, policies regulating vial contents, size, and sharing between patients are absent or vary between agencies [i.e., Food & Drug Administration (FDA), CMS, CDC, USP, National Institute for Occupational Safety and Health (NIOSH), etc.], creating ambiguity and confusion for practitioners and health administrators.

Recommendations

Drug waste generated from the preparation of IV cancer therapies is costly to the health care system, patients undergoing treatment, and society overall. It represents both a direct cost to healthcare systems and an indirect cost to patients through increased premiums and out-of-pocket expenses. Billing for waste is not the solution. This practice increases work for providers, requires insurance companies to pay for medication that has been disposed, and ultimately trickles down to patients in the form of higher out-of-pockets costs for medications and insurance premiums. Additionally, disposal of pharmaceutical waste is expensive for healthcare facilities and can pose a hazard to the environment. Adoption of waste-reduction strategies aligns with environmental stewardship initiatives and regulatory compliance (EPA, USP <800>). Lastly, given the frequency of drug shortages, disposal of unused medication is in direct conflict with the need to ensure patients have access to these life-saving therapies.

Therefore, we urge policymakers and stakeholders to consider the following mitigation strategies to reduce the generation of drug waste with IV therapies:

Regulatory Agencies

- Convene stakeholders to reconcile and align regulatory policies governing sterile compounding and repackaging, specifically promoting multi-dose vials whenever possible and supporting safe utilization of single-dose vials for multiple individual doses to minimize or omit waste.
- Require manufacturers to make vials sizes in alignment with fixed dosing recommendations.
- Recognize benefit of utilization of CSTD to extend sterility of single dose vials, allowing utilization for multiple doses.

Pharmaceutical Manufacturers

- Design trials to support fixed dosing when safe and feasible, conduct additional trials after approval to assess safety and efficacy of converting from weight-based to fixed dosing.
- Determine vial sizes to support fixed dosing when applicable and determine optimal vial sizes to ensure maximal dosing flexibility with minimal or no waste.
- Increase the availability of medications in MDV formulations.
- Manufacture hazardous drugs in vials compatible with the use of CSTDs and demonstrate stability data before FDA approval on medications compounded with CSTDs to allow for dose vial optimization (DVO).
- Develop programs to take back unused medications and reimburse for waste accordingly.

Investigators and Healthcare Institutions

- Examine dosing strategies in early phase investigations and work with pharmaceutical manufacturers to identify optimal vial strengths prior to commercialization.
- Develop dose-capping or dose-banding and DVO protocols to align prescribed doses with available medication vial strengths. Follow guidance by HOPA to adjust doses up or down to the nearest vial size within 10% of the prescribed dose. This concept should transcend to investigational studies and be considered by investigators during clinical trial protocol development.
- Implement collaborative practice agreements for advanced practice practitioners (i.e., clinical pharmacists) to ensure prescribing aligns with available medication vial strengths.
- Increase use of available tools to report waste, thus improve the available data and financial impact of drug waste on insurers, providers/institutions, and patients.

Additionally, we recognize the following secondary factors, albeit indirect, related to drug waste:

- *Billing for Waste:* We recommend evaluation of policies regarding when and how billing for drug waste occurs. CMS' recommendation to strategically schedule patients to reduce waste conflicts with its "one vial for one patient" policy as well as with other government agencies' requirements that restrict this type of scheduling. For commercial payers that do allow billing and payment for drug waste, requirements are inconsistent and may or may not follow the CMS guidance for use of the JW code. The burden of billing/reimbursement for drug waste falls mostly on providers/pharmacies, ultimately impacting the patient. We recommend commercial payers should be accountable to reimburse for drug waste. These stakeholders should play a key role in the development of a comprehensive plan to address the financial impact and reimbursement of drug waste. Until an effective alternative is crafted, the JW modifier should remain in place and be in consistent use throughout the industry.
- *Automation:* Where available, HOPA encourages the use of technology to track the individual use of vials when automation is used for compounding medications within a facility or healthcare system.

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1. National Health Expenditure Data (2024) CMS.gov. Available at: https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet
2. Shrank WH, Rogstad TL, Parekh N. Waste in the US Health Care System: Estimated Costs and Potential for Savings. JAMA. 2019;322(15):1501–1509.
3. Bach PB, Conti RM, Muller RJ, Schnorr GC, Saltz LB. Overspending driven by oversized single dose vials of cancer drugs. BMJ. 2016 Feb 29;352:i788. doi: 10.1136/bmj.i788. PMID: 26932932; PMCID: PMC6894487.