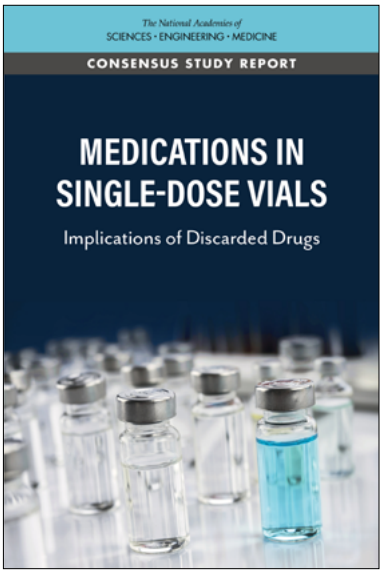
Consensus Study Report
HIGHLIGHTS
FEBRUARY 2021

Medications in Single-Dose Vials

Implications of Discarded Drugs



Every year, significant amounts of expensive drugs are discarded. This is due in part to the growing number of prescription drugs that are administered in variable doses (rather than fixed or flat doses) based on a patient's weight or body size. Because of safety considerations, the typical approach for manufacturers in the United States is to package these weight-based medications in single-dose vials that are intended for use by a single patient, though the medicine in each vial typically exceeds the required dosages for the average patient. Strict regulations and guidance generally prohibit or severely restrict the acceptable timeframe for sharing medication from single-dose vials among patients so the unused amount will typically be discarded. Many of the weight-based drugs in single-dose vials are among the more expensive drugs on the market, and they are paid for by federal health care programs, private health plans, and patients who have copayment and coinsurance obligations.

Due to the current system for producing, administering, and paying for drugs in the United States, significant—but indeterminate—amounts of expensive prescription drugs in single-dose vials are discarded each year. In light of this, the U.S. Congress mandated that the Centers for Medicare & Medicaid Services (CMS) enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to organize a committee that would conduct a study on the federal health care costs, safety, and quality concerns associated with discarded drugs that result from the weight-based dosing of medicines contained in single-dose vials. The committee's resulting report, *Medications in Single-Dose Vials: Implications of Discarded Drugs*, responds to that charge.

CONTEXT FOR THIS REPORT

Drug costs in the United States have been increasing faster than overall health care costs for at least the past few decades. A major driver of this ongoing increase is spending on specialty drugs—many of which are weight-based drugs in single-dose vials. These medications account for half of the overall U.S. expenditures on prescription drugs even though they make up only about 2 percent of the total number of prescriptions written each year.

Many weight-based, single-dose vial drugs are very expensive—thousands of dollars per treatment is not unusual. But making appropriate and effective policy choices in this area requires a clear understanding of the concept of drug "waste." While there are many ways to define waste, the committee defined it in the context of efficiency in health care spending, in which "waste" refers to any spending that does not produce as much value as it could have if it were directed differently. This type of waste can occur in various forms, such as administrative waste (e.g., excess overhead costs), operational waste (e.g., duplication of services), or clinical waste (e.g., practices that do not improve health outcomes or are detrimental to the patient). In the context of this report, waste refers to the discarded portions of weight-based drugs.

COSTS OF DISCARDED WEIGHT-BASED DRUGS

At first glance, discarding significant portions of the drug in single-dose vials that can cost thousands of dollars seems wasteful. For example, one estimate indicated that in 2016, approximately $2.8 billion was spent by the federal government and private health care payers on discarded portions of single-use vials of cancer drugs. However, there are a variety of complex factors that could affect the accuracy of these estimates. It is easy enough to add up the per-milliliter cost of the drug multiplied by the number of milliliters discarded each year to get a value for how much is "wasted." But these figures do not accurately capture the "economic value" of discarded drugs or the excess costs to patients and the system, because the price of a drug is typically based not on how much is used, but on the willingness to pay for the drug's therapeutic benefit.

The underlying concern with discarded weight-based drugs is that payers believe that they are paying for discarded medication. Potential approaches to address this issue include sharing vials among multiple patients or seeking reimbursement from manufacturers for unused drugs. However, widespread use of these practices would likely encourage drug manufacturers to raise drug prices because more patients would be treated with the same amount of a given drug in the first case, and manufacturers would account for reimbursement of unused portions in the second case. Higher drug prices combined with costs associated with developing methods to safely treat multiple patients from single-dose vials or to collect reimbursements would likely lead to no actual financial savings to payers. These additional costs would, however, reflect true economic "waste" in the sense that paying to implement these changes is unlikely to generate additional medical benefits for patients or cost reductions for payers.

Ultimately, because of the way drugs are priced and paid for in the U.S. health care system, the committee concluded that there is no money to recoup when a drug is discarded. Therefore, there is limited economic value to discarded injectable or infused drugs from single-dose vials. Instead of focusing on recouping payment for discarded medications, the committee recommended that the federal government focus on improving efficiencies in the existing system that lead to excess costs. To read the committee's nine consensus recommendations, see the report Recommendations insert.

ALIGNING INCENTIVES AND INCREASING EFFICIENCY TO IMPROVE QUALITY OF CARE

The committee developed recommendations to lay the foundation for strategies to reduce inefficiencies that lead to discarded drugs—while still ensuring patient safety and quality care. The committee developed **two broad goals** and **eight associated recommendations**.

In formulating its recommendations, the committee considered the ways in which a proposed action could change if another action is not carried out. Accordingly, the committee's recommendations should be implemented together, rather than in isolation. The two goals are:

- **Goal 1: Promote the effective, efficient, and safe use of infused or injectable drugs.**
- **Goal 2: Implement an efficient and effective reimbursement system for the clinician administration of infused or injected drugs.**

PROMOTE THE EFFECTIVE, EFFICIENT, AND SAFE USE OF INFUSED OR INJECTABLE DRUGS

Despite the widespread use of weight-based dosing, particularly in cancer treatment, data-driven evidence supporting this practice is limited. Currently, when a dosing regimen based on body size is used in pivotal studies as part of the drug development process, that is the dosing regimen that will ultimately be approved by the U.S.

Food and Drug Administration (FDA). Alternatives to weight-based dosing might be just as safe and effective, but weight-based dosing is seldom compared with alternative dosing in pivotal trials. To increase evidence for alternative methods, the committee recommended that FDA should require fixed dosing for pivotal trials or registration, except where safety and efficacy would be compromised.

In addition, different U.S. agencies have settled on different approaches to the use of single-dose vials, with conflicting guidance from FDA, CMS, and the Centers for Disease Control and Prevention. The situation would be greatly improved if inconsistent regulatory guidelines were harmonized—and, preferably, modeled on successful protocols in other countries that allow vials to be used for multiple patients. The committee recommended that the Secretary of the U.S. Department of Health and Human Services (HHS) should direct CMS, FDA, and CDC to work with key nonfederal partners to review and harmonize existing policies and guidance. The Secretary of HHS should initiate interagency partnerships among these agencies and others, such as the U.S. Department of Defense and the U.S. Department of Veterans Affairs, who have expertise in systems engineering and industrial design. The Secretary of HHS should also encourage drug manufacturers to use multi-dose vials when it is safe to do so.

IMPLEMENT AN EFFICIENT AND EFFECTIVE REIMBURSEMENT SYSTEM FOR THE CLINICIAN ADMINISTRATION OF INFUSED OR INJECTED DRUGS

Under the current system in the United States for producing, administering, and paying for drugs, health care providers do not have incentives that encourage the efficient use of infused or injectable drugs from single-dose vials. This lack of incentives could discourage efforts to reduce the amount of discarded drugs. There are also additional problems with the current reimbursement system, including add-on fees for administering drugs that are based on the cost of the drug rather than the complexity of treatment administration and safety monitoring. The committee recommended that the Secretary of HHS mandate that CMS uncouple add-on payments to clinicians for infused or injected drug administration under Medicare Part B from the drug average sales price. The Secretary of HHS should also mandate that the Center for Medicare & Medicaid Innovation design and evaluate new payment models focused on treatment episode, rather than by volume or cost of drug vial.

Since January 2017, CMS has required health care providers to report the portion of the drug from a single-dose vial that is discarded and eligible for payment under the "discarded drug policy" with a particular code, known as the JW modifier. Under this CMS policy, health care providers receive payment for the total amount of drug indicated on the vial or package label of a single-dose product, including that which is discarded. However, health care providers' use of the JW modifier is inconsistent, which makes it difficult for health care payers to accurately or definitively determine the amount of discarded drugs and the associated payments. Due to a number of factors, which include inconsistent use and reporting, the committee recommended that CMS discontinue the use of the JW modifier.

CONCLUDING REMARKS

The nation's biopharmaceutical sector is a complex, interconnected system. Changes in one part of the system inevitably affect other parts, often in unanticipated or even undesirable ways. Ultimately, ensuring drug affordability will require a broad and sustained effort, but the interdependent set of recommendations offered in this report would yield significant results if they are leveraged with other strategies aimed at lowering drug prices. Because of various factors such as an aging society and the rising cost of health care, it is more important than ever that the United States act now to address these issues.

Committee on Implications of Discarded Weight-Based Drugs

Edward Shortliffe (*Chair*)
Columbia University
Arizona State University
Weill Cornell Medical College

Julie Donohue
University of Pittsburgh

Anupam Jena
Harvard Medical School
Massachusetts General Hospital

Tracy Lieu
Kaiser Permanente Northern California

Gary Lyman
University of Washington School of Medicine
Fred Hutchinson Cancer Research Center

Kavita Patel
The Brookings Institution

Harold Paz
The Ohio State University

Deborah Schrag
Dana-Farber Cancer Institute
Harvard Medical School

Ya Chen Tina Shih
The University of Texas MD Anderson Cancer Center

Kenneth Silverman
AstraZeneca

Holly Taylor
National Institutes of Health

Jonathan Watanabe
University of California, Irvine, School of Pharmacy and Pharmaceutical Sciences

Alastair Wood
Vanderbilt University

Robin Yabroff
American Cancer Society

Study Staff

Francis Kwadwo Amankwah
Study Director

Alexandra Andrada
Associate Program Officer

Annalee Gonzales
Administrative Assistant

Tracy A. Lustig
Senior Program Officer

Sharyl J. Nass
Senior Director, Board on Health Care Services

Study Sponsor

U.S. Department of Health and Human Services

To read the full report, please visit
nationalacademies.org/drugvialsize