



Defining and Evaluating In-Home Drug Disposal Systems for Opioid Analgesics

A Workshop

June 26-27, 2023



National Academies Keck Center, Room 100
500 5th Street NW
Washington, DC 20001



Defining and Evaluating In-Home Drug Disposal Options for Opioid Analgesics- A Workshop

June 26-27, 2023

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Defining and Evaluating In-Home Drug Disposal Systems for Opioid Analgesics

A Workshop

June 26-27, 2023 ▪ Washington, DC

The proper disposal of unused or expired prescription drugs, particularly controlled substances, is critically important to help prevent a serious risk of nonmedical use or overdose. In 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) provided the U.S. Food and Drug Administration (FDA) the authority to require that drug manufacturers provide patients with a safe drug disposal system when the prescription is dispensed if FDA determines that the disposal system may mitigate a serious risk of abuse or overdose.

Several in-home drug disposal systems in addition to mail-back envelopes are currently available. However, how well these systems work to achieve the public health goal of mitigating the risk of nonmedical opioid use and overdose is not fully understood.

This public workshop will provide an opportunity for stakeholders to examine the in-home drug disposal systems, with a focus on removing unused opioid analgesics from the home.

The public workshop will feature invited presentations and discussions to:

- Explore the types of in-home drug disposal options, other than mail back envelopes, that could be used to remove unused opioid analgesics from the home.
- Examine the current landscape of laws and regulations that apply to in-home opioid disposal systems.
- Discuss scientific, behavioral, health equity, and policy considerations for assessing the safety, use, and effectiveness of in-home opioid disposal systems, including the following questions:
 - What is known/unknown about the methods (e.g., sequestration, adsorption, absorption) used in in-home disposal systems for rendering opioids unavailable for nonmedical use assuming the product is used as intended?
 - What approaches/methodologies are needed to evaluate the safe and correct use of in-home opioid disposal systems in real-world settings?
 - How could person-centered design inform the development and use of in-home opioid disposal systems?
- Consider potential strategies for encouraging and assessing the development and use of in-home drug disposal systems that support the public health goal of mitigating the risk of nonmedical use or overdose associated with opioids.

The planning committee will organize the workshop, develop the agenda, select and invite speakers and discussants, and moderate or identify moderators for the discussions. A proceedings of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

Planning Committee

Alastair Wood (co-chair)

Vanderbilt University Medical School

Mark Bicket

University of Michigan Medical School

Irene Chan

Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Ruchi Fitzgerald

Rush University &
PCC Community Wellness Center

Lewis Grossman

Washington College of Law
American University

Stephen Hoag

School of Pharmacy
University of Maryland

Elizabeth McGinty (co-chair)

Weill Cornell Medicine

Robert Morones

Indian Health Service
U.S. Department of Health & Human Services

Thomas Prisinzano

College of Pharmacy
University of Kentucky

Jessica Young

Recycling and Generator Branch
U.S. Environmental Protection Agency

Patricia Zettler

Moritz College of Law
The Ohio State University

Defining and Evaluating In-Home Drug Disposal Systems for Opioid Analgesics- A Workshop

June 26, 2023, 9:00 am – 5:30 pm (ET)

June 27, 2023, 8:30 am – 1:00 pm (ET)

**National Academies Keck Center, Room 100
500 5th Street NW, Washington, DC 20001**

Join online [HERE](#).

PURPOSE

This public workshop, convened by the National Academies' Forum on Drug Discovery, Development, and Translation will provide a venue for stakeholders to discuss the development and use of in-home drug disposal systems with a focus on removing unused opioid analgesics from the home.

The public workshop will feature invited presentations and discussions to:

- Explore the types of in-home drug disposal systems, other than mail back envelopes, that could be used to remove unused opioid analgesics from the home.
- Examine the current landscape of laws and regulations that apply to in-home drug disposal systems.
- Discuss scientific, behavioral, health equity, and policy considerations for assessing the safety, use, and effectiveness of in-home drug disposal systems, including the following questions:
 - What is known/unknown about the methods (e.g., sequestration, adsorption, absorption) used in in-home disposal systems for rendering opioids unavailable for nonmedical use assuming the product is used as intended?
 - What approaches/methodologies are needed to evaluate the safe and correct use of in-home drug disposal systems in real-world settings?
 - How could person-centered design inform the development and use of in-home drug disposal systems?
- Consider potential strategies for encouraging and assessing the development and use of in-home drug disposal systems that support the public health goal of mitigating the risk of nonmedical use or overdose associated with opioids.

DAY 1: MONDAY, JUNE 26, 2023

9:00 am WELCOME

ALASTAIR WOOD, *Workshop Co-chair*
Professor of Medicine Emeritus
Vanderbilt University

9:05 am FDA AUTHORITY FOR IN-HOME OPIOID DISPOSAL

MARTA SOKOLOWSKA
Deputy Center Director for Substance Use and Behavioral Health
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

9:15 am FIRESIDE CHAT: LIFECYCLE OF PRESCRIBED OPIOIDS

ROBERT HOFFMAN, *Speaker*
Professor, Department of Emergency Medicine
New York University Grossman School of Medicine

BETH MCGINTY, *Workshop Co-chair, Moderator*
Chief, Division of Health Policy and Economics
Professor, Department of Population Health Sciences
Weill Cornell Medicine

9:55 am SESSION I: ENVISIONING DISPOSAL SYSTEMS TO REMOVE OPIOIDS FROM THE HOME

Session Objectives:

- Describe the properties or characteristics that an ideal in-home disposal system might possess such that it minimizes barriers to patient use.
- Consider under what circumstances people will use an in-home disposal system, with a focus on conditions that impede use and how those can be overcome.
- Discuss how human-centered design can inform the goals, development, and use of in-home disposal systems.
- Discuss health equity considerations developing and implementing in-home disposal systems.

9:55–10:15 Presentation

LAURA BIX
Assistant Dean for Teaching, Learning and Academic Analytics
Michigan State University College of Agriculture & Natural Resources

10:15–11:15 Panel Discussion

RUCHI FITZGERALD, *Moderator*
Assistant Professor, Rush University
Service Chief of Inpatient Addiction Medicine, PCC Community Center

Panelists

Health Care Innovation Perspective

ANISH AGARWAL
Assistant Professor of Emergency Medicine
University of Pennsylvania Perelman School of Medicine

Behavioral Science Perspective

KATHLEEN EGAN

Assistant Professor, Health Education and Promotion
East Carolina University College of Health and Human Performance

Consumer/Patient Perspective

LINDSAY BARAN

Senior Research Director
Health Care Evaluation Department
NORC at University of Chicago

Opioid Stewardship Perspective

LYEN HUANG

Assistant Professor of Surgery
University of Utah Spencer Fox Eccles School of Medicine

11:15–11:45 *Coffee Break (30 minutes)*

11:45 am SESSION II: REGULATORY LANDSCAPE FOR HOUSEHOLD OPIOID DISPOSALSession Objectives:

- Examine the current landscape of laws and regulations that apply to in-home drug disposal systems.
- Explore the role of state and local policies on drug disposal and how FDA regulations may interact with those policies, including any unintended consequences.
- Consider the intersection of federal, state, and local waste disposal policies regarding the use of in-home disposal systems for opioid analgesics.

11:45–12:05 **Presentation**

HANZ ATIA

Associate, Policy and Programs
Product Stewardship Institute

12:05–1:05 **Panel Discussion**

LEWIS GROSSMAN, *Moderator*

Professor
American University College of Law

Panelists**EPA Regulatory Perspective**

KRISTIN FITZGERALD

Environmental Protection Specialist
Office of Resource Conservation and Recovery
U.S. Environmental Protection Agency

State Drug Disposal Policy Perspective

MARY KELLINGTON

Safe Medication Return Program Manager
Washington State Department of Health

FDA Regulatory Perspective

PATRICK RAULERSON
Senior Regulatory Counsel
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Federal Opioid Policy Perspective

UTTAM DHILLON
Partner
Michael Best & Friedrich LLP

1:05–2:00 *Lunch Break (55 minutes)*

2:00 pm SESSION III: SCIENTIFIC CONSIDERATIONS FOR IN-HOME OPIOID DISPOSALSession Objectives:

- Identify ideal characteristics of an in-home disposal system from a mechanistic, safety, and environmental perspective.
- Explore the scientific considerations for in-home drug disposal systems that could be used to remove unused opioid analgesics from the home.
- Discuss what is known/unknown about available and developing methods (e.g., sequestration, adsorption, absorption) by which in-home disposal systems work, assuming the product is used as intended.
- Discuss scientific approaches for assessing and gathering data on the environmental impact for in-home drug disposal systems.

2:00–2:20 **Presentation**
MARGARET SHIELD
Owner and Principal
Community Environmental Health Strategies LLC

2:20–3:20 **Panel Discussion**
JESSICA YOUNG, *Moderator*
Chief, Recycling and Generator Branch
U.S. Environmental Protection Agency

Panelists**Opioid Chemistry Perspective**

ANDREW COOP
Professor, Pharmaceutical Sciences
Associate Dean for Academic Affairs
University of Maryland School of Pharmacy

Toxicology Perspective

KAITLYN BROWN
Clinical Managing Director
America's Poison Centers

FDA Perspective

MARTA SOKOLOWSKA
Deputy Center Director for Substance Use and Behavioral Health
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Environmental Chemistry Perspective

PAUL BRADLEY

Project Lead

Drinking-Water and Wastewater Infrastructure Integrated Science Team

Ecosystems Mission, Environmental Health Program

U.S. Geological Survey

3:20-3:50

Coffee Break (30 minutes)

3:50 pm

SESSION IV: REAL-WORLD USE AND IMPLEMENTATION OF IN-HOME OPIOID DISPOSAL SYSTEMSSession Objectives:

- Consider what approaches/methodologies are needed to evaluate the safe and correct use of in-home drug disposal systems in real-world settings.
- Explore approaches for engaging consumers on how to use in-home disposal systems safely and as intended.
- Consider best practices to promote safe and effective use of in-home disposal systems, including the roles of clinicians, prescribers, and pharmacists.
- Discuss use studies to lay out tangible examples of unintended consequences.

3:50-4:10

Presentation

CHAD BRUMMETT

Bert N LaDu Professor of Anesthesiology

Co-Director, Opioid Research Institute

Co-Director, Opioid Prescribing Engagement Network

University of Michigan

4:10-5:20

Panel Discussion

MARK BICKET, *Moderator*

Assistant Professor, Department of Anesthesiology

Director, Pain & Opioid Research, Institute for Healthcare Policy and Innovation

University of Michigan Medical School

Panelists**Implementation Perspective**

ANDREA TSATOKE

Injury Prevention Specialist

Indian Health Service, Headquarters

Program Evaluation Perspective

ELEANOR LEWIS

Deputy Director, Program Evaluation & Resource Center

U.S. Department of Veterans Affairs

REMS Design & Implementation Perspective

JAMES SHAMP

Vice President for Data Intelligence & Program Analytics

United BioSource LLC

Retail Pharmacy Perspective

KEVIN NICHOLSON

Vice President, Public Policy, Regulatory, and Legal Affairs
National Association of Chain Drug Stores

Behavioral Science and Communication Perspective

TAMAR KRISHNAMURTI

Assistant Professor, Medicine and Clinical and Translational Science
Department of Medicine Center for Research on Health Care
University of Pittsburgh

5:20 pm DAY 1 SUMMARY REMARKSALASTAIR WOOD, *Workshop Co-chair***END OF DAY 1****DAY 2: TUESDAY, JUNE 27, 2023**

8:30 am DAY 2 OPENING REMARKSBETH MCGINTY, *Workshop Co-chair***8:50 am RISK EVALUATION AND MITIGATION STRATEGIES: AN OVERVIEW**

LYNN MEHLER

Practice Area Lead, Pharmaceuticals & Biotechnology
Hogan Lovells LLP

9:15 am SESSION V: THE ROLE OF IN-HOME OPIOID DISPOSALSession Objectives:

- Consider the role of an ideal in-home disposal system in addressing the public health goal of mitigating the risk of nonmedical use or overdose associated with opioids.
- Discuss how previous workshop discussions may inform the design, implementation, and evaluation of in-home disposal systems.
- Consider data needs and practical approaches for assessing the use and effectiveness of disposal systems in real-world settings.

9:15-9:35**Presentation**

KATHLEEN EGAN

Assistant Professor, Health Education and Promotion
East Carolina University College of Health and Human Performance

9:35-10:45**Panel Discussion**ROBERT MORONES, *Moderator*

Injury Prevention Coordinator
Indian Health Service (Phoenix Area)
U.S. Department of Health & Human Services

Panelists

Pediatric Injury Prevention Perspective

CHRISTOPHER GAW

Pediatric Emergency Medicine Fellow

Associate Fellow, Center for Injury Research and Prevention

Children's Hospital of Philadelphia

Overdose Prevention Perspective

JEFF HORWITZ

Chief Executive Officer

SAFE Project

Harm Reduction Perspective

SUSAN SHERMAN

Bloomberg Professor of American Health

Department of Health, Behavior and Society

Johns Hopkins Bloomberg School of Public Health

National Institute on Drug Abuse Perspective

WILSON COMPTON

Deputy Director, National Institute on Drug Abuse

National Institutes of Health

10:45-11:15 *Coffee Break (30 minutes)*

11:15 am SYNTHESIS DISCUSSION

Purpose:

- Integrate information gathered throughout the workshop in a discussion on the properties and characteristics of an ideal in-home disposal system, factors impacting implementation, and regulatory considerations for household opioid disposal.

11:15-12:15 **Moderated Panel Discussion**

ALASTAIR WOOD, *Workshop Co-chair, Moderator*

Panelists

Implementation Perspective

MARK BICKET

Assistant Professor, Department of Anesthesiology

Director, Pain & Opioid Research, Institute for Healthcare Policy and Innovation

University of Michigan Medical School

Overdose Prevention Perspective

JEFF HORWITZ

Chief Executive Officer

SAFE Project

Human-Centered Design Perspective

LAURA BIX

Assistant Dean for Teaching, Learning and Academic Analytics
Michigan State University College of Agriculture & Natural
Resources

Food and Drug Administration Perspective

PATRICK RAULERSON

Senior Regulatory Counsel
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Pharmaceutical Sciences Perspective

ANDREW COOP

Professor, Pharmaceutical Sciences
Associate Dean for Academic Affairs
University of Maryland School of Pharmacy

12:15-12:45 **Panel Discussion with Audience Engagement**

12:45 pm **CLOSING REMARKS**

BETH MCGINTY, *Workshop Co-chair*

MEETING ADJOURNS

Defining and Evaluating In-Home Drug Disposal Systems for Opioid Analgesics – A Workshop

Planning Committee Biographies

Committee Co-Chairs

EMMA ELIZABETH (“BETH”) MCGINTY, MS, PhD is the Chief of the Division of Health Policy and Economics in the Department of Population Health Sciences at Weill Cornell Medicine. Dr. McGinty conducts health policy research related to mental health, substance use, and chronic pain and is a leading expert in prescription opioid policy. She has served on multiple prominent advisory groups including a United Nations technical consultation panel on stigma reduction and drug use and a White House task force on suicide prevention. Dr. McGinty received her PhD in Health and Public Policy from the Johns Hopkins Bloomberg School of Public Health in 2013.

ALASTAIR J.J. WOOD, MB, ChB, FRCP, FACP was Professor of both Medicine and Pharmacology at Vanderbilt University Medical School and served as Assistant Vice Chancellor for Clinical Research and Associate Dean, Vanderbilt Medical School, before being appointed Emeritus Professor of Medicine and Emeritus Professor of Pharmacology in 2006. He served as the Drug Therapy Section Editor of the New England Journal of Medicine from 1985 to 2004. He was a Partner at Symphony Capital LLC, a Private Equity Company investing in the clinical development of novel bio-pharmaceutical products from 2006-2018 and was a member of the Board of Directors of the Critical Path Institute until 2022.

Dr. Wood has been honored by being elected to The National Academy of Medicine (formerly the IOM), The American Association of Physicians (AAP), The American Society for Clinical Investigation (ASCI), Honorary Fellow, American Gynecological and Obstetrical Society (AGOS), Fellowship of The American College of Physicians, Fellowship of The Royal College of Physicians of London, and Fellowship of The Royal College of Physicians of Edinburgh. He was the 2005 recipient of the Rawls-Palmer Award and in 2008 received the honorary degree of Doctor of Laws, honoris causa, from the University of Dundee.

Dr. Wood is a past member of The FDA’s Cardio-Renal Advisory Committee and The Non-Prescription Drug Advisory Committee, which he also chaired. He is currently an advisor to the Tufts University spin out Immediate Therapeutics. Dr. Wood has served on a number of Editorial Boards including the New England Journal of Medicine Editorial Board and his research has resulted in over 300 articles, reviews and editorials.

Committee Members

MARK C. BICKET, MD, PhD, FASA, is the Co-Director of the Opioid Prescribing Engagement Network, whose mission is to change the trajectory of the opioid crisis. He is also Director of Pain and Opioid Research and Assistant Professor of Anesthesiology and Health Management and Policy at the University of Michigan. Dr. Bicket and his colleagues have published around 100 peer-reviewed articles on prescription opioid use, non-opioid treatments for acute and chronic pain, the quality and safety of pain treatment in diverse healthcare settings, and clinical trials and health services research. He previously served on the National Academies of Sciences, Engineering, and Medicine Committee on Evidence-based Clinical Practice Guidelines for

Prescribing Opioids for Acute Pain. Dr. Bicket has provided scientific guidance on healthcare, opioid, and pain policy to government departments and agencies at the federal, regional, and state levels, including the White House Office of Science and Technology Policy and Center for Medicare and Medicaid Services. He formerly directed the Fellowship Program and Quality and Safety for Pain Medicine at Johns Hopkins, where he trained and mentored fellows, residents, and medical students while treating patients in East Baltimore. He received his MD and PhD from Johns Hopkins University. He completed anesthesiology residency at Johns Hopkins Hospital, where he served as Chief Resident, and pain medicine fellowship training at Massachusetts General Hospital.

Irene Z. Chan, PharmD is the Deputy Director in the Office of Medication Error Prevention and Risk Management (OMEPRM) within the Center for Drug Evaluation and Research (CDER) at the FDA. Prior to this, Captain (CAPT) Chan served as the Director in the Division of Medication Error Prevention and Analysis I in CDER. CAPT Chan has expertise in regulatory science, human factors, risk management, and pharmacovigilance. CAPT Chan is responsible for managing, planning, and providing guidance for the pre-market and post-market operations, programs, functions, and activities of four Divisions in FDA that focus on minimizing use error related to the naming, labeling, packaging, or design of drug products and developing effective and efficient Risk Evaluation and Mitigation Strategies (REMS) for certain drug products that ensure the benefits outweigh its risks. She is also CDER's representative on the Association for the Advancement of Medical Instrumentation (AAMI) Human Factors Committee. CAPT Chan received a B.S. in Pharmacy and Doctor of Pharmacy degrees from Rutgers University Ernest Mario School of Pharmacy.

RUCHI M. FITZGERALD, MD, FAAFP is an Assistant Professor in the Departments of Family Medicine and Psychiatry/Behavioral Sciences at Rush University. She is also the Associate Program Director of the Rush University Addiction Medicine Fellowship. She is the Service Chief of Inpatient Addiction Medicine at PCC Community Wellness Center, a federally qualified health center system that serves the West Side of Chicago. Dr. Fitzgerald is a National Academy of Medicine James C. Puffer/American Board of Family Medicine fellow.

Dr. Fitzgerald's work has focused on promoting cross-sector collaboration to improve care for persons affected by substance use disorders, with an emphasis in the perinatal/child health arena. Her scholarly work has focused on addressing stigma, building capacity in primary care for treating opioid use disorder in special populations, and implementing evidence-based substance use disorder curricula in the next generation of clinicians.

Dr. Fitzgerald received her MD from the University of Michigan Medical School and completed her Family Medicine training with the Montana Family Medicine Residency and her Addiction Medicine fellowship with Rush University.

LEWIS GROSSMAN, PHD, JD is Professor of Law at the Washington College of Law, where he has taught since 1997 and where he served as Associate Dean for Scholarship from 2008 to 2011. He teaches and writes in the areas of food and drug law, health law, American legal history, and civil procedure. He has also been a Visiting Professor of Law at Cornell Law School and a Law and Public Affairs (LAPA) Fellow at Princeton University. Prior to joining the American University faculty, he was an associate at Covington & Burling LLP in Washington, D.C. Before that, he clerked for Chief Judge Abner Mikva of the U.S. Court of Appeals for the D.C. Circuit. Professor Grossman's scholarship has appeared in the Cornell Law Review, Law and History Review, Yale Journal of Health Policy, Law & Ethics, and Administrative Law Review, among others. He has made recent contributions to volumes published by Oxford University Press and Columbia University Press. He is the co-author of Food and Drug Law: Cases and Materials (with Peter Barton Hutt and Richard A. Merrill) and of a widely used supplement to the first-year civil procedure course titled A Documentary Companion to A Civil Action (with Robert G. Vaughn). In 2021, Oxford University Press will publish Professor Grossman's book titled Choose Your Medicine: Freedom of Therapeutic Choice in America. He has served as a member or

legal consultant on three previous committees of the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine (formerly the Institute of Medicine). Professor Grossman earned his Ph.D. in History from Yale University, where he was awarded the George Washington Egleston Prize for Best Dissertation in the Field of American History. He received a J.D. magna cum laude from Harvard Law School and a B.A. summa cum laude from Yale University.

STEPHEN W. HOAG, PHD is a professor at the University of Maryland, Baltimore School of Pharmacy. He received a BS in biochemistry from the University of Wisconsin Madison and a Ph.D. in Pharmaceutical Science from the University of Minnesota Twin Cities. His primary research interests are in oral delivery systems, controlled release polymers, excipient functionality, stability testing, excipient functionality testing, abuse deterrent formulations, pediatric formulations and the use of Raman and NIR spectroscopy in PAT applications. Dr. Hoag is the Director of the School of Pharmacy GMP facility and a member of NIPTE, Steering Committee for the Handbook of Pharmaceutical Excipients, the editorial board of the journal of Pharmaceutical Development Technology and an AAPS Fellow.

ROBERT MORONES, MPH is currently the Area Injury Prevention Specialist for the Phoenix Area Indian Health Service (IHS). He is responsible for managing the Phoenix Area Injury Prevention Program, focusing on assisting over 40 Arizona, California, Nevada, and Utah tribes and IHS professional staff in the development of community-based injury prevention programs and initiatives. Robert's past positions include being assigned as a Service Unit Environmental Health Officer at the Fort Yuma Service Unit in Winterhaven, CA and as an Environmental Health Specialist at the Centers for Disease Control & Prevention (CDC) in Atlanta, GA. His education background includes a B.S. in Environmental Health Sciences from Wright State University and an MPH from the University of Massachusetts at Amherst.

TOM PRISINZANO, PHD received his B.S. in Chemistry from the University of Delaware (1995) and a doctorate in Pharmaceutical Sciences from Virginia Commonwealth University in Richmond, VA (2000). From 2000-2003, he was an Intramural Training Award (IRTA) Fellow in the National Institute of Diabetes and Digestive and Kidney Diseases. In 2003, Dr. Prisinzano began his independent career in the Division of Medicinal & Natural Products Chemistry in the College of Pharmacy at the University of Iowa. From 2007-2019, he was a faculty member in the Department of Medicinal Chemistry in the School of Pharmacy at the University of Kansas. In 2019, he joined the University of Kentucky College of Pharmacy. He currently serves as Director of the Center for Pharmaceutical Research and Innovation (CPRI) and Chair of the Pharmaceutical Sciences Department. His research combines medicinal and natural products chemistry and is directed toward elucidation of the structure and function of neurotransmitter systems in the central nervous system in normal, drug-altered and pathological states and the development of medications for the treatment of drug abuse and pain.

JESSICA YOUNG, MS is the chief of the Recycling and Generator Branch in EPA's Office of Resource Conservation and Recovery within the Office of Land and Emergency Management. During her 17 years at EPA, Jessica has worked to ensure solid and hazardous waste are properly managed, recycled, and disposed. Jessica has been the branch chief for 9 years. Jessica's branch at EPA covers the cradle part of the RCRA cradle-to-grave hazardous waste regulations including pharmaceutical waste issues, definition of solid waste (DSW) recycling exclusions, hazardous waste generators, and more. For her work on many projects Jessica has earned EPA bronze awards including for her work and leadership on the Hazardous Waste Pharmaceuticals Rule for Healthcare Facilities. Jessica earned a master degree in Environmental Science and Policy from John Hopkins University and a bachelor degree in Science of Earth Systems from Cornell University.

PATRICIA J. ZETTLER, JD is an associate professor at The Ohio State University Moritz College of Law and a member of Ohio State's Drug Enforcement and Policy Center and its Comprehensive Cancer Center. Her research and teaching focus on FDA law and policy, torts, and legislation and regulation. Her scholarship has appeared in leading legal and health sciences journals such as the New England Journal of Medicine, JAMA, and Science, and has covered various topics including expanded access, biohacking, stem cell interventions, opioids, cannabis products, tobacco and nicotine products, and COVID-19 countermeasures. Zettler also is a co-author of the 5th edition of Food and Drug Law: Cases and Materials (with Peter Barton Hutt, the late Richard A. Merrill, Lewis A. Grossman, Nathan Cortez, and Erika Lietzan). She currently serves on the Food and Drug Law Institute's Board of Directors and as co-chair of the International Society of Cell & Gene Therapy's Committee on the Ethics of Cell and Gene Therapy, also chairing its subcommittee on expanded access. Previously she served on the National Academies of Sciences, Engineering, and Medicine's (NASEM) Committee on Reviewing the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and as a consultant to the NASEM Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse. Before entering academics, Zettler served as an associate chief counsel in the Office of the Chief Counsel at FDA. She received her undergraduate and law degrees from Stanford University, both with distinction.

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Speaker and Panelist Biographies

ANISH K. AGARWAL, MD, MPH, MS is an Assistant Professor and Chief Wellness Officer of Emergency Medicine at the University of Pennsylvania. His research interests lay at the intersection of health care delivery, innovation, and digital health. Dr. Agarwal seeks to utilize advancements in mobile health to help create and build learning health systems. His work specifically has been applied to the opioid epidemic, health care workforce well-being, and remote patient engagement.

Dr. Agarwal's work has been published in *NEJM*, *JAMA*, *Annals of Emergency Medicine*, *Journal of General Internal Medicine*, *Circulation*, *Resuscitation*, and *Critical Care Medicine* and his work has been featured throughout multiple media outlets. Dr. Agarwal's work has been currently funded by the Food and Drug Administration, AHRQ, PCORI, NIH, and Foundation grants.

HANZ ATIA, MPH is an Associate, Policy & Programs at the Product Stewardship Institute, a policy advocate and consulting nonprofit that pioneered product stewardship in the United States. Hanz completed an MPH with a concentration in epidemiology and biostatistics from Tufts University, where they discovered how product stewardship blended their passion for public health and the environment. They joined PSI in 2022 to work on several product categories and now manages programs to expand take-back infrastructure for medical sharps and pharmaceuticals in Oklahoma and Missouri.

LINDSAY BARAN, MS is a Senior Research Director in the Health Care Evaluation department at NORC at the University of Chicago, where her work focuses on disability and health equity. Baran's background is in disability policy, and she has extensive experience in chronic pain and opioids policy and advocacy. Prior to her work at NORC, Baran worked as the policy director at the National Council on Independent Living (NCIL), a national grassroots disability rights organization, where she started the Chronic Pain and Opioids Task Force. She currently serves as a board member for the National Pain Advocacy Center. Baran has lived with chronic pain for most of her life.

Lindsay currently works with the CMS Office of Minority Health on several activities to improve health equity and reduce disparities. She also manages an evaluation of the Minnesota Department of Human Services' Home and Community Based Services (HCBS) assessment process for racial and ethnic disparities. In addition, she manages a federal project to enhance data analysis and evidence building capacity.

Prior to joining NORC, Lindsay worked as the Policy Director at the National Council on Independent Living (NCIL), a national disability rights organization based in Washington, DC, where she oversaw and implemented the organization's national policy and advocacy agenda. Earlier in her career, Lindsay worked at the National Center on Health Promotion Research for Persons with Disabilities, where she managed a study on the impact of improving the accessibility of health-related facilities and the built environment for people with disabilities.

LAURA BIX, PhD is the Assistant Dean for Graduate Studies for the College of Agriculture and Natural Resources, and a Professor at the School of Packaging at Michigan State University, where she leads the Packaging HUB. HUB researchers quantify the interface between people and packaging with the goal of improving health outcomes by influencing both product design and policy. Her efforts have been recognized with an Excellence in Teaching Award; a Phi Kappa Phi Excellence in Interdisciplinary Scholarship Award; and appointment as an Academic Fellow to the CIC ALP. She has an appointed expert to national and international panels convened by ISO, US FDA, the US CDC, the Consumer Healthcare Products Association (CHPA) and the Gerontological Society of America. She has also received distinction from industry as one 100 most notable people in the medical device industry named in *Medical Device and Diagnostics Magazine* in 2008.

PAUL BRADLEY, PhD, MS is a Research Hydrologist with the U.S. Geological Survey, Ecosystems Mission, Environmental Health Program. He is Co-Lead of the USGS Environmental Health Program, Drinking-Water and Wastewater Infrastructure Integrated Science Team. His research focuses on human exposures to and potential effects of inorganic, organic, and microbial contaminant mixtures in drinking water at the point of use and on exposures and adverse ecological-health effects of stormwater and wastewater contaminant mixtures, including pharmaceuticals, on aquatic ecosystems.

KAITLYN BROWN, PHARM D, DABAT is the Clinical Managing Director for America's Poison Centers. In this role, she promotes the use of poison center data by public health, industry, and non-government agencies to reduce poisoning. She serves on national committees that provide support for surveilling and responding to emerging hazards. As an Adjunct Assistant Professor for the University of Utah and through her previous experience at the Utah Poison Control Center, she has contributed to clinical toxicology research and education. Dr. Brown holds a Doctor of Pharmacy degree from Wilkes University and completed a fellowship in Clinical & Applied Toxicology at the Utah Poison Control Center. She is a Diplomate of the American Board of Applied Toxicology.

CHAD M. BRUMMETT, MD is a Professor at the University of Michigan where he serves as Co-Director of the Opioid Research Institute and as the Senior Associate Chair for Research. He has more than 270 publications, including articles in top journals such as JAMA, JAMA Surgery, Anesthesiology, and Annals of Surgery. He is also the Co-Director of the Opioid Prescribing Engagement Network (OPEN) at the University of Michigan, which aims to apply a preventative approach to the opioid epidemic in the US through appropriate prescribing after surgery,

dentistry, and emergency medicine, including opioid disposal. In addition, his research interests include predictors of acute and chronic post-surgical pain and failure to derive benefit from interventions and surgeries primarily performed to treat pain. He is the Co-PI of multiple NIH grants studying these concepts, and receives funding from the Michigan Department of Health and Human Services, SAMHSA, CDC, and multiple foundations.

WILSON COMPTON, MD, MPE is Deputy Director of the National Institute on Drug Abuse (NIDA) of the National Institutes of Health, where he has worked since 2002. Dr. Compton received his undergraduate education at Amherst College and medical education, including psychiatry training, at Washington University in St. Louis. Over his career, Dr. Compton has authored over 250 publications and often speaks at high-impact venues. He was a member of DSM-5's Revision Task Force and has led, for NIDA, development of the Population Assessment of Tobacco and Health Study, jointly sponsored by NIDA and the U.S. Food and Drug Administration (FDA), with 45,971 participants. Dr. Compton has received multiple awards, including FDA awards for collaboration in 2012, 2013 and 2017, and the Health and Human Services Secretary's Awards for Meritorious Service in 2013 and Distinguished Service in 2015, 2018 and 2019.

ANDREW COOP, PHD is Professor and Associate Dean for Academic Affairs at the University of Maryland School of Pharmacy. Dr. Coop has received funding from the National Institute on Drug Abuse for his chemistry research on opioids, stimulants, and depressants. Dr. Coop is a recipient of the Joseph Cochin Young Investigator Award from the College on Problems of Drug Dependence (CPDD), is a Fellow of both the CPDD and the American Association of Pharmaceutical Scientists.

Dr. Coop served as the Biological Coordinator of the Drug Evaluation Committee of CPDD, where he coordinated with the FDA, DEA, and NIDA on obtaining biological data on compounds under emergency schedule to aid in final scheduling decisions.

He is sought for lectures on his expertise on the chemistry of opioids, has served as an expert witness in criminal trials, and testified to the US Senate HELP Committee on approaches to treat pain during the opioid crisis.

UTTAM DHILLON, MA, JD is an accomplished attorney with more than 30 years of legal experience, including over 20 years in key roles within the federal government. During his storied career, Uttam has served in high-profile positions at the White House, the Drug Enforcement Administration, the Department of Homeland Security, INTERPOL Washington, and the House of Representatives.

His law practice is centered on legislative and regulatory oversight, government investigations, and white collar defense. In addition to his role as a partner at Michael Best, Uttam is also a principal at Michael Best Consulting LLC. Previously, Uttam was a co-founder and principal of DC Consulting LLC, a consulting firm specializing in law enforcement and drug-related issues.

KATHLEEN EGAN, PhD, MS is an Assistant Professor in the Department of Health Education and Promotion at East Carolina University. She completed a Postdoctoral Fellowship at the University of Florida Substance Abuse Training Center in Public Health. She earned her PhD in Community Health Education from University of North Carolina at Greensboro and a MS in Clinical and Translational Population Science from Wake Forest University School of Medicine. Her overarching research agenda aims to reduce harms associated with substance use through the implementation of interventions and policies in medical, community, and academic settings. She has been funded by the National Institute on Drug Abuse, Centers for Disease Control and Prevention, and Substance Abuse and Mental Health Services Administration to lead projects pertaining to secure storage and disposal of unused opioid medications.

Dr. Egan's research is focused on preventing harms associated with opioid, cannabis, and polysubstance use among adolescents and young adults. Her research involves the development and assessment of substance use prevention strategies that are implemented in community, medical, and academic settings. Dr. Egan is currently the principal investigator on a NIH-funded R34 (NIDA) research study that aims to develop and pilot test a text-message intervention to facilitate secure storage and disposal of unused prescription opioids (1R34DA051710-01). Her work is also supported by the Centers for Disease Control and Prevention (CDC) and North Carolina Division of Health and Human Services (NCDHHS). Dr. Egan teaches Program Evaluation at both the undergraduate and graduate level. Outside of work, Dr. Egan can be found running (literally) around town, on a stand-up paddleboard, or walking with her dogs and family.

KRISTIN FITZGERALD, MS has been with the U.S. EPA since 2001, working primarily on sector-based rulemakings for hazardous waste generators. Kristin started working with the Resource Conservation and Recovery Act (RCRA) over thirty years ago, answering questions on the RCRA/Superfund Hotline. She holds a B.A. in Government from St. Lawrence University in New York and an M.S. in Environmental Science and Policy from George Mason University in Virginia.

CHRISTOPHER GAW, MD, MPH, MBE is a Pediatric Emergency Medicine Fellow Physician and an Associate Fellow at the Center for Injury Research and Prevention at Children's Hospital of Philadelphia. Dr. Gaw's research is primarily focused on the epidemiology and prevention of pediatric injury and poisoning. In the past decade, he has worked with several research groups to study a wide array of topics, including head traumas, unintentional poisonings, and consumer product-related injuries. Dr. Gaw has significant experience leveraging large, administrative databases to better characterize injury and poisoning hazards to children with the goal of informing education, advocacy, and policy initiatives. His research also has utilized survey science and qualitative methods to understand provider views toward injury control. In addition to his injury prevention research, Dr. Gaw has academic interests in bioethics and medical education and has authored works on medical trainee wellness, shared decision-making, and end-of-life care.

ROBERT HOFFMAN, MD received his MD and completed a 3-year internship and residency in Internal Medicine followed by a Fellowship in Medical Toxicology all at NYU School of

medicine. He achieved and maintains Board Certification in Internal Medicine, Medical Toxicology, and Emergency Medicine. In 1989 Dr. Hoffman became the director of the Fellowship in Medical Toxicology at the New York City Poison Center, and in 1994 he became the Director of the New York City Poison Center. He was the Director of the Division of Medical Toxicology at NYU School of Medicine from 2014 through 2020. Dr. Hoffman has authored over 500 publications in peer-reviewed journals covering various aspects of toxicology. He has been an editor of Goldfrank's Toxicologic Emergencies for the last 7 editions. Dr. Hoffman has held offices in all 3 American Toxicology Societies and is a recipient of the ACMT Ellenhorn Award, the EAPCCT Louis Roche Award, and the AACT's Career Achievement award. Dr Hoffman's current interests focus on the development and propagation of evidence-based recommendations in toxicology. He is a co-chair of the Extracorporeal Treatments in Poisoning (EXTRIP) workgroup and the co-chair of the international Clinical Toxicology Recommendations Collaborative. In December of 2022 Dr. Hoffman became the co-Editor-in-Chief of Clinical Toxicology.

JEFF HORWITZ, JD, MS joined SAFE Project in January 2018 as the Chief Executive Officer of SAFE Project. Jeff comes with over 30 years of administrative, management and leadership experience. SAFE Project is a national 501(c)(3) nonprofit committed to overcoming the addiction epidemic in the United States. Founded by Admiral James and Mary Winnefeld in 2017 following the loss of their 19-year-old son Jonathan to an opioid overdose. SAFE Project provides transformative programming, training, and technical assistance based upon a collaborative, multipronged and nonpartisan approach within each of our key initiatives – SAFE Campuses, SAFE Communities, SAFE Workplaces and SAFE Veterans.

Prior to arriving at SAFE Project, Jeff served 28 years in the United States Navy. He retired as a Captain in 2014. In addition to his final assignment as the General Counsel of the White House Military Office, Jeff served in multiple assignments including Command Judge Advocate on board the USS Harry S. Truman (CVN 75), Staff Judge Advocate, COMNAVAIRFOR, Counsel for the Commander, U.S. Naval Forces in Northern Europe and the United Kingdom and as the Director of Navy's Legislative Program for nearly 9 years. In his free time, Jeff serves on the Board of St. Joseph's University's Center for Addiction and Recovery Education (CARE) and Heartshine, a resilience and trauma support community program in Harrisburg, Pennsylvania.

Jeff earned a Juris Doctor (JD) degree from the University of Pittsburgh, a Master of Science in Homeland Security from American Military University, and a Bachelor of Science in International Affairs from Seton Hall University.

LYEN HUANG, MD, MPH, FACS, FASCRS is an Assistant Professor of Surgery at the Spencer Fox Eccles School of Medicine and Adjunct Assistant Professor of Family & Preventative Medicine and Population Health Sciences at the University of Utah. He is a board-certified general and colorectal surgeon and provides care to patients with colorectal cancer, inflammatory bowel disease, and other gastrointestinal tract diseases. His research spans the breadth of perioperative opioid stewardship including patient education, screening, patient-centered prescribing, prescribing guided by machine learning, transitional pain services, naloxone co-prescribing, and opioid disposal. He was a University of Utah CTSI KL2 Mentored Career Development Scholar from 2020-2022.

MARY KELLINGTON joined the Washington State Department of Health in 2000 and began managing Washington's Safe Medication Return system July 2021. The impact of the environment on populations and of populations on the environment has intrigued Mary Kellington throughout her public health career and informed her work developing and implementing public health programs. Her earlier work focused on maternal and infant health, adolescent health, and sexual and reproductive health. Mary enjoys working with a variety of stakeholders and facilitating collaboration among groups with conflicting priorities. She strives to make healthy choices easy choices.

TAMAR KRISHNAMURTI, PHD is an Assistant Professor of Medicine at the University of Pittsburgh. Dr. Krishnamurti works on issues at the intersection of health, risk, technology, and communication. Dr. Krishnamurti was the 2020 recipient of the Kuno Award for Applied Science to develop mobile health strategies to address maternal morbidity and mortality risks. She leads the FemTech Collaborative at the University of Pittsburgh and is a co-founder of Naima Health, whose flagship product, MyHealthyPregnancy, offers early risk assessment and intervention for adverse pregnancy outcomes.

ELEANOR T. LEWIS, PHD is the Deputy Director of the Program Evaluation and Resource Center (PERC) in the Office of Mental Health and Suicide Prevention in the Veterans Health Administration (VHA). PERC's mission is to use program evaluation and advanced informatics to promote more Veteran-centered, effective, and cost-efficient care for Veterans with mental health conditions and substance use disorders. In addition to supporting PERC's operational mission broadly, Dr. Lewis has participated in multiple research projects on opioid use and misuse and helped implement opioid safety and risk mitigation initiatives in VA for more than a decade. She helps lead implementation of the VHA Stratification Tool for Opioid Risk Mitigation (STORM) which shows promise for targeting prevention interventions to reduce mortality in patients who are prescribed opioids. STORM was profiled on the AHRQ Patient Safety Network.

KEVIN NICHOLSON, R.PH., JD is Vice President, Public Policy, Regulatory & Legal Affairs for the National Association of Chain Drug Stores (NACDS). In this role, he is responsible for the strategic direction of the Association's public policy and regulatory affairs activities. Nicholson oversees activities and staff in providing legislative and regulatory policy analysis in federal and state healthcare issues. He and his team provide expertise to lobbyists and other Association staff, as well as chain members. He has over 30 years of experience in the pharmacy industry, including six years as a practicing community pharmacist.

PATRICK RAULERSON, JD has been with FDA for 14 years, focusing on regulation of opioids, biosimilars, combination products, and medical gases. He has been part of FDA's efforts to work with Congress on several major pieces of legislation including The SUPPORT Act, The 21st Century Cures Act, and FDASIA. Patrick has been particularly involved with FDA's efforts to incentivize and appropriately regulate abuse-deterrent formulations of opioids and safety-

enhancing packaging and disposal technologies for drugs of abuse. He has also helped develop and implement FDA's approach towards the labeling and nonproprietary naming of biosimilar products.

JAMES SHAMP is an entrepreneur, technologist, and business executive with over 18 years of experience in the design, development, operation, and assessment of REMS and Risk Management programs. He is currently the Vice President of Data Intelligence and Program Analytics at United BioSource, LLC (UBC). He was the founder and former President of J Shamp Consulting LLC. He is the former Managing Partner of Examoto LLC, which was acquired by UBC. Examoto, a UBC Company, focuses on innovation with the goal of maximizing the benefits and safe use of prescription drugs, while reducing the burden to patients, healthcare providers, and the healthcare delivery system.

SUSAN SHERMAN, PHD, MPH is a Professor in the Department of Health, Behavior, and Society who focuses on improving the health of marginalized populations, particularly that of drug users and sex workers. She is interested in the structural drivers of health and risk in both the conduct of observational and intervention research. She has over 17 years of experience in developing and evaluating HIV prevention, peer-outreach behavioral and microenterprise interventions in Baltimore, Pakistan, Thailand, and India. She is the Co-Director of the Baltimore HIV Collaboratory and a part of the Executive Leadership Committee of the Johns Hopkins Center for AIDS Research. She co-leads the Addiction and Overdose workgroup of the Bloomberg American Health Initiative. She is the PI of a study that examines the role of the police on the STI/HIV risk environment of street-based sex workers and includes the first cohort of sex workers in the US. She is also evaluating an innovative pre-booking diversion program for low level drug offenders. She has a new study which focusing on the effects of a structural level intervention with sex workers in Baltimore, which will create a full service drop-in center for sex workers in Baltimore. She serves on several Baltimore City and state advisory commissions on syringe exchange and overdose prevention initiatives, as well as the Board Secretary of the National Harm Reduction Coalition.

MARGARET SHIELD, PHD is a public health and environmental health consultant based in Seattle. She combines a background as a health sciences researcher with over eighteen years of experience working on legislative and regulatory initiatives at the local, state, and national levels. Since 2008, Margaret has been working on solutions for safe, convenient, and environmentally sound disposal of unwanted and expired medications from residents to reduce misuse, diversion, poisonings, and pollution. She has operational and policy experience with residential drug take-back programs, pharmaceutical waste regulation, and drug stewardship policies at the national, state, and local levels. She began this work as policy staff for King County Washington's Local Hazardous Waste Management Program as they worked with partners to develop a secure and convenient pharmacy-based medicine return program. These model protocols informed development of the DEA's 2014 rule on controlled substances disposal. Margaret was the lead policy staff for the King County Board of Health's process to pass a 2013 county-wide Secure Medicine Return regulation and subsequently consulted for local health agencies in four other counties that also enacted local pharmaceutical stewardship ordinances. Margaret was a leader in

passing the WA Secure Drug Take-Back Act in 2018, the first law in the nation requiring the pharmaceutical industry to provide this critical service. She consulted for the Oregon Department of Environmental Quality on their similar 2019 Safe Drug Disposal law. Margaret researched two reports for the San Francisco Department of the Environment examining medicine disposal products and whether available information supports their performance claims.

LCDR ANDREA TSATOKE, MPH is currently the Indian Health Service (IHS), Headquarters Injury Prevention Specialist, focusing on the Tribal Injury Prevention Cooperative Agreement Program (TIPCAP). She previously served for six years in the IHS Phoenix Area Division of Environmental Health Services as the District Injury Prevention Coordinator. She managed the Eastern Arizona Injury Prevention Program assisting tribal communities by focusing on the injuries affecting its ~50,000 service population. LCDR Tsatoke's career also included IHS assignments in Nevada, California, Alaska, and North Dakota. She has a Bachelor of Science in Environmental Health from Illinois State University and a Master's in Public Health Leadership from the University of North Carolina-Chapel Hill. She is also a graduate of the IHS Injury Prevention Fellowship.

Funding and Disclaimers

This workshop was supported by the pooled funds of the Forum on Drug Discovery, Development, and Translation. A list of sponsors can be found on page 27 in this briefing book or at <https://www.nationalacademies.org/our-work/forum-on-drug-discovery-development-and-translation/about>.

Statements, recommendations, and opinions expressed here today are those of individual presenters and participants and are not necessarily endorsed or verified by the National Academies. Discussions should not be construed as reflecting any group consensus.

The National Academies standards of high quality and integrity requires that staff ensure the membership of these committees be qualified, inclusive, and appropriately balanced. Appointed members must be free of financial conflicts of interest and transparent about other information relevant to their service on the committee. The planning committee for this workshop completed a composition, balance, and conflict of interest discussion at the start of its planning. Learn more: <https://www.nationalacademies.org/about/institutional-policies-and-procedures/conflict-of-interest-policies-and-procedures>

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The National Academies of Sciences, Engineering, and Medicine (NASEM) are committed to the principles of diversity, integrity, civility, and respect in all of our activities. We look to you to be a partner in this commitment by helping us to maintain a professional and cordial environment. All forms of discrimination, harassment, and bullying are prohibited in any NASEM activity. This commitment applies to all participants in all settings and locations in which NASEM work and activities are conducted, including committee meetings, workshops, conferences, and other work and social functions where employees, volunteers, sponsors, vendors, or guests are present.

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Sexual harassment is unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature that creates an intimidating, hostile, or offensive environment.

Other types of harassment include any verbal or physical conduct directed at individuals or groups of people because of their race, ethnicity, color, national origin, sex, sexual orientation, gender identity, age, religion, disability, veteran status, or any other characteristic protected by applicable laws, that creates an intimidating, hostile, or offensive environment.

Bullying is unwelcome, aggressive behavior involving the use of influence, threat, intimidation, or coercion to dominate others in the professional environment.

REPORTING AND RESOLUTION

Any violation of this policy should be reported. If you experience or witness discrimination, harassment, or bullying, you are encouraged to make your unease or disapproval known to the individual, if you are comfortable doing so. You are also urged to report any incident by:

- Filing a complaint with the Office of Human Resources at 202-334-3400, or
- Reporting the incident to an employee involved in the activity in which the member or volunteer is participating, who will then file a complaint with the Office of Human Resources.

Complaints should be filed as soon as possible after an incident. To ensure the prompt and thorough investigation of the complaint, the complainant should provide as much information as is possible, such as names, dates, locations, and steps taken. The Office of Human Resources will investigate the alleged violation in consultation with the Office of the General Counsel.

If an investigation results in a finding that an individual has committed a violation, NASEM will take the actions necessary to protect those involved in its activities from any future discrimination, harassment, or bullying, including in appropriate circumstances the removal of an individual from current NASEM activities and a ban on participation in future activities.

CONFIDENTIALITY

Information contained in a complaint is kept confidential, and information is revealed only on a need-to-know basis. NASEM will not retaliate or tolerate retaliation against anyone who makes a good faith report of discrimination, harassment, or bullying.

Updated June 7, 2018



ABOUT THE FORUM

The Forum on Drug Discovery, Development, and Translation (the forum) of the National Academies of Sciences, Engineering, and Medicine (the National Academies) was created in 2005 by the National Academies Board on Health Sciences Policy to foster communication, collaboration, and action in a neutral setting on issues of mutual interest across the drug research and development lifecycle. The forum membership includes leadership from the National Institutes of Health, the U.S. Food and Drug Administration, industry, academia, consortia, foundations, journals, and patient-focused and disease advocacy organizations.

Through the forum's activities, participants have been better able to bring attention and visibility to important issues, explore new approaches for resolving problem areas, share information and find common ground, and work together to develop ideas into concrete actions and new collaborations.

Forum work is based on four thematic priorities:

Spurring INNOVATION and IMPLEMENTATION

Revolutionary advances in biomedical research and technology present new and exciting opportunities for the discovery and development (R&D) of new therapies for patients. The evolution of health care is expanding possibilities for integration of clinical research into the continuum of clinical care and new approaches are enabling the collection of data in real-world settings. Innovative modalities, such as digital health technologies and artificial intelligence applications, can now be leveraged to overcome challenges and advance clinical research. The forum unites key stakeholders to identify opportunities, address bottlenecks, and spur innovation in drug discovery, development, and translation.

Increasing PERSON-CENTEREDNESS and EQUITY

There is much greater awareness around the need for more person-centered and inclusive approaches that prioritize lived experience, equity, and justice in the discovery, development, and translation of new treatments. The forum seeks to center priorities of people living with disease and those who have been traditionally under-represented or excluded from the clinical trials enterprise, advance the science of patient input, and help bring to fruition innovations that better address the needs of patients.

Promoting COLLABORATION and HARMONIZATION

The forum provides a neutral platform for communication and collaboration across sectors and disciplines to better harmonize efforts throughout the drug R&D life cycle. It does this by convening a broad and evolving set of stakeholders to help integrate patients, caregivers, researchers, trialists, community practitioners, sponsors, regulators, payers, patient and disease advocacy groups, and others into the continuum of research and clinical care. The forum also strives to enable shared decision-making and ensure that patients have input into research questions, researchers have insight into clinical practice, and practitioners are engaged in the clinical trials enterprise.

Enhancing the WORKFORCE and INFRASTRUCTURE

The forum has fostered the development of strategies to improve the discipline of innovative regulatory science and continues to focus on building a workforce that is diverse, adaptable, and resilient. Considerable opportunities remain to improve and expand the evolving clinical trials workforce and infrastructure, integrate community-based practices, and engage early-career scientists and clinicians in drug discovery, development, and translation. The forum will continue to anticipate and promote adaptation to changes in the infrastructure of health care delivery.

For more information about the Forum on Drug Discovery, Development, and Translation, please visit at:

[NATIONALACADEMIES.ORG/DRUGFORUM](https://www.nationalacademies.org/drugforum)

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ROUNDTABLES AND FORUMS

IN THE HEALTH AND MEDICINE DIVISION

nationalacademies.org/HMD

The background of the page is a photograph of a large, classical-style building with a stone facade and a prominent entrance. A large tree with green leaves is in the foreground on the left, partially obscuring the building. The image is overlaid with a semi-transparent blue filter. The text is centered in white, all-caps, serif font.

**ROUNDTABLES AND FORUMS
IN THE HEALTH
AND MEDICINE DIVISION:
ADVANCING THE DISCUSSION
AND FOSTERING
DIALOGUE ON CRITICAL
HEALTH TOPICS**

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The National Academies of Sciences, Engineering, and Medicine ("the National Academies") provide independent, objective analysis and advice to the nation, and conduct other activities to solve complex problems and inform public policy decisions. The National Academies also encourage education and research, recognize outstanding contributions to knowledge, and increase public understanding in matters of science, engineering, and medicine.

The Health and Medicine Division (HMD) is a program unit of the National Academies. The aim of HMD is to help those in government and the private sector make informed health policy decisions by providing evidence upon which they can rely. HMD advises the nation through consensus committees but also provides opportunities for open dialogue on complex and diverse topics through roundtables and forums.

Representatives from government, private businesses, academia, and other stakeholder groups gather regularly on neutral ground in order to identify and discuss contemporary issues of mutual interest and concern. Roundtables and forums cover a range of topics, including health care at the local and global levels, health literacy, health equity, health professional education, obesity solutions, violence prevention, and medical and public health preparedness.

Contact HMD:

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ROUNDTABLES AND FORUMS

Roundtables and forums create communal environments to foster dialogue across sectors and institutions. Although roundtables and forums do not produce solutions themselves, they illuminate issues that need to be resolved, and opportunities for further work often develop from their meetings, workshops, and publications. For example, the activities of a roundtable or forum may result in the establishment of separate consensus study committee.

Unlike a consensus committee, which publishes a report with conclusions and recommendations, a roundtable or forum may not issue work with such advice.

ROUNDTABLE AND FORUM MEMBER SELECTION

Usually, roundtable and forum members are selected based on each individual's expertise, but other considerations may be a factor. Since roundtables and forums do not give advice, their membership is not restricted with regard to financial or other types of bias and conflicts of interest.

The membership of a roundtable or forum is approved by the HMD Executive Office and appointed by the chair of the National Academies for three years (or a shorter duration, depending on the activity). Government officials from sponsoring agencies are appointed on an ex officio basis upon the recommendation of their agencies, and the length of their service will match the length of their term in office. Nongovernmental membership appointments to the roundtable or forum may also be considered ex officio if they are by virtue of the office in a professional society, corporation, or other independent organization—particularly if the sponsoring organization chooses the person and office to be on the roundtable or forum.

ROUNDTABLE AND FORUM ACTIVITIES

Roundtables and forums host a number of activities such as discussion meetings, workshops, and symposia. Within the scope of their approved topic, roundtables

and forums are self-governing in that, for example, they decide their own agendas for meetings. A chair, who presides at the meetings, is nominated by HMD and appointed by the chair of the National Academies, just as the members are.

Because they do not give advice, roundtables, forums, and their activities are not subject to Section 15 of the Federal Advisory Committee Act, an act that guarantees independence from government interests and necessitates disclosure of all reference materials to the public.

However, roundtable and forum meetings and workshops are announced on the HMD website in advance and are open to the public, except in two cases: if the meeting includes only members and is dedicated to administrative matters, or if the meeting will discuss issues described in U.S. Code Title 5 Section 552(b). Under this law, closed meetings may be held if the discussion delves into such topics as security, privacy, or legal matters.

Roundtables and forums often use authored background papers or workshops to help inform their discussions. These follow the same rules of public access as above. Workshops are organized by planning committees, which may include roundtable or forum members. A roundtable or forum member may also serve as a speaker at a workshop.



PLANNING COMMITTEES

Planning committees develop workshop agendas for roundtables and forums and are not subject to the same rules and limitations placed on study committees. However, all planning committee members must complete bias and conflict of interest forms, which ask about affiliations and opinions, and they must also participate in bias and conflict of interest discussions.

Potential sources of bias usually relate to individuals holding positions that arise from the close identification or association with a particular point of view.

Most, if not all, planning committee members will have some level of intellectual bias in relation to a particular topic, but those biases should be declared. An ideal planning committee will represent a balance of positions. In the face of evidence, an ideal member of a planning committee will be able to engage in dialogue with others and consider adopting a new point of view.

INNOVATION COLLABORATIVES

Roundtables and forums may establish innovation collaboratives—also called action collaboratives—to engage participants with similar interests and responsibilities in cooperative activities to advance aspects of each roundtable or forum’s statement of task. These ad hoc convening activities foster information sharing and

collaboration toward roundtable and forum aims as well as evaluation on progress on findings and recommendations highlighted in prior National Academies reports.

PUBLICATIONS

If a roundtable or forum holds a workshop, this workshop may result in a Proceedings of a Workshop or a Proceedings of a Workshop—in Brief, published by the National Academies Press (NAP), the publishing arm of the National Academies. Workshop proceedings are typically authored by some combination of HMD staff and hired consultants, serving as rapporteurs.

Like consensus committee reports, workshop proceedings are reviewed by an independent panel of experts, which may include roundtable and forum members. The Proceedings may not be transmitted to a sponsor or released to the public until review has been completed to the satisfaction of the Report Review Committee of the National Academies and the HMD Executive Office.

Other types of publications may develop from roundtables and forums. Independent, cooperative projects between sponsors and members, spin-off studies, and individually authored papers are some of the most common projects that grow out of roundtable and forum discussions. For instance, discussion papers and commentaries (collectively termed Perspectives) are individually

authored with the goal of further elucidating topics covered in roundtable or forum discussions. Small groups of roundtable or forum members, or individual members, may author a discussion paper or commentary to offer a particular perspective on a topic. Though distributed by the National Academy of Medicine (NAM), the views in the discussion papers and commentaries represent only those of the authors, not necessarily of the authors' organizations, the NAM, or the National Academies. These papers are not subject to the review procedures of the National Academies. All discussion papers and commentaries are designed to be shared publicly.

ROLE OF HMD STAFF

Each roundtable and forum is assisted in its work by a team of highly qualified staff members. Staff assist with research contributing to meetings and workshops, and they may act as the authors of a workshop proceedings. As with any HMD activity, staff may not insert their personal opinions into the publication. Overall, HMD staff is responsible for ensuring that the institutional procedures are followed and that the roundtable or forum stays within its budget.

COMMUNICATIONS

Although roundtables and forums do not issue advice or recommendations, it is important to emphasize communications to stimulate further discussion, attract workshop attendees, hold successful workshops, issue informative workshop proceedings, and inform a broader readership.

To help with these goals, HMD and the National Academies have a number of offices focused on communications support:

The HMD Office of Communications is responsible for HMD's report production functions as well as communications strategies and activities. One of its primary objectives is to communicate effectively the active messages of HMD activities and publications to its key audiences.

The Office of Congressional and Government Affairs is responsible for dissemination and outreach to congressional members and staffs. This may include congressional briefings and testimonies.

The Office of News and Public Information (ONPI) is the liaison between the National Academies and the news media and general public. ONPI should be informed of substantive conversations with the news media, especially if there is a problem.

The NAP website (nap.edu) makes all National Academies publications available online. All publications are free in PDF format to the public. As volunteers, roundtable and forum members receive a 25 percent discount on all books purchased from the NAP.

Our ROUNDTABLES AND FORUMS

FOOD FORUM

Sylvia Rowe, Chair
Heather Cook, Director

Established in 1993, the Food Forum convenes scientists, administrators, and policymakers from academia, government, industry, and public sectors on an ongoing basis to discuss problems and issues related to food, food safety, and regulation. The forum provides a mechanism for these diverse groups to explore possible approaches for addressing food and food safety problems and issues surrounding the often complex interactions among industry, academia, regulatory agencies, and consumers.

FORUM ON AGING, DISABILITY, AND INDEPENDENCE

Stephen Ewell and Rebecca Jackson Stoeckle,
Co-Chairs
Tracy Lustig, Director

The Forum on Aging, Disability, and Independence fosters dialogue and addresses issues of interest and concern related to aging and disability. This includes aging and the related disabling conditions that can occur, as well as aging with an existing disability. The forum seeks to promote bridging of the research, policy, and practice interests of the aging and disability communities to accelerate the transfer of research to practice and identify levers that will effect change for the benefit of all. Of particular concern is promoting healthy aging, independence, and community living for older adults and people with disabilities. This is a joint activity of HMD and the Division of Behavioral and Social Sciences and Education.



FORUM FOR CHILDREN'S WELL-BEING: PROMOTING COGNITIVE, AFFECTIVE, AND BEHAVIORAL HEALTH FOR CHILDREN AND YOUTH

Cheryl Polk and David W. Willis, Co-Chairs
Erin Kellogg, Director

Cognitive, affective, and behavioral disorders incur high psychosocial and economic costs for the young people who experience them, their families, and the communities in which they live, study, and will work. The Forum for Children's Well-Being aims to inform a forward-looking agenda for building a stronger research and practice base around the development and implementation of programs, practices, and policies to promote the health and well-being of all children, including those with disabilities. Forum members engage in dialogue and foster partnerships to connect the prevention, treatment, and implementation sciences with the places where children are seen and cared for, including health care settings, schools, social service and child welfare agencies, and the juvenile justice system. This is a joint activity of HMD and the Division of Behavioral and Social Sciences and Education.

FORUM ON DRUG DISCOVERY, DEVELOPMENT, AND TRANSLATION

Ann Taylor and Gregory Simon, Co-Chairs
Carolyn Shore, Director

The Forum on Drug Discovery, Development, and Translation was created in 2005 by the Board on Health Sciences Policy to provide a unique platform for dialogue and collaboration among thought leaders and stakeholders in government, academia, industry, foundations, and patient advocacy with an interest in improving the system of drug discovery, development, and translation. The forum brings together leaders from private sector sponsors of biomedical and clinical research, federal agencies sponsoring and regulating biomedical and clinical research, the academic community, and patients. The forum has identified four core components of translational science across this continuum that serve as thematic pillars to frame the forum's focus areas and activities: (1) Innovation and the Drug Development Enterprise; (2) Science Across the Drug Development Lifecycle (Basic, Translational, and Regulatory Sciences); (3) Clinical Trials and Clinical Product Development; and (4) Infrastructure and Workforce for Drug Discovery, Development, and Translation.



FORUM ON MEDICAL AND PUBLIC HEALTH PREPAREDNESS FOR DISASTERS AND EMERGENCIES

Suzet McKinney and Dan Hanfling, Co-Chairs
Scott Wollek and Lisa Brown, Co-Directors

The Forum on Medical and Public Health Preparedness for Disasters and Emergencies was established in September 2007 and provides a neutral venue for broad-ranging discussions that serve to facilitate coordination and cooperation among public and private stakeholders and enhance the nation's medical and public health preparedness for, response to, and recovery from disasters and other emergencies. The forum also serves as a catalyst for collaboration among voluntary public-private partners; raises attention and visibility to important preparedness, response, and recovery issues; explores new approaches for identifying and resolving challenges; sets the stage for future policy action; and elevates the understanding of medical and public health preparedness among the broader research, public policy, and practice communities.

FORUM ON MENTAL HEALTH AND SUBSTANCE USE DISORDERS

Margarita Alegria and Howard Goldman,
Co-Chairs
Alexandra Andrada, Director

The Forum on Mental Health and Substance Use Disorders, launched in early 2019, provides a structured environment and neutral venue to discuss data, policies, practices, and systems that affect the diagnosis and provision of care for people with mental health and substance use disorders. Forum participants engage in dialogue on a range of issues, such as facilitating access to care services in various settings; coordination and integration of services in primary and specialty health care delivery systems; advancing patient-centered care; promising strategies to translate knowledge to practice and to monitor implementation; innovative practices to facilitate and optimize data collection, integration, and use; and improving care spanning the medical, mental health and substance use disorder workforce and care delivery systems. Forum sponsors include federal agencies, health professional associations, addiction treatment providers, pharmaceutical manufacturers, and other public and private sector organizations.



FORUM ON MICROBIAL THREATS

Peter Daszak, Chair;
Kent E. Kester and Rima F. Khabbaz, Vice Chairs
Julie Liao, Director

The Forum on Microbial Threats was created in 1996 at the request of the U.S. Centers for Disease Control and Prevention and the National Institutes of Health to provide a structured opportunity for discussion and scrutiny of critical, and possibly contentious, scientific and policy issues related to infectious disease research and the prevention, detection, surveillance, and responses to emerging and reemerging threats in humans, plants, and animals as well as the microbiome in health and disease. The forum brings together leaders from government agencies, industry, academia, nonprofit and philanthropic organizations, facilitating cross-sector dialogue and collaboration through public debate and private consultation, to stimulate original thinking about the most pressing issues across the spectrum of microbial threats.

FORUM ON NEUROSCIENCE AND NERVOUS SYSTEM DISORDERS

Frances Jensen and John Krystal, Co-Chairs
Clare Stroud, Director

The Forum on Neuroscience and Nervous System Disorders was established in 2006 to provide a venue for building partnerships, addressing challenges, and highlighting emerging issues related to brain disorders, which are common, major causes of premature mortality, and, in aggregate, the largest cause of disability worldwide. The Forum's meetings bring together leaders from government, industry, academia, disease advocacy organizations, and other interested parties to examine significant—and sometimes contentious—issues concerning scientific opportunities, priority setting, and policies related to research on neuroscience and brain disorders; the development, regulation, and use of interventions for the nervous system; and related ethical, legal, and social implications.



FORUM ON REGENERATIVE MEDICINE

Timothy Coetzee and Katherine Tsokas, Co-Chairs
Sarah Beachy, Director

The Forum on Regenerative Medicine provides a convening mechanism for interested parties from academia, industry, government, patient/provider organizations, regulators, foundations, and others to discuss difficult issues in a neutral setting. The overall goal is to engage in dialogue that addresses the challenges facing the application of, and the opportunities for, regenerative medicine to improve health through the development of effective new therapies. The forum identifies potential barriers to scientific and therapeutic advances and discusses opportunities to facilitate more effective partnerships among key stakeholders. The forum examines the impact of current policies on the discovery, development, and translation of regenerative medicine therapies and addresses the unique challenges of identifying, validating, and bringing regenerative medicine applications to market. Ethical, legal, and social issues posed by regenerative medicine advances are also explored.

GLOBAL FORUM ON INNOVATION IN HEALTH PROFESSIONAL EDUCATION

Patrick DeLeon and Zohray Talib, Co-Chairs
Patricia Cuff, Director

The Global Forum on Innovation in Health Professional Education brings together stakeholders from multiple nations and professions to network, discuss, and illuminate issues within health professional education. Currently, there are over 55 appointed members to the Forum who are academic experts and health professionals representing 18 different disciplines from 8 developed and developing countries. Of these members, 46 are sponsors. Members of the forum gather twice a year to attend forum-sponsored events that address critical issues within the education to practice continuum. Topics for these activities have included discussions on financing health professional education; addressing the social determinants of health; and ensuring a mentally and physically stable health workforce.



NATIONAL CANCER POLICY FORUM

Edward Benz, Jr., Chair
Sharyl Nass and Erin Balogh, Co-Directors

The National Cancer Policy Forum serves as a trusted venue in which experts can work collaboratively to identify emerging high-priority policy issues in cancer research and care and to examine those issues through convening activities that promote discussion about opportunities for action. The forum provides a continual focus within the National Academies on cancer, addressing issues in science, clinical medicine, public health, and public policy that are relevant to the goal of reducing the cancer burden, through prevention and by improving the care and outcomes for those diagnosed with cancer. Forum activities inform stakeholders about critical policy issues through published proceedings and often inform consensus committee studies. The forum has members with a broad range of expertise in cancer, including patient advocates; clinicians; and basic, translational, and clinical scientists. Members represent patients, federal agencies, academia, professional organizations, nonprofits, and industry.

ROUNDTABLE ON ENVIRONMENTAL HEALTH SCIENCES, RESEARCH, AND MEDICINE

Kathleen Stratton, Director

The Roundtable on Environmental Health Sciences, Research, and Medicine was organized in 1988 to provide a mechanism for parties interested in environmental health from the academic, industrial, and federal research perspectives to meet and discuss sensitive and difficult environmental health issues of mutual interest in a neutral setting. Since its inception, the roundtable has addressed current and emerging issues in environmental health through discussions related to the state of the science, research gaps, and policy implications. The roundtable has moved toward an increasingly global perspective in its discussions on the UN Sustainable Development Goals, the relationship between trade and health, and corporate social responsibility in environmental health. The roundtable is currently focused on issues of domestic and international importance, such as climate change, sustainable drinking water, transportation-related energy use, and environmental health decision making.

ROUNDTABLE ON GENOMICS AND PRECISION HEALTH

W. Gregory Feero and Michelle Ann Penny,
Co-Chairs
Sarah Beachy, Director

The Roundtable on Genomics and Precision Health provides both a mechanism and a venue for interested parties from government, academia, industry, and other stakeholder groups to discuss global issues of mutual interest and concern regarding the translation of genomic research findings for medicine and health in a neutral setting. The purpose of the roundtable is to foster dialogue across sectors, as well as to illuminate and scrutinize critical scientific and policy issues in which roundtable engagement will help further the field. The roundtable explores strategies for improving health through the translation of genomics and genetics research findings into medicine, public health, education, and policy. Current areas of emphasis include precision therapeutics; clinical implementation of genomic medicine; health care disparities related to the introduction of a new technology; health information technology and digital health; use of genomic information for health care decision making; use of genomic information and data science to generate knowledge for clinical practice and research; education; and ethical, legal, and social issues.

ROUNDTABLE ON HEALTH LITERACY

Lawrence G. Smith, Chair
Rose M. Martinez, Acting Director

The Roundtable on Health Literacy envisions a society in which the demands of the health and health care systems respect and align with people's skills, abilities, and values. The mission of the roundtable is to inform, inspire, and activate a wide variety of stakeholders to support the development, implementation, and sharing of evidence-based health literacy practices and policies, with the goal of improving the health and well-being of all people. In order to accomplish its mission, the roundtable brings together leaders from academia, industry, government, foundations and associations, and patient and consumer groups to meet in a neutral setting in order to discuss complex issues regarding health literacy research, practice, and strategies for promoting health literacy through mechanisms and partnerships in both the public and the private sectors.



ROUNDTABLE ON OBESITY SOLUTIONS

Nicolaas Pronk, Chair; Christina Economos and
Ihuoma Eneli, Vice Chairs
Heather Cook, Director

The Roundtable on Obesity Solutions engages leadership from multiple sectors to solve the obesity crisis. Many sectors have recognized the need for action, and a number of groups have formed across the country to tackle specific aspects of the epidemic. Nonetheless, a significant gap exists between what we have learned about obesity solutions and the implementation of those solutions. Through meetings, public workshops, background papers, and innovation collaboratives, the roundtable provides a trusted venue for accelerating the discussion, development, and implementation of multisectoral collaborations and policy, as well as environmental and behavioral initiatives, that will reduce the prevalence and adverse consequences of obesity and eliminate obesity-related health disparities.

ROUNDTABLE ON POPULATION HEALTH IMPROVEMENT

Raymond J. Baxter and Kirsten Bibbins-Domingo,
Co-Chairs
Alina Baci, Director

The Roundtable on Population Health Improvement brings together multiple sectors and disciplines to broaden the national conversation about the factors that shape our health and to support cross-sector relationships and engagement to transform the conditions for health across US communities. By hosting workshops, spurring individually-authored papers, and organizing action collaboratives, the roundtable engages members and outside experts, practitioners, and stakeholders around models, best practices, and other evidence about actions that will contribute to building a strong, healthy, and productive society that cultivates human capital and equal opportunity. The roundtable has explored a range of connected issues including collaboration between the education and health sectors, partnerships between faith-based and health sector entities, the shifting definitions of value that are helping reorient investments in the health care and business sectors toward health and well-being, and the nature and needs of the population health workforce, broadly conceived.



ROUNDTABLE ON THE PROMOTION OF HEALTH EQUITY

Kat Anderson, Director

The Roundtable on the Promotion of Health Equity serves as the conveners of the nation's experts in health disparities and health equity, with the goal of raising awareness and driving change. The roundtable promotes health equity and the elimination of health disparities by: (1) advancing the visibility and understanding of inequities in health and health care among racial and ethnic subpopulations; (2) amplifying research, policy, and community centered programs; and (3) catalyzing the emergence of new leaders, partners, and stakeholders.

ROUNDTABLE ON QUALITY CARE FOR PEOPLE WITH SERIOUS ILLNESS

Peggy Maguire and James A. Tulsky, Co-Chairs
Laurie Graig, Director

The Roundtable on Quality Care for People with Serious Illness, which launched in mid-2016, works to foster an ongoing dialogue about critical policy and research issues to accelerate and sustain progress in care for people of all ages with serious illness. Inspired by previous work at the National Academies, including the 2014 Institute of Medicine report *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life*, the roundtable convenes key stakeholders to focus on five priority areas: (1) delivery of person-centered, family-oriented care; (2) communication and advance care planning; (3) professional education and development; (4) policies and payment systems; and (5) public education and engagement. Roundtable membership includes patient advocates, health care professional organizations, health care providers and insurers, foundations, federal agencies, researchers, and others interested in the topic.



MAKING A DIFFERENCE

Our convening activities bring together stakeholders from across the health spectrum, creating a communal environment to explore complex health topics and work toward shared understanding.



INFLUENCE

Policies & Programs

Our work can inform policy and legislation; programmatic planning, direction, and budgets; educational initiatives, such as curricula and training programs; and other activities.



FOSTER

Relationships & Collaboration

By bringing together a diverse group of participants around a particular topic, our activities foster new professional relationships, facilitate cross-sector collaborations, and enable professional development and networking, including the cultivation of new leaders.



INSPIRE

New Ideas & Shape the Field

Our work can advance and shape the field by framing issues and shining a light on important topics, and by generating novel approaches to overcome existing challenges, spurring progress and inspiring action.

Impact Highlights from our Roundtables and Forums



INFLUENCE

Policies & Programs

A January 2015 report issued by Senator Lamar Alexander and Senator Richard Burr, "Innovation for Healthier Americans: Identifying Opportunities for Meaningful Reform to Our Nation's Medical Product Discovery and Development," cited a workshop series of the Forum on Drug Discovery, Development, and Translation addressing clinical trials, which began in 2008, as a foundational resource in identifying and addressing the challenges facing the U.S. clinical trials enterprise. The report highlights concepts Congress might consider to better align public policy to support medical innovation and patient access to new medicines and technologies. One key concept explored in the report is the modernization of clinical trials.



FOSTER

Relationships & Collaboration

The Global Genomic Medicine Collaborative (G2MC), an action collaborative launched in 2014 under the auspices of the Roundtable on Genomics and Precision Health, was incorporated as a 501(c)3 nonprofit organization and obtained administrative support provided by the Global Alliance for Genomics and Health (GA4GH) between 2016 and 2017. During their time as an action collaborative, G2MC hosted three international meetings (in Washington DC, Singapore, and Athens), bringing together more than 25 countries to work towards creating a global toolbox for genomic medicine implementation; facilitating collaborations that could enable effective implementation; and discussing solutions for obstacles encountered during implementation. As a result of the collaborative's work, participants have published papers in journals such as Science Translational Medicine and began hosting virtual Grand Rounds on topics related to genetics education. G2MC currently has six working groups including Education; Evidence; IT/Bioinformatics, National Programs and Implementation; Pharmacogenomics, and Policy, and has hosted additional meetings to convene more than 40 countries in Durham, NC, and Cape Town, South Africa.



INSPIRE

New Ideas & Shape the Field

Nemours Children's Health System published a white paper, "State Quality Rating and Improvement Systems: Strategies to Support Achievement of Healthy Eating and Physical Activity Practices in Early Care and Education Settings," in June 2016, focusing on four strategies to prevent childhood obesity: healthy eating, breastfeeding, physical activity, and limited screen time (referred to as "HEPA"). The Roundtable on Obesity Solutions' Early Care and Education (ECE) Innovation Collaborative, whose members include researchers, practitioners, and policy makers with expertise in ECE or childhood obesity prevention, identified the need for the study and served as the advisory group for this project. Throughout the project, ECE IC members provided input on key deliverables during their quarterly meetings. The goal of the study was to measure the extent to which states with Quality Rating Improvement Systems are using specific implementation strategies to promote HEPA practices in ECE settings.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Disabilities, The President's Committee for People With Intellectual Disabilities

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The President's Committee for People with Intellectual Disabilities (PCPID) will hold a virtual meeting for members to discuss issues related to Home and Community Based Services (HCBS) that will be a part of the Committee's Report to the President. All the PCPID meetings, in any format, are open to the public. This virtual meeting will be conducted in a discussion and presentation format with testimony from people with intellectual disabilities and other stakeholders to provide more information about their experiences with HCBS.

DATES: May 1, 2023 from 12 p.m. to 5 p.m. (EST).

Agenda: The Committee will discuss emerging issues identified by four PCPID workgroups related to HCBS: Direct support professionals, competitive integrated employment, community living, and Federal support programs. This discussion will help develop a general framework for the preparation of the PCPID Report to the President.

Additional Information: For further information, please contact Mr. David Jones, Director, Office of Intellectual Developmental Disabilities, 330 C Street SW, Switzer Building, Room 1126, Washington, DC 20201. Telephone: 202-795-7367. Fax: 202-795-7334. Email: David.Jones@acl.hhs.gov.

SUPPLEMENTARY INFORMATION:

Stakeholder input is very important to the PCPID. Comments and suggestions, especially from people with intellectual disabilities, are welcomed. If there are comments related to HCBS or other areas that you would like to inform the PCPID, please share them through the following ACL.gov link: https://acl.gov/form/pcpid?j=1555178&sfmc_sub=191090082&l=6707_HTML&u=34777761&mid=515008575&jb=0.

Comments received by April 21st will be shared with the PCPID at the May 1st meeting.

Webinar/Conference Call: The virtual meeting is scheduled for Monday, May 1, 2023 from 12:00 p.m. to 5:00 p.m. (EST) and may end early if discussions are finished. The meeting is open to the

public and will be held through a zoom meeting platform. In order for members of the public to observe the proceedings, you must register in advance at the following link: https://www.zoomgov.com/webinar/register/WN_jjKOBx7ARW-EjJdzKgawWg.

Background Information on the Committee: The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services, and supports for individuals with intellectual disabilities. The PCPID Charter stipulates that the Committee shall: (1) provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President and the Secretary of Health and Human Services to promote full participation of people with intellectual disabilities in their communities, such as: (A) expanding educational opportunities; (B) promoting housing opportunities; (C) expanding opportunities for competitive integrated employment; (D) improving accessible transportation options; (E) protecting rights and preventing abuse; and (F) increasing access to assistive and universally designed technologies; and (3) provide advice to the President and the Secretary of Health and Human Services to help advance racial equity and support for people with intellectual disabilities within underserved communities.

Dated: March 30, 2023.

Jill Jacobs,

Commissioner, Administration on Disabilities.

[FR Doc. 2023-06938 Filed 4-3-23; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0917]

In-Home Disposal Systems for Opioid Analgesics; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information; establishment of a public docket.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to obtain information and comments that will assist the Agency in assessing whether in-home disposal products can be expected to meet the

public health goal of mitigating the risk of nonmedical use or overdose if the Agency were to require drug manufacturers to make in-home disposal products available to patients under a risk evaluation and mitigation strategy (REMS). The Agency would like information and comments on the issues to be discussed at the public workshop convened by the National Academies of Sciences, Engineering and Medicine's (NASEM's) Forum on Drug Discovery, Development, and Translation entitled "Defining and Evaluating In-Home Disposal Systems for Opioid Analgesics" on June 26 and 27, 2023.

DATES: Submit either electronic or written comments, data, or information by August 28, 2023.

ADDRESSES: You may submit data and comments as follows. Please note that late, untimely filed comments will not be considered. The docket will close on August 28, 2023. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 28, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2023-N-0917 for “In-Home Disposal Systems for Opioid Analgesics; Request for Information.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts

and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Nonmedical use,¹ accidental exposure, and overdose associated with prescription opioid analgesics remain a serious problem in the United States. Patients commonly report having unused opioid analgesics after treatment of acute pain, such as pain following surgical procedures (Refs. 1 and 2). Opioid analgesics prescribed to treat chronic pain conditions can also result in unused drugs. When not properly disposed, these opioid analgesics provide opportunities for nonmedical use, accidental exposure, and overdose. Accordingly, FDA’s efforts to address the opioid crisis include a focus on encouraging appropriate disposal of unused opioid analgesics (for additional information, see the **Federal Register** notice “Providing Mail-Back Envelopes and Education on Safe Disposal With Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments” (April 21, 2022, 87 FR 23869; Sec. I., Background (Docket No. FDA-2022-N-0165)). The Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115-271), signed into law on October 24, 2018, provides FDA authorities to address the opioid crisis. The SUPPORT Act authorized FDA to require through a REMS that a safe disposal packaging or safe disposal system be dispensed to certain patients with opioids or other drugs that pose a serious risk of abuse or overdose if, among other things, FDA determines that such safe disposal packaging or system may mitigate such risks and is sufficiently available (21 U.S.C. 355-1(e)(4)).

II. Topic for Public Input

This request for information is part of FDA’s ongoing efforts to determine

¹ We use the term “nonmedical” in this document to refer to misuse of a drug, abuse of a drug, or both. “Misuse” is the intentional use, for therapeutic purposes, of a drug in a manner other than prescribed. “Abuse” is the intentional, non-therapeutic use of a drug, even once, for its desirable psychological or physiological effects.

whether in-home disposal products can be expected to meet the public health goal of mitigating the risk of nonmedical use or overdose if the Agency were to require drug manufacturers to make these products available to patients under a REMS. On June 26 and 27, 2023, NASEM’s Forum on Drug Discovery, Development, and Translation will hold a public workshop entitled “Defining and Evaluating In-Home Disposal Systems for Opioid Analgesics.”

The purpose of the workshop is to provide an opportunity for stakeholders to examine in-home drug disposal systems, with a focus on removing unused opioid analgesics from the home. The workshop will feature invited presenters and discussions to explore the types of in-home drug disposal options, other than mail-back envelopes, which could be used to remove unused opioid analgesics from the home. This will include, among other things, a discussion of the scientific, behavioral, health equity, and policy considerations for assessing the safety, use, and effectiveness of in-home drug disposal options.

Workshop participants will address questions about the methods (e.g., sequestration, adsorption, absorption) used in in-home disposal options for rendering opioids unavailable for nonmedical use, assuming the in-home disposal product is used as intended. In addition, workshop participants will discuss approaches and methodologies needed to evaluate the safe and correct use of in-home drug disposal options in real-world settings. Finally, workshop participants will consider potential strategies for encouraging and assessing the development and use of in-home drug disposal options. Additional meeting information, including the briefing document, agenda, and presentations, will be made available at <https://www.nationalacademies.org/our-work/advancing-regulatory-science-for-defining-and-evaluating-in-home-safe-disposal-systems-a-workshop> closer to the workshop date. FDA is seeking information and comments on the topics discussed at this meeting.

III. References

The following references are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some references may be available at the website address, if listed. The references below are available for viewing only at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the web addresses, as of the date this

document publishes in the **Federal Register**, but websites are subject to change over time.

1. Bicket, M.C., J.J. Long, P.J. Pronovost, et al., "Prescription Opioid Analgesics Commonly Unused After Surgery: A Systematic Review," *JAMA Surgery*, vol. 152(11), pp. 1066–1071, 2017, <https://doi.org/10.1001/jamasurg.2017.0831>.

2. Mallama, C.A., C.A. Greene, A.A. Alexandridis, et al., "Patient-Reported Opioid Analgesic Use After Discharge from Surgical Procedures: A Systematic Review," *Pain Medicine*, vol. 23(1), pp. 22–44, 2022, <https://doi.org/10.1093/pm/pnab244>.

Dated: March 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06650 Filed 4–3–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Privacy Act of 1974; System of Records

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice of a new system of records, and rescindment of system of records notices.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS) is establishing a new department-wide system of records titled Personnel (Employee and Non-Employee) Recruitment Program Records Not Covered by Other Notices, system number 09–90–2301. HHS is also rescinding two related systems of records: OGC Attorney Applicant Files, system number 09–90–0066; and Fellowship Program and Guest Researcher Records, system number 09–20–0112.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice is applicable April 4, 2023, subject to a 30-day period in which to comment on the routine uses, described below. Please submit any comments by May 4, 2023.

ADDRESSES: The public should submit written comments, by mail or email, to Beth Kramer, HHS Privacy Act Officer, 200 Independence Ave. SW, Suite 729H, Washington, DC 20201, or beth.kramer@hhs.gov. Comments received will be available for review at this location without redaction, unless otherwise advised by the commenter. To review comments in person, please contact

Beth Kramer at beth.kramer@hhs.gov or (202) 690–6941.

FOR FURTHER INFORMATION CONTACT:

General questions about the system of records should be submitted by mail, email, or phone to Beth Kramer, HHS Privacy Act Officer, 200 Independence Ave. SW, Suite 729H, Washington, DC 20201, or beth.kramer@hhs.gov, or (202) 690–6941.

SUPPLEMENTARY INFORMATION:

I. Background on New System of Records 09–90–2301

This new department-wide system of records will cover (1) recruitment and related records about individuals recruited or identified for possible recruitment for fellowship and other non-employee positions at HHS, including those who become applicants and those who do not become applicants; and (2) recruitment records about individuals recruited or identified for possible recruitment for employee positions at HHS who do not become applicants. Recruitment records about individuals who apply for employee positions at HHS are excluded, because they are covered by other system of records notices (SORNs); specifically:

- Records about Public Health Service Commissioned Corps applicants are covered by 09–40–0001 Public Health Service (PHS) Commissioned Corps General Personnel Records; and
- Records about applicants for other HHS positions are covered by OPM/GOVT–5 Recruiting, Examining, and Placement Records (however, OPM/GOVT–5 does not include records about non-applicant recruits and recruitment candidates).

Only records for recruitment programs that retrieve records by subject individuals' names or other personal identifiers constitute Privacy Act records and are covered by the new system of records. Currently, only HHS' National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) maintain recruitment program records that need to be covered by the new system of records. A report on the new system of records was sent to the Office of Management and Budget (OMB) and the two Congressional committees that oversee privacy, in accordance with 5 U.S.C. 552a(r).

II. Rescindment of Systems of Records 09–90–0066 and 09–20–0112

HHS is rescinding two related System of Records Notices (SORNs):

- HHS is rescinding HHS Office of the General Counsel SORN 09–90–0066, titled OGC Attorney Applicant Files, as

duplicative of OPM/GOVT–5. SORN 09–90–0066 includes only records about individuals who have applied for an employment position with the HHS Office of General Counsel (OGC), and those records are entirely within the scope of OPM/GOVT–5. The records covered by SORN 09–90–0066 are still maintained by OGC, but will now be covered only by OPM/GOVT–5.

- HHS is rescinding Centers for Disease Control and Prevention SORN 09–20–0012, titled Fellowship Program and Guest Researcher Records, HHS/CDC/PMO, as replaced by and duplicative of new department-wide SORN 09–90–2301. SORN 09–20–0012 includes only records used to recruit individuals for nonemployee positions, so those records are entirely within the scope of new SORN 09–90–2301.

Dated: March 27, 2023.

Alfred C. Johnson,

Deputy Director for Management, National Institutes of Health.

SYSTEM NAME AND NUMBER:

Personnel (Employee and Non-Employee) Recruitment Program Records Not Covered by Other Notices, 09–90–2301.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The address of each agency component responsible for this system of records is as shown in the System Manager(s) section below.

SYSTEM MANAGER(S):

The system managers are as follows:

- *For National Institutes of Health (NIH) records:* NIH Chief Officer for Scientific Workforce Diversity, 1 Center Dr., Bldg. 1, Rm. 316, Bethesda, MD 20892; Telephone: (301) 451–4296.
- *For Centers for Disease Control and Prevention (CDC) records:* Deputy Director, Division of Scientific Education and Professional Development, Mail Stop V24–5, Centers for Disease Control and Prevention, 1600 Clifton Rd. NE, Atlanta, GA 30333; Email: fellowships@cdc.gov.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 1302, 2301(b)(1), 3301 *et seq.*; 42 U.S.C. 209(g) and (h), 241, 247b–8, and 284(b).

PURPOSE(S) OF THE SYSTEM:

Records about individuals recruited or considered for recruitment for employee positions at HHS are used to fulfill particular candidate sourcing requests directed at meeting specific HHS workforce recruiting goals and to respond to reporting requests.

SUPPORT Act text giving FDA authority over in-home drug disposal products and the language change from the Consolidated Appropriations Act, 2023

The 2018 SUPPORT Act amended Section 505-1(e)(4) of the Federal Food, Drug, and Cosmetic Act to include the following text (emphasis added):

505-1(e)(4) PACKAGING AND DISPOSAL

The Secretary may require a risk evaluation mitigation strategy for a drug for which there is a serious risk of an adverse drug experience described in subparagraph (B) or (C) of subsection (b)(1), taking into consideration the factors described in subparagraphs (C) and (D) of subsection (f)(2) and in consultation with other relevant Federal agencies with authorities over drug disposal packaging, which may include requiring that—

(A) the drug be made available for dispensing to certain patients in unit dose packaging, packaging that provides a set duration, or another packaging system that the Secretary determines may mitigate such serious risk; or

(B) the drug be dispensed to certain patients with a safe disposal packaging or safe disposal system ~~for purposes of rendering drugs nonretrievable (as defined in section 1300.05 of title 21, Code of Federal Regulations (or any successor regulation))~~ if the Secretary determines that such safe disposal packaging or system may mitigate such serious risk and is sufficiently available.

The Consolidated Appropriations Act, 2023, passed in December 2022, included a section to amend Section 505-1(e)(4)(B) of the Federal Food, Drug, and Cosmetic Act by striking “for purposes of rendering drugs nonretrievable.” The Consolidated Appropriations Act text is below. The line removed is indicated in red above.

SEC. 3221. SAFER DISPOSAL OF OPIOIDS.

Section 505-1(e)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355-1(e)(4)(B)) is amended by striking “for purposes of rendering drugs nonretrievable (as defined in section 1300.05 of title 21, Code of Federal Regulations (or any successor regulation))”.

Legal definition of “nonretrievable” per 21 CFR § 1300.05

SEC. 1300.05. DEFINITIONS RELATING TO THE DISPOSAL OF CONTROLLED SUBSTANCES

Non-retrievable means, for the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and

thereby renders the controlled substance unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.



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COMMENTARY

Prescription drug disposal: Products available for home use

Fiona Imarhia, Tyler J. Varisco, Matthew A. Wanat^{*}, J. Douglas Thornton

ARTICLE INFO

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ABSTRACT

Objective: Unused medications in the home are often improperly stored and may lead to unintentional harm, misuse, and diversion. Single-use disposal systems products allow consumers to safely inactivate unused medication and provide an environmentally friendly alternative to flushing medication down the toilet or discarding in the trash. The objective of this commentary was to review current medication disposal options and inform pharmacists of new products that may be used by patients to dispose of medications in the home setting. **Data sources:** Current recommendations on medication disposal from U.S. regulatory agencies (e.g., the Environmental Protection Agency) were reviewed and summarized comparatively. Information on the mechanism of action, price, and method of use of 8 new single-use disposal systems suitable for outpatient use were taken from each product manufacturer's website.

Summary: Eight single-use disposal systems were identified. Seven products used chemical deactivation to render medication safe for disposal, and 1 product allowed consumers to mail medication to a central processing facility for incineration. Products ranged in size from 2 oz to 1 gal, offering consumers the ability to dispose of anywhere from 60 to 3000 tablets per unit, respectively. Unit costs varied widely from \$5 per single-use pouch to \$190 for a 40-gal box intended for incineration.

Conclusion: Pharmacists and consumers must consider cost, effectiveness, and environmental impact when recommending and selecting products for medication disposal at home. More research is needed to understand the cost-effectiveness of each disposal system and to identify strategies to encourage uptake by health systems and use by consumers. Including content on home medication disposal in pharmacist–continuing education activities and raising workforce awareness of these products are critical to improving public safety.

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Objective

According to the Centers for Disease Control and Prevention (CDC), 58 opioid prescriptions were written for every 100 Americans in 2017.¹ Although a steady decline in opioid prescribing patterns has been observed since 2010, opioid-related hospitalizations, emergency department visits, and mortality have continued to increase.² From 1999 to 2017, there were more than 400,000 opioid-related deaths in the United States, with more than 70,000 in 2017 alone.³ Unused and improperly

stored opioid medications are risk factors for opioid misuse and diversion. An estimated 56% of individuals who misused opioids in 2013–2014 obtained their medication from a friend or family member at no cost.^{4,5} To combat the opioid epidemic, tools such as electronic prescription drug monitoring programs and CDC's Opioid Overdose Surveillance Program have been implemented.³ In addition to improved monitoring, enabling patients to safely dispose of unused opioids can play a role in preventing opioid-related harm. Health care providers rarely counsel patients on the safe disposal of controlled substance medications. In 1 nationwide sample of chronic opioid users, only 22% of patients had received counseling on medication disposal from a pharmacist.⁶ The objective of this commentary is to review current medication disposal options and introduce 8 new products that may be used by patients to dispose of medications in the home setting. More information on available options for medication disposal will likely pharmacists and other providers the knowledge needed to counsel

Disclosure: The authors declare no relevant conflicts of interest or financial relationships.

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Key Points**Background:**

- Only 22% of patients receive counseling from a pharmacist on medication disposal.
- Educating the pharmacy practice workforce on safe and effective medication disposal practices is critical to preventing prescription drug misuse.

Findings:

- There are currently 8 commercially available products indicated for the disposal of medications at home. Seven of these use chemical deactivation, and 1 uses incineration to render medications inactive.
- Costs, ease of use, and availability vary widely; however, all are more environmentally friendly options when compared with flushing down the toilet and are more convenient than current Drug Enforcement Administration–sanctioned drug take-back events and drop boxes.

their patients on the importance of disposing unused medication.

Data sources

Regulatory agencies in the United States including the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and the Environmental Protection Agency (EPA) have all offered guidance on outpatient medication disposal. This commentary will compare and contrast guidance for disposal from each of these agencies and then discuss the advent of single-use disposal systems. Because these are new products, little regulatory guidance on the use of single-use disposal systems currently exists. To enable pharmacists to understand the place of these products in practice, we gathered information on each product's mechanism of action, method of use, product size, and retail pricing from each manufacturer's web page and reviewed them in the latter half of this article.

Current drug disposal options

FDA recommends 3 main strategies for the safe disposal of unused or expired medications: medication take-back events or kiosks, disposal in household trash, and flushing certain potentially dangerous medications down the toilet.⁷ Periodically scheduled medication take-back events are sanctioned by DEA and provide caregivers and patients the opportunity to safely dispose of all medications, including controlled substances and over-the-counter products.⁷ In addition to scheduled national take-back events, medications can be disposed at DEA-registered permanent collection sites located in various community pharmacies, hospitals, clinics, and law enforcement facilities, such as sheriff's departments, throughout the country. For patients and caregivers unable to participate in medication take-back events, FDA recommends that unused

medications should be mixed with unpalatable substances such as dirt, coffee grounds, and/or cat litter, sealed in a plastic bag, and disposed of in the household trash.⁷ Finally, when medication take-back options are not available, FDA recommends flushing potentially harmful medications (e.g., opioids, benzodiazepines, barbiturates, and stimulants) down the toilet as a safe alternative to prevent accidental exposure.^{3,8}

Similar to recommendations by FDA, EPA also endorses medication take-back events and household medication disposal as safe disposal options.⁹ According to EPA, medication take-back events are the preferred disposal option, with disposal guidelines encouraging patients to call their local waste management providers to learn more about the availability of local hazardous waste and drug take-back events.⁹ EPA prefers a medication take-back event, when available, because it is a more environmentally conscious method of safe disposal. However, EPA diverges from FDA recommendations and does not recommend flushing medications down the toilet as a disposal option. Flushing medications down the toilet or in drains increases chemical exposure to the aquatic system, such as lakes, streams, and rivers, and increases the risk of drinking water contamination.^{10–12} Conflicting advice from regulatory agencies along with the scarcity of DEA-sanctioned drug take-back events and kiosks makes the need for other disposal options evident.

Health care providers play a pivotal role in encouraging appropriate medication disposal and can be instrumental in educating patients about the availability of various medication disposal products. To address concerns associated with current medication disposal practices, several safe medication disposal products suitable for home use have been developed. Most of these agents provide the convenience of home use and neutralize medications before disposal, thereby preventing potential abuse of disposed materials.

*New products for home disposal of medication**Mechanisms of action*

Two broad categories of single-use disposal systems exist: deactivation and incineration. Deactivation products use a chemical process to denature medications added to the system, rendering them inert. Products such as Deterra,¹³ Drug Buster,¹⁴ and Rx Destroyer¹⁵ use activated carbon to deactivate chemical compounds present in medications through absorption into carbon particles.¹⁶ Similarly, Pill Catcher contains bentonite clay, which absorbs chemical compounds in a similar manner as activated carbon.¹⁷ DisposeRx¹⁸ and Element MDS¹⁹ use unnamed cross-linking polymers and organic plant-based powder, respectively, to sequester the combination of medications and active ingredients into a viscous gel. The active ingredient in Pill Terminator,²⁰ calcium hypochlorite, is a strong oxidizing agent that releases chloride gas upon reaction with other substances, thereby creating an unpleasant, deterrent odor to prevent abuse of disposed medications.²⁰ Finally, Takeaway Medication Recovery System uses a mail-back approach for medication incineration.²¹

Directions for use

Although there are some differences in how these products work, all are designed to be easily used by patients in the home setting. Deterra, Pill Catcher, and Pill Terminator are sold as

Table 1
Single-use disposal systems

Product name	Manufacturer	Active ingredient	Mechanism of action	Directions for use	Preparations/capacity/pricing information (June 2019)	Product availability for purchase
Deterra	Verde Technologies, 12701 Whitewater Dr., Suite 280, Minnetonka, MN 55343	Activated carbon	Deactivation; deactivates and renders medication inert	1. Fill pouch with medications. 2. Fill halfway with tap water. 3. Wait for 30 s, then gently shake. 4. Dispose of sealed pouch in garbage or solid waste.	2-oz pouches • Holds 15 tablets, 60 mL, 2 patches • \$14.97/3-pack 6-oz pouches • Holds 45 tablets, 180 mL, 6 patches • \$17.97/3-pack 12-oz pouches • Holds 90 tablets, 360 mL, 12 patches • \$20.97/3-pack 60-oz pouches • Holds 450 tablets, 1.8 L, 60 patches 1.6-gal pouches • Holds 1400 tablets, 6 L, 185 patches 2.5-gal pouches • Holds 2000 tablets, 9.5 L, 265 patches Pricing from the manufacturer's website	www.deterasystem.com ; www.amazon.com
DisposeRx	DisposeRx Inc, 503 Carthage St., Suite 202, Sanford, NC 27330	Cross-linking polymer	Deactivation; sequesters into viscous polymer gel, rendering inert	1. Add warm tap water into medication vial until up to two thirds of vial is full. 2. Empty content of packet into vial, replace cap, and shake for 30 s. 3. Discard in garbage or solid waste.	30count of packets • \$33.40 100count of packets • \$127.04 600count of packets • \$646 2000count of packets • \$2200 Pricing from www.walmart.com	www.dispose.rx.com , www.walmart.com
Drug Buster	Medline, Three Lakes, Dr. Northfield, IL 60093	Activated carbon	Deactivation; deactivates and renders medication inert	1. Place unwanted drugs—tablets, liquids, narcotics, and transdermal patches into the bottle. 2. Invert and swish the bottle twice. 3. After 2 h or when full, discard in garbage or solid waste.	4-oz bottle • \$5.58/container • Destroys 50 tablets 16-oz bottle • Destroys 300 tablets • \$15.99/bottle 64-oz bottle • Destroys 1500 tablets • \$34.99/bottle Pricing from www.amazon.com	www.medline.com , www.amazon.com
Pill Catcher	The Pill Catcher, P.O. Box 700741, Plymouth, MI 48170	Bentonite clay and other unknown dry ingredients	Deactivation; absorbs and encapsulates medication, rendering inert	1. Add unwanted medications to the bottle. 2. Add tap water to the first line of the bottle. 3. Replace cap and shake for 40 s. 4. Dispose in garbage/solid waste.	Pint bottles • Holds 120 tablets/450 mL of liquid • \$4.95/bottle Quartz bottles • Holds 300 tablets/700 mL of liquid • \$6.95/bottle Gallon bottles • Holds 1500 tablets/2500 mL of liquid • \$22.60/bottle Pricing from the manufacturer's website	www.mcssl.com

(continued on next page)

Table 1 (continued)

Product name	Manufacturer	Active ingredient	Mechanism of action	Directions for use	Preparations/capacity/pricing information (June 2019)	Product availability for purchase
Pill Terminator	Combined Distributors Inc, 2360 Lakewood Rd., Suite 3-420, Toms River, NJ 08755	Fuller's earth, absorbent polymer, calcium hypochlorite	Deactivation; destroys medications by denaturing chemical composition	1. Place unwanted medications in container and add warm water. 2. Close with child resistant cap and shake for 5 s. 3. Dispose in garbage or solid waste and do not reopen.	300-mL bottle • Eliminates up to 300 medium-sized tablets • \$9.95/bottle Gallon size • Eliminates up to ~2000 tablets • \$24.95/bottle Pricing from www.amazon.com	www.pillterminator.com , www.amazon.com , www.walmart.com
Rx Destroyer	C2R Global Manufacturing Inc, 701 Blackhawk Dr. Suite A, Burlington, WI 53105	Activated carbon and proprietary agents	Deactivation; deactivates and renders medication inert	1. Load unwanted medications into bottle. 2. Tightly replace cap and gently shake to mix solution. 3. Discard contents into trash following disposal regulations as applicable.	4-oz bottle • Holds ~50 tablets 16-oz bottle • \$14.60 • Holds 8 oz of liquid/~300 tablets/patches 64-oz bottle • \$29.84 • Holds 32 oz of liquid/~1500 tablets/patches 1-gal container • Holds 64 oz of liquid/~3000 tablets/patches 5-gal container • Holds ~500 oz of liquid/~15,000 tablets/patches 30-gal drum • Holds ~90,000 tablets Pricing from www.amazon.com	www.rxdestroyer.com , www.amazon.com , www.walmart.com
Element MDS	V23 LLC, 300 North Kanawha St., Suite 201 Beckley, WV 25801	Organic plant-based powder	Deactivation; sequesters medication into viscous gel, rendering inert	1. Add unwanted medication into pouch or bottle. 2. Add water until it is just above medications and shake vigorously. 3. Reseal pouch or close bottle with cap and dispose in trash.	4-oz packs • Holds 250 tablets/5 oz of liquid • \$10/3–4-oz packs 17-oz bottles • Holds 750 tablets/17 oz of liquid • \$279.99/50 17-oz bottles Pricing from the manufacturer's website	www.elementmds.com , www.amazon.com
Takeaway Medication Recovery System	Sharps Compliance, Inc, 9220 Kirby Dr. Suite 500, Houston, TX 77054	n/a	Incineration; medication is mailed back and incinerated	1. Insert medications per included instructions. 2. Seal and return via mail for proper disposal. 3. Do not include more than 4 oz of liquid per mailing.	Envelopes (prepaid postage) • \$84/12 envelopes • \$150/25 envelopes • \$300/50 envelopes • \$1375/250 envelopes 1-gal box • \$61/box 2-gal box • \$81/box 3-gal box • \$70/box 10-gal box • \$104/box 40-gal box • \$190/box Pricing from the manufacturer's website	www.sharpsinc.com , www.amazon.com , www.CVS.com

Abbreviation used: n/a, not applicable.

self-contained delivery systems. To use these products, the patient has to add the medication they wish to dispose directly into the pouch or bottle containing the powdered form of the disposal product, add water, and shake it vigorously to mix and deactivate the contents. The whole container is then disposed of in the regular household waste.^{12,15,16} Also, Drug Buster and Rx Destroyer are available in liquid form and do not require additional water. Medication is added directly into the container, and when the container is full, it may be shaken to ensure that all the medication is deactivated and disposed into household waste.^{14,17} In contrast, to use the Sharp's Takeaway Medication Recovery System, patients can purchase prepaid postage envelopes or boxes online, fill with medications (in their original containers), seal, and return for mail at local U.S. Postal Service locations.¹⁹ The medication is then incinerated by the manufacturer of the disposal system. Detailed directions of use for each product can be found in [Table 1](#).

Efficacy of single-use disposal systems

Although these products have not been evaluated by DEA or EPA, many have demonstrated almost complete deactivation capacity. Several products including DisposeRx and Rx Destroyer claim to meet or exceed DEA's "nonretrievable" standard for destruction of controlled substances. Non-retrievable, for the purpose of destruction, is defined as the "condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes."²² However, limited efficacy data are available for these products. Data are available with Deterra that show an average adsorption rate of 98.7% within 8 hours and more than 99.9% deactivated drug at the end of a 28-day study.²³ Toxicity characteristic leaching procedure analyses conducted with Pill Catcher to simulate leaching through a landfill showed undetectable traces of organic chemicals when tested on more than 20 organic chemicals.¹⁷ High-pressure liquid chromatography conducted with the Pill Terminator showed a 45% release of morphine after 2 hours of extraction with water; however, the extraction rate declined to 2% after 30 minutes of shaking.¹⁴ C2R Global Manufacturing Inc, manufacturer of Rx Destroyer, provided independent testing results on its website.¹⁹ According to these results, when tested on 5 g of methamphetamine, 65% of methamphetamine was adsorbed in 2 hours, 86% in 24 hours, 94% in 4 days, and 100% by day 7.¹⁵ Other chemical products such as DisposeRx, Drug Buster, and Element MDS lack readily available efficacy data. None of these products are approved by DEA or EPA or currently endorsed by any professional organization, including the American Pharmacists Association. There is a clear need for further studies assessing the comparative effectiveness of these drug disposal products and patient factors associated with their use.

Cost considerations

Unlike disposing medication in a kiosk, single-use disposal systems are consumable goods and, thus, must be purchased by either the patient or the provider because most insurance plans do not currently cover medication disposal. Prices generally range between \$5 and \$35 for smaller-sized items

and \$25–\$190 for larger, gallon plus–sized items. Smaller, 2-oz packages are large enough to dispose of 60 tablets or 60 mL of liquid and are best for individual home use. Gallon sizes hold 3000 tablets or 5 L of liquid and are suitable for use in health care facilities or nursing homes.

Items are typically available for purchase on the manufacturers' websites, through online retailers, and at local pharmacies. Costs associated with these products may pose a barrier to access for low-income individuals, and more work is needed to understand the association between cost and access to safe home disposal systems. Community pharmacies have partnered with companies that offer these disposal options to provide them at reduced or no cost to patients receiving prescriptions for controlled substances; however, it is yet to be seen if removing out-of-pocket costs is associated with increased use.²⁴ Insurance companies do not generally offer coverage for these medications; however, the prescription benefit manager for the Department of Veterans Affairs recently announced the availability of Sharps Takeaway envelopes at selected Veterans Affairs Hospital facilities.²⁵ This early commitment from a federal payer may provide the impetus needed for expanded private sector coverage.

Environmental considerations

The long-term environmental effects of drug disposal systems remain unstudied. In 2012, EPA published a memorandum recommending that medications collected by take-back events, mail-back, and other collection programs should be incinerated to minimize the potential for environmental contamination and diversion.²⁶ Unlike sewage and trash disposal, by-products of pharmaceutical incineration consist mainly of carbon dioxide and water and therefore, pose minimal environmental risk.^{26,27} Although most of these household disposal products claim to be safe for landfills, long-term data assessing leaching potential and effect on landfill are lacking. An exception is the Takeaway Medication Recovery System, which employs incineration for the disposal of mail-back medications.²⁵

Summary

The major distinguishing factors between the single-use disposal systems are mechanisms of action (deactivation vs. incineration), product sizes, and cost. Products that work via deactivation (all except Takeaway Medication Recovery System) pose an advantage of in-home use and disposal, thereby bypassing the need to transport medications to local U.S. Postal Service locations for eventual incineration. Smaller product sizes are more portable and are advantageous for patients with limited quantity of medications versus larger products, which are more appropriate for use in medical facilities. Costs vary by product; however, deactivation products are generally cheaper than incineration. Despite the higher costs, incineration minimizes the potential for leaching into landfills and groundwater. Reduced environmental impact may offset some of the external costs associated with deactivation. Therefore, there is a need for stringent economic analysis aimed at identifying the most cost-effective disposal option.

Pharmacists are in a unique position to counsel patients on medication disposal, however, current evidence suggests that fewer than 30% of patients receive counseling from pharmacists on medication disposal.^{6,26} As pharmacies are widely accessible, stocking and promoting the availability of medication disposal products may increase consumer awareness of proper disposal practices and provide a public health benefit. In 2018, Walmart Pharmacy announced that they would begin including DisposeRx systems with each opioid prescription dispensed.²⁴ Although this program undoubtedly encourages disposal, no data are captured on how patients are using the disposal pouches, and it is unclear how regularly and thoroughly pharmacists are educating their patients on disposal. If these systems are not being used by patients because of inadequate education, then mass distribution may serve as a major source of medical waste. The need for health services research on the effective implementation of medication disposal programs is evident. In an example from Texas, single-use disposal pouches (both deactivation and incineration) have been distributed through partnerships with community substance abuse prevention organizations as part of the Texas Targeted Opioid Response.²⁸ Although the project is ongoing, the results are expected to help provide a framework for future disposal interventions.

Training pharmacists and other providers on appropriate disposal is necessary to bridge the gap between distribution of single-use disposal systems and realized use of the same. Recent legislation in many states mandates that prescribers and pharmacists receive training on safe controlled substance use, and FDA recommends that content on medication disposal be included in programs designed to meet the requirements of their opioid use risk evaluation and mitigation strategy (REMS).²⁹ Historically, however, regulatory agencies, including FDA, have taken a laissez-faire approach in the development of qualifying programs. FDA does not mandate that prescribers and dispensers of opioids participate in REMS training, and state boards of pharmacy vary widely in what qualifies as continuing education on controlled substance prescribing.²⁹ Without regulatory action, providers will continue to ignore the importance of medication storage and disposal when counseling patients perpetuating the cycle of improper storage and harm.

Conclusion

Home medication disposal products are convenient, efficient, and safe options intended to help reduce harm related to the improper storage of unused medications in the home setting. Although these medications vary in mechanism of action and cost, they all offer consumers the ability to dispose of medication safely at home without the potential environmental impacts associated with flushing medication down the toilet or disposal in the household waste. Because these products are new, their use is currently limited by a lack of evidence regarding their cost-effectiveness, efficacy, and ease of use. Implementation and dissemination research on the use of single-use disposal systems is needed to improve consumer accessibility and use of these products in the outpatient setting. Over time, these products may help pharmacists

answer that constant patient question: “What do I do with these tablets?”

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Understanding factors that contribute to the disposal of unused opioid medication

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Purpose: Drivers of excess controlled substance disposal behaviors are not well understood. A survey of patients who had received opioid-based medications was conducted to inform the design of future innovative drug take-back programs.

Methods: This was a cross-sectional survey study conducted in 152 participants who received treatment with an opioid within the previous 2 years and had possession of unused medication following either switching to a different opioid or discontinuation of pain.

Results: Approximately one-third of patients had disposed of their unused opioid medication. Education about the importance of and appropriate methods for drug disposal was associated with a significantly increased likelihood of patients disposing of unused medication, and it was observed that patients prescribed an immediate-release/short-acting opioid were twice as likely to keep their medication compared to those prescribed an extended-release/long-acting opioid. The most commonly reported methods for disposal were via drug return kiosks and flushing the medication down the toilet. Some of the most impactful drivers of unused opioid disposal were routine practice of disposing of all unused drugs and instruction from a health care provider, and the most common driver of keeping unused medication was the desire to have it on-hand should there be a need to treat pain in the future. Over 80 % of patients indicated that they would be more likely to use a drug take-back service if they were offered compensation or if the kiosk was in a location that they visited frequently, and approximately half of the patients indicated that they would be willing to request an initial partial fill of an opioid prescription to reduce the volume of unused medication.

Conclusion: There is a clear need to increase patient awareness about the importance and methods of proper medication disposal, and a great opportunity for health care providers to increase patient education efforts. These study findings also highlight key areas for improvement in drug take-back programs that may promote and incentivize more patients to utilize the services.

Keywords: pain management, patient education, drug diversion, medication safety, drug take back

Introduction

Despite the national- and state-level implementation of many regulatory processes focused on reducing drug trafficking, inappropriate prescribing practices, and indiscriminate dispensing, the constant rise in the number of opioid-related deaths highlights a need to look into other factors contributing to this epidemic. Drug diversion occurring at the patient level subsequent to appropriate prescribing and dispensing is of significant concern. The 2016 National Survey on Drug Use and Health indicates that in the US ~3.3 million people 12 years or older are current misusers of prescription

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pain relievers, with ~53% of these individuals obtaining the pain medication from friends or family with or without their knowledge.¹

According to the National Community Pharmacists Association, up to 40% of prescription medications are not completely used and are likely to remain inside the home where the storage of these medication doses may not be secure posing a risk for unintentional poisoning events or diversion.² Given these statistics, proper disposal of unused prescription opioid medications is imperative in minimizing the incidence of opioid misuse and reducing the risks for accidental poisoning.³

Since 2010, the Drug Enforcement Administration has supported disposal efforts and has collected more than 9 million pounds of potentially dangerous unused, unwanted, or expired prescription drugs at biannual National Prescription Drug Take-Back Days. Although a significant amount of medicine has been collected at these events, there is a lack of data that specifically captures the motivations of controlled substance disposal behaviors.^{4,5} A survey was conducted to better understand drivers of disposal behavior and to inform the design of future disposal and take-back programs.

Methods

A cross-sectional survey study was conducted from September 2016 to October 2016 to assess the behaviors and drivers of the disposing of unused opioid medication. An invitation to participate in the survey was disseminated via e-mail to patients belonging to an independent research group. This study met the criteria for exemption from full IRB review as it posed minimal risk of harm to patients and no identifying information was collected.

Eligibility for inclusion in this study was determined by participant responses to a brief questionnaire that was completed prior to beginning the survey. Patients were included if they had a history of acute or chronic pain, had been treated with prescription opioid medication within the preceding 2 years, and had unused (leftover) opioid medication. Demographic data and participant characteristics collected included type of pain, opioid(s) prescribed, quantity originally prescribed, and quantity remaining. Survey questions addressed history of disposing of unused opioid medication, motivations for disposing of or keeping unused medication, beliefs about incentives used to promote safe opioid disposal, and barriers to utilizing medication take-back programs. Data analysis was performed using only completed survey responses and results are presented as descriptive statistics. Categorical data are presented as counts and percentages. Subgroup analyses

were performed using Fisher's exact test with an alpha of 0.05, and relative risk was calculated.

Results

The survey response rate was 8.9% (n=1,111), and of the patients who met the inclusion criteria the survey completion rate was 85.9% (n=152) (Figure 1). Participant demographics and characteristics are summarized in Table 1. The majority of patients included in this study were female and aged 35–64 years. The most common types of pain for which opioids were prescribed were back/neck pain and arthritis, and the most commonly prescribed opioids were hydrocodone/acetaminophen and oxycodone/acetaminophen. Greater than 50% of patients were prescribed only an immediate-release or short-acting (IR/SA) opioid.

Education about opioid medication disposal

Forty percent (n=60) of patients reported that they received information about the importance of properly disposing of unused opioid medication, and of these 50% (n=30) reported that they received the information from a pharmacist and 33.3% (n=20) reported that they received the information from a prescriber or someone affiliated with the prescriber. Similarly, 36.2% of patients reported that they received information about appropriate methods for disposing of unused medication, and of these 45.5% (n=25) received the information from a pharmacist and 45.5% (n=25) received the information from their prescriber or someone affiliated with their prescriber. This information was communicated to patients most frequently in the setting of an in-person conversation (47%) or provided in the form of printed material containing all of the necessary information (34.7%).

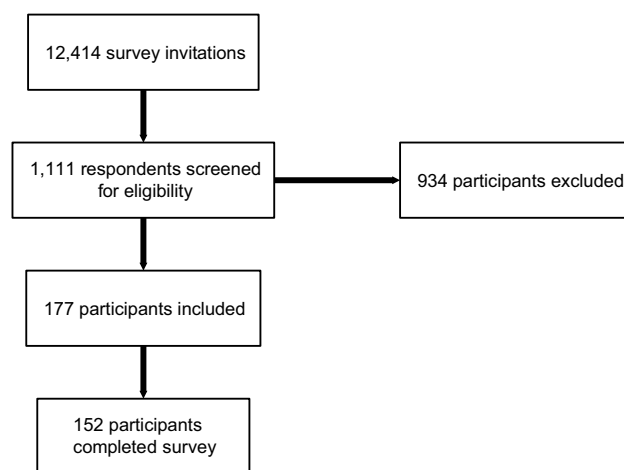


Figure 1 Participant flow diagram.

Table 1 Demographics and characteristics of patients

Characteristics	No. of patients (%)
Gender	
Male	48 (31.6)
Female	102 (67.1)
Unspecified	2 (1.3)
Age (years)	
18–34	6 (3.9)
35–64	115 (75.7)
65 +	31 (20.4)
Type of pain	
Acute	14 (9.2)
Chronic	52 (34.2)
Both acute and chronic	86 (56.6)
Type of chronic pain (N=138)	
Arthritis	80 (58.0)
Back/neck pain	92 (66.7)
Fibromyalgia	27 (19.6)
Gastrointestinal	35 (25.4)
Neuropathy	32 (23.2)
Headache	44 (31.9)
Other	26 (18.8)
Prescriber	
Primary care practitioner	60 (39.5)
Pain specialist	35 (23.0)
Physician assistant (PA)	1 (0.7)
Dentist	8 (5.3)
Other	48 (31.6)
Opioid prescribed	
Codeine	18 (11.8)
Fentanyl	6 (3.9)
Hydrocodone	19 (12.5)
Hydrocodone/acetaminophen	79 (52.0)
Hydromorphone	8 (5.3)
Meperidine	3 (2.0)
Methadone	3 (2.0)
Morphine	11 (7.2)
Oxycodone	27 (17.8)
Oxycodone/acetaminophen	47 (30.9)
Buprenorphine	3 (2.0)
Other	9 (5.9)
Unsure	5 (3.3)
Opioid dosage form prescribed	
Immediate-release or short-acting (IR/SA)	94 (61.8)
Extended-release or long-acting (ER/LA)	17 (11.2)
Both IR/SA and ER/LA	21 (13.8)
Unsure	20 (13.2)
Opioid day's supply prescribed	
<3 days	4 (2.6)
3–7 days	38 (25.0)
8–14 days	33 (21.7)
15–29 days	22 (14.5)
30 days or more	54 (35.5)
Unsure	1 (0.7)
Mean quantity prescribed (SD)	45.7 (±46.4)
Mean quantity unused (SD)	13.0 (±13.7)

Additional forms of communication included printed material with a link to a website to obtain more information (8.7%), a conversation over the phone (4.4%), and electronic communication (4.3%). Additionally, 12.5% (n=19) of patients reported that they received a reminder to dispose of unused opioid medication from a pharmacist, prescriber, or someone other than a health care provider.

Unused medication disposal behavior

Only 33% (n=50) of patients reported that they disposed of their unused opioid medication. Most patients kept the medication, and a few gave the medication to someone else or reported “other” when asked what they did with their unused opioid medication (Figure 2). The most frequently reported methods for disposal were via a drug disposal kiosk or other local take-back program (50%; n=25) and flushing the medication down the toilet (26%; n=13). Additional methods included disposing the medication in the trash (16%; n=8) and other unspecified methods (8%; n=4). Most patients (62%; n=31) reported disposing of their unused medication within less than 1 week to 1 month of discontinuing the opioid, 26% (n=13) of patients waited 1–3 months before disposal, 8% (n=4) waited up to 1 year before disposal, and 4% (n=2) kept the unused medication longer than 1 year before disposing it of.

The factors influencing patients' decisions to dispose of or keep unused opioid medication are summarized in Tables 2 and 3, respectively, and ranked according to weight of influence. The greatest influencing factor in the decision to

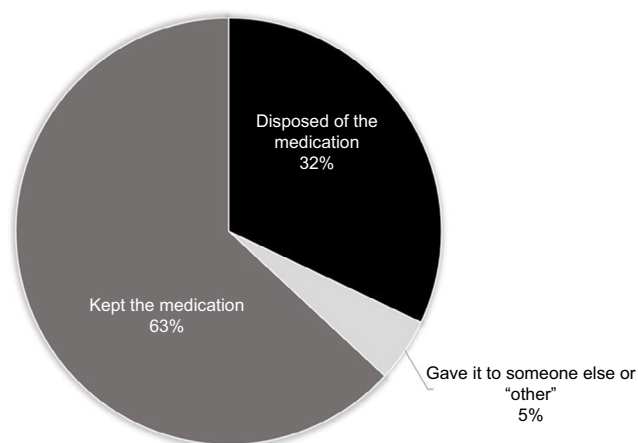
**Figure 2** Participant behavior regarding unused opioid medication.

Table 2 Motivations of unused opioid medication disposal

Rank	Influencing factors
1	I dispose of all unused prescription medication as a routine practice
2	I dispose of all opioids because I am particularly aware of the risk they pose
3	I dispose of my medications when they reach the expiration date
4	I was instructed by a health care practitioner whom I trust
5	I was concerned about someone taking and using them
6	I was concerned a child could accidentally find and ingest the opioids
7	Other
8	I was concerned I would feel pressured to give my unused opioids to someone
9	I was concerned I might be tempted to use the leftover opioids in the future
10	I received a reminder

dispose of unused opioid medication was a routine practice of disposing of “all” unused medication, and the least influential factor was receipt of a reminder. For patients that kept their unused opioid medication, the greatest influencing factor was a desire to have the medication on-hand should they need it in the future, and the least influential factor was a reported addiction to opioids.

In a subgroup analysis, it was observed that patients that received information about the importance of and methods for appropriate medication disposal reported a greater frequency of unused opioid medication disposal compared to those that did not receive any information. Additionally, a significantly greater proportion of patients that were prescribed only an extended-release or long-acting opioid (ER/LA) disposed of their unused medication compared to those who were prescribed only an IR/SA form (Table 4).

Table 3 Motivations of unused opioid medication retention

Rank	Influencing factor
1	A desire to have effective pain therapy immediately available should you require such pain therapy in the future for the same condition
2	A desire to have effective pain therapy immediately available should you require such pain therapy in the future for a different condition
3	A belief that the unused prescription opioids have a value and should not simply be thrown away even though you had no specific use in mind
4	A desire to have effective pain therapy immediately available should a friend or family member ever require such pain therapy in the future
5	Concern about the environmental impact of disposing of unused prescription opioids via the methods recommended to me (eg, flushing the tablets or throwing them out in the trash)
6	Other
7	Insufficient information or awareness of the disposal methods that were available to you
8	Inconvenience of disposing of unused prescription opioids via take-back programs or disposal kiosks, and insufficient motivation or time to dispose of the medication despite being aware that all unused opioids should be disposed of
9	A desire to recreationally use the unused prescription opioids to achieve psychoactive effects
10	The stigma associated with disposing of unused prescription opioids via take-back programs or disposal kiosks
11	An addiction to prescription opioids that made you desire them even after your pain was relieved

Table 4 Subgroup analysis of proportion of patients who disposed of unused opioid medication

Subgroups	No. of patients (%)	RR (95% CI)	P-value
Received information about the importance of proper opioid medication disposal (n=60)			
Yes	31 (51.7)	2.50 (1.56–4.00)	<0.0001
No	19 (20.7)		
Received information about appropriate methods for opioid medication disposal (n=55)			
Yes	31 (56.4)	2.88 (1.81–4.58)	<0.0001
No	19 (19.6)		
Opioid dosage form			
Immediate-release or short-acting (IR/SA) only (n=94)	24 (25.5)	^a 0.43 (0.26–0.73)	^a 0.01
Extended-release or long-acting (ER/LA) only (n=17)	10 (58.8)		
Both IR/SA and ER/LA (n=21)	9 (42.9)	^b 0.60 (0.33–1.09) ^c 1.37 (0.73–2.59)	^b 0.19 ^c 0.51

Notes: ^aIR/SA vs ER/LA; ^bIR/SA only vs both; ^cER/LA only vs both.

Incentives to promote safe medication disposal

A high percentage of patients (82.9%; n=126) reported that they would be more likely to use a medication disposal kiosk or mail-in program if a small incentive was offered (eg, US\$1–\$5 value). The preferred type of incentive was cash, and patients reported a desired value ranging from US\$1 to the original cost of the prescription. Additional forms of compensation that patients agreed would incentivize them to dispose of unused medication are summarized in Figure 3.

When asked about the likelihood of utilizing a drug take-back program, most patients reported that they would be “very likely” or “somewhat likely” to use a medication

disposal kiosk at a location that they frequented, less than 50% indicated that they would be likely to use a kiosk at a location they did not normally visit, and over half of the patients indicated that they would be likely to use a licensed mail-in program that provided a prepaid envelope (Figure 4).

Of those patients who indicated that they were unlikely to use a medication disposal kiosk at a location they already frequented (n=8), the most commonly reported barriers to using this method were that they did not plan to dispose of medications at all (n=4), concerns for privacy (n=1), and concerns that the opioid would “fall into the wrong hands” (n=3).

Of those patients who indicated that they were unlikely to use a mail-in program (n=24), the barriers to using this method were that they did not plan to dispose of medica-

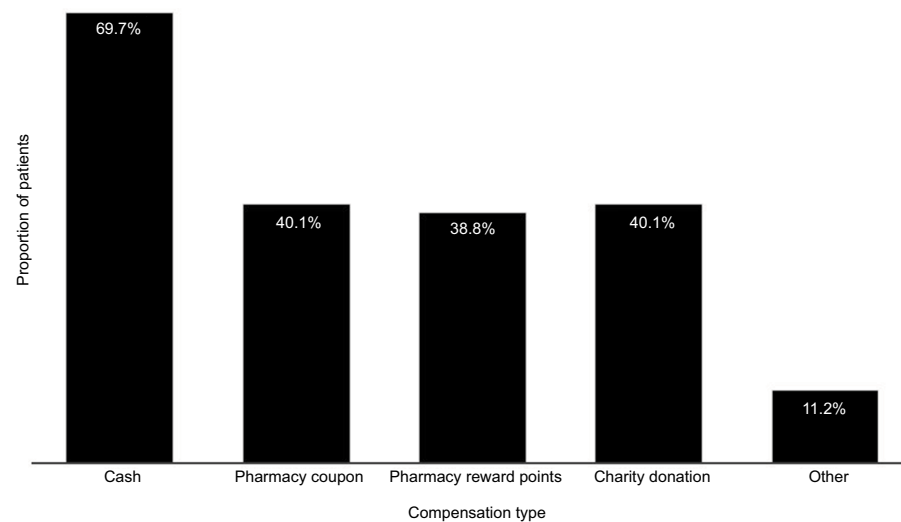


Figure 3 Proportion of patients who reported that compensation would lead them to dispose of unused opioid medication.

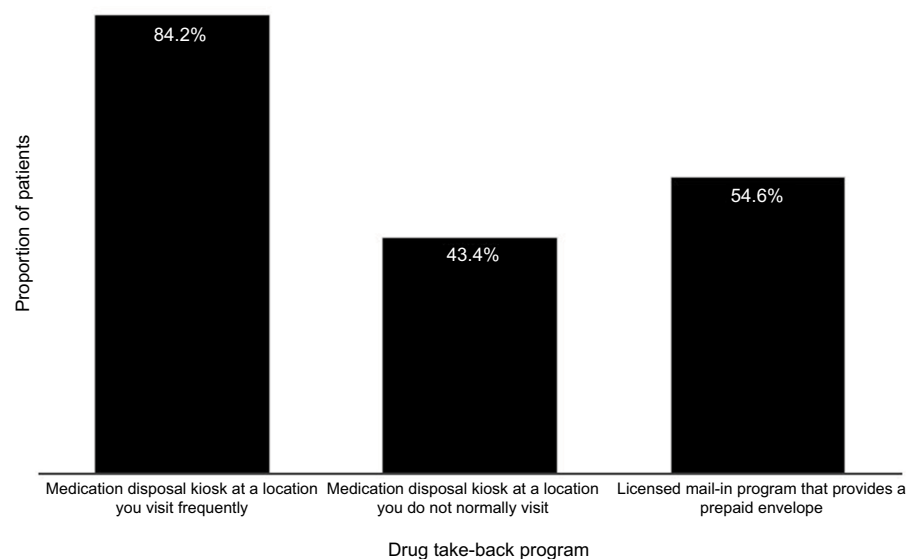


Figure 4 Proportion of patients “very likely” or “somewhat likely” to utilize a medication disposal kiosk or mail-in drug take-back program.

tions at all (n=6), concerns for privacy (n=3), concerns that the opioid would “fall into the wrong hands” (n=12), and convenience (n=3).

When asked about the likelihood of requesting a partial fill of an opioid prescription if given the option, about 51% (n=77) of the patients indicated that they would be “very likely” or “likely” to select this option (Figure 5). In those who indicated they would be unlikely to request a partial fill (n=51), the most significant barrier indicated was concern that they would not have the medication if needed (n=35), the inconvenience of returning to the pharmacy to fill the remaining quantity (n=30), belief that the prescriber wrote a prescription for the correct number of days (n=25), the desire to have leftover medication should it be needed in the future (n=24), and the desire to receive the full quantity of medication prescribed given that the co-pays would be the same for either a partial fill or for the full quantity (n=28).

Discussion

These study data offer insights into the motivations driving the decisions to dispose of or keep unused opioid medication. Roughly one-third of the patients in this study reported disposing of their medication, and a similar proportion indicated that they had received education on the importance of and appropriate methods for disposal. The most common forms of opioid disposal were via a drug disposal kiosk or other drug take-back program and flushing them down the toilet. A significantly greater proportion of patients who received

education about unused opioids reported disposing of them compared to those who received no information. Patients who were counseled about appropriate methods for disposal were approximately three times as likely to dispose of medication compared to those who received no counseling. Additionally, the majority of patients in this study reported having unused IR/SA opioids, and ~60% indicated they had received treatment for acute pain or acute and chronic pain. A disparity in the provision of patient education when prescribing for acute vs chronic pain and/or overprescribing of opioids for acute conditions may also contribute to the increased proportion of unused IR/SA opioids compared to ER/LA.

Other observational studies support these findings and demonstrate the importance and significant impact of patient, family, and caregiver education on unused opioid disposal behaviors.^{6–8} A wealth of literature exists regarding the prescribing patterns and opioid disposal education in post-surgical settings. These studies have demonstrated that most patients felt that they were prescribed too many opioids after surgery and up to 75% of these patients had unused medication after their pain dissipated,^{9,10} and have illustrated the staggeringly low rates of patient education on opioid disposal provided to this patient population.¹¹ Based on this evidence, there is a clear and critical need to increase patient education and awareness with regard to proper medication disposal.

Patients in this study who disposed of unused opioids were more likely to do so as part of a routine practice of disposing of all excess medication, an awareness of the risks posed by unused opioids, or with instruction from a trusted health care provider. Very few patients received a reminder to dispose of medication; however, it was observed that reminders were ranked as one of the least influential factors in deciding to dispose of unused opioids. Those who kept their unused medication indicated that the most influential factor in their decision was a desire to have an opioid readily available should they require for future pain management therapy; the least influential factors were for recreational use or opioid addiction, and the stigma associated with disposing of unused prescription opioids via take-back programs or disposal kiosks. Additionally, a correlation between opioid dosage form and disposal was observed. Patients who were prescribed only an IR/SA were twice as likely to keep their unused medication compared to those who were prescribed only an ER/LA opioid. As the majority of patients in this study reported suffering from both acute and chronic pain, these data may be reflective of a desire for patients with difficult to manage or unpredictable pain syndromes to have medication on-hand for acute self-management of symptoms.

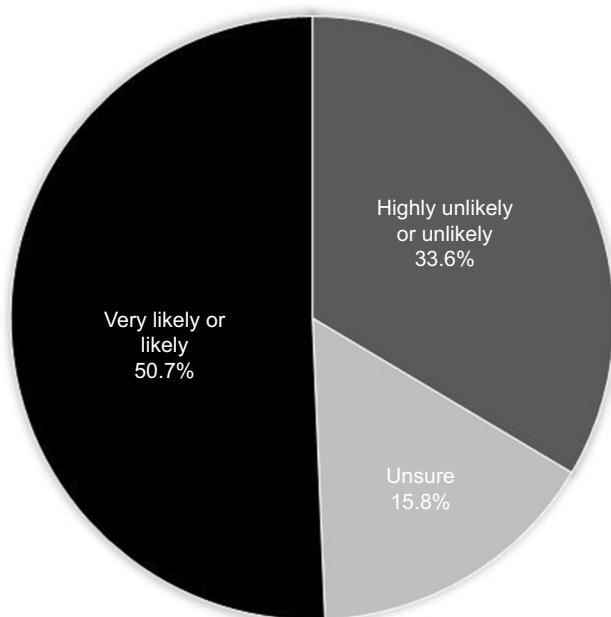


Figure 5 Likelihood of patients to request a partial fill if given the option.

This study also collected crucial data which address the utility of medication disposal kiosks and mail-in drug take-back programs, as well as common barriers to use of these methods. Over 80% of patients indicated that they would be more likely to use one of these disposal methods if a small incentive was offered, and the preferred incentive was monetary compensation at an amount ranging from US\$1 to the cost of the original prescription. Additional accepted forms of compensation included coupons, pharmacy rewards points, and even charitable donations. As the purpose of this study was to determine what motivates patients to engage in safe medication disposal practices, this hypothetical scenario was included as a survey question. On a national or global scale, it may not be economically feasible to provide compensation (cash or other benefit) for the return of unused opioids. However, these data may serve as support for the development of smaller-scale pilot programs at point-of-care entities (eg, pharmacy or health care system) to evaluate the utility of patient compensation as a motivator.

It was also noted that nearly 85% of patients would be likely to use a drug disposal kiosk if it was placed in a location that they visited frequently. Addressing both of these concerns may be an effective means of incentivizing patients to utilize these programs. National drug take-back events have been successful in recovering a large volume of unused noncontrolled substances as they are a highly advertised, convenient way for patients to return unused medication. However, controlled substances account for less than 10% of the total quantity of medications collected, and it remains unclear what proportion of all unused opioids are represented by these data.^{12,13} Other drug disposal programs such as kiosks or mail-in services have much less available data. Further research should evaluate the implementation of compensation (monetary or other benefits) and/or the increased advertising of conveniently located programs for the safe disposal of unused opioid medication.

Finally, this study assessed the likelihood of patients to request a partial fill of opioids as a way to reduce the quantity of unused medication they are left with. Patients were presented with a hypothetical scenario in which they could opt to initially fill a 7-day supply (original prescription for 30-day supply) and request to fill the remainder of the prescription if additional medication was needed. About 50% of patients indicated that they would be likely to request a partial fill initially if given the option. Since this survey was conducted, the US Controlled Substances Act was amended to allow the partial filling of schedule II controlled substances

(CII), if requested by the patient or provider, and not prohibited by state law.¹⁴ Several states have since followed suit and amended legislation to allow patients and prescribers to request a partial fill of CII prescriptions. Efforts should be made to increase patient and prescriber awareness of this option in eligible states. Additional research and trend analysis would provide valuable metrics for the evaluation of effective patient motivation factors surrounding opioid waste reduction, ultimately reducing the risk of prescription drug abuse and diversion.

This survey included a convenience sample of 152 patients from an established patient repository. Patients self-selected to participate in the survey research group panel, and the response rate in this study was low, which introduces the potential for nonresponse bias. Additionally, selection bias is inherent in this study due to the use of a research panel, and the limited demographic data collected could further increase the potential for bias. It cannot be assumed that the respondents are representative of all patients who have unused opioid medication. Finally, the validity of these data relies on the accuracy of self-report, and the nature of the survey questions may have produced a social desirability bias where patients who did not dispose of their medication may have felt pressure to indicate that they did so (making the observed 33% disposal rate too high).

Conclusion

These results demonstrate the importance and positive impact of patient education on medication disposal behaviors and highlight the need to address patients' concerns regarding what to do with unused opioid medication and the barriers to accessing drug disposal kiosks or take-back programs. The most common motivation for keeping unused opioids, and the primary concern with requesting a partial fill, was the desire to have it on-hand should it be needed for pain relief in the future. These study data reveal the need for health care providers to educate every patient on the importance of and the appropriate methods for the disposal of unused opioid medications, and to engage the patient in the development of an individualized pain management care plan to ensure safe and effective treatment outcomes.

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Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults

The prescription opioid epidemic continues with few signs of abatement.¹ Most adolescents and adults reporting recent non-medical use of opioid medications obtain these medications through their family or friends.² Minimal research has examined knowledge and practices related to opioid medication sharing, storage, and disposal among US adults who recently received prescriptions for these medications despite this group serving as a source for individuals using opioid medications for nonmedical purposes. We conducted a national survey among US adults with recent opioid medication use to examine the pervasiveness of sharing opioid medications, medication storage and disposal practices, and the sources of information received.

Methods | We sampled survey participants from a source³ that uses probability- and address-based sampling to construct a nationally representative panel. We sampled randomly from the general pool of adult panelists and oversampled adults with at least 1 child living in the household. Data were deidentified. A screening question restricted the sample to adults with opioid medication use during the past year. This study was reviewed and approved by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board. The study was conducted from February 24 to March 16, 2015.

Among the 4836 sampled panelists, 3281 (67.8%) completed the screening question. Among the 1055 individuals determined to be eligible based on their past-year use of opioid medications, 1032 (97.8%) completed the survey. Respondents answered questions about their practices and beliefs related to sharing, storing, and disposal of opioid medications as well as sources of information received on these topics. Statistical analyses incorporated survey weights to account for sampling design and nonresponse.

Results | A total of 20.7% (weighted percentage) reported ever having shared opioid medications with another person (Table 1). Among this group, the primary reason for sharing medication was to help the other person manage pain (73.0%). Few respondents reported being likely to let a relative (13.7%) or close friend (7.7%) use their opioid medication in the future. Some respondents reported storing their opioid medication in a locked (8.6%) or locked or latched (20.9%) location.

At the time of the survey, 440 respondents (46.7%) were still using opioid medications. More than half of the respondents had or expected to have leftover medication. Among those with leftover opioid medications, 61.3% reported keeping them for future use.

Nearly half of the adults with recent opioid medication use did not recall receiving information on safe storage (48.7%) or proper disposal (45.3%) (Table 2). Among the 505 participants who reported receiving information on safe storage practices, primary sources of information included medication packaging (46.7%), the pharmacist (44.1%), and the physician or nurse (32.3%). Among the 548 respondents who reported receiving information on proper disposal, sources included the pharmacist (34.7%), print or television news (31.3%), and medication packaging (29.6%).

Discussion | Findings suggest that current practices related to sharing, storing, and disposing of opioid medications, as well as communication of information on these topics, are suboptimal. Altering prescribing practices to reduce the quantity of opioid medications that patients receive may limit the opportunities for nonmedical use of the drugs. Evaluating the effects of the Centers for Disease Control and Prevention's recently released guidelines for prescribing opioid medications for chronic pain⁴ and the US Food and Drug Administration's opioid medication labeling changes⁵ are important areas for research.

A limitation of this study was use of self-reported data, which may be subject to social desirability bias although

Table 1. Opioid Medication Sharing, Storage, and Disposal Practices

Characteristic	Weighted Percentage (SE)		
	All Respondents (N = 1032) ^a	No Longer Using Opioid Medication (n = 592)	Using Opioid Medication (n = 440)
Sharing opioid medication			
Ever shared	20.7 (1.6)	20.8 (2.1)	20.6 (2.5)
Shared most recently prescribed opioid medication	6.5 (1.0)	5.1 (1.2)	8.1 (1.7)
Likely to let family member use opioid medication in the future ^b	13.7 (1.4)	15.7 (1.9)	11.4 (1.9)
Likely to let close friend use opioid medication in the future ^b	7.7 (1.1)	9.4 (1.6)	5.9 (1.3)
Primary reason to share (n = 221)			
Help the other person treat pain	73.0 (4.0)	78.8 (4.6)	66.4 (6.5)
Recipient could not afford opioid medication/did not have insurance	17.4 (3.4)	17.0 (4.4)	17.8 (5.3)
Other (eg, recreational use)	9.6 (2.7)	4.2 (1.9)	15.8 (5.3) ^c
Storage of opioid medication			
Most often kept in location that locks	8.6 (1.1)	5.9 (1.3)	11.5 (2.0) ^c
Most often kept in location that locks or latches	20.9 (1.6)	17.4 (1.9)	24.8 (2.7) ^c
Respondents who had/expect to have leftover opioid medication ^d	57.2 (2.0) [n = 570]	60.6 (2.6) [n = 339]	53.3 (3.0) [n = 231]
Disposal of opioid medication ^d			
Keep for future use	48.8 (2.7)	61.3 (3.4)	32.4 (3.8) ^c
Flush down the toilet	13.8 (1.9)	9.1 (1.9)	19.9 (3.5) ^c
Throw out in the trash	7.1 (1.3)	7.4 (1.7)	6.6 (1.8)
Throw out in the trash after mixing to prevent further use ^e	6.4 (1.3)	6.7 (1.8)	6.1 (1.9)
Turn in to pharmacist or "take-back" program	12.1 (1.8)	6.6 (1.7)	19.2 (3.4) ^c
Sell	1.0 (0.7)	1.0 (1.0)	1.1 (0.9)
Other, do not know, or do not remember	10.8 (1.7)	7.9 (2.0)	14.7 (3.1)

Abbreviation: ND, not determined.

^a Numbers for the subgroups total 1032 because they include the 7 respondents who skipped the disposal methods questions but answered other questions about sharing opioid medications and storage of opioid medications.

^b Proportion of respondents reporting a value of 5 to 7 on a 7-point scale assessing the likelihood of sharing medication (from extremely unlikely [1] to extremely likely [7]).

^c $P < .05$ in χ^2 tests of differences in proportions among respondents using and no longer using opioid medications. Estimates were adjusted with survey weights that account for sampling design, including the oversampling of households with children 17 years or younger.

^d Respondents still using opioid medications reported on whether they expected to have leftover opioid medications and their anticipated method of disposing this leftover medication. Respondents no longer using opioid medications reported on their disposal methods.

^e Mixing with, for example, coffee grounds.

the web-based panel survey mode reduces this concern. Although respondents were sampled from a nationally representative panel, there is no census of adults with past-year opioid medication use; therefore, we cannot verify that this study sample is representative of US adults with recent opioid medication use.

More research is needed to identify effective strategies to advance safer practices related to opioid medication sharing, storage, and disposal.⁶ In the meantime, reducing the prescribing of large quantities of opioid medications and disseminating clear recommendations on safe storage and disposal of opioid medications widely to the public and prescribers may reduce risks.

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Table 2. Sources and Content of Information on Safe Storage and Proper Disposal of Opioid Medications

Receipt of Information	Weighted %, (SE) [No.] ^a
Safe Storage	
Received no information	48.7 (2.0) [523]
Received information	51.3 (2.0) [505]
Source of information	
Included with medication	46.7 (2.8)
Pharmacist	44.1 (2.8)
Physician or nurse	32.3 (2.7)
Print or television news	18.2 (2.2)
Family or friends	14.0 (2.0)
Online	12.0 (1.8)
Social media	6.7 (1.4)
Entertainment media ^b	4.6 (1.1)
Instructions received	
Store out of reach of children	86.7 (1.9)
Store in a cool, dry place	72.9 (2.6)
Store in a locked cabinet, closet, or drawer	40.2 (2.8)
Proper Disposal	
Received no information	45.3 (2.0) [480]
Received information	54.7 (2.0) [548]
Source of information	
Included with medication	29.6 (2.5)
Pharmacist	34.7 (2.6)
Physician or nurse	23.7 (2.4)
Print or television news	31.3 (2.5)
Family or friends	9.9 (1.6)
Online	16.2 (1.9)
Social media	7.3 (1.4)
Entertainment media	6.2 (1.2)
Instructions received	
Turn in to a pharmacist or "take back" program	69.3 (2.6)
Throw out in the trash after mixing to prevent further use ^c	24.3 (2.4)
Flush them down the toilet	19.7 (2.1)
Throw them out in the trash	7.3 (1.4)

^a A total of 1028 respondents completed this section of the questionnaire. Proportions do not total 100 because respondents could indicate more than 1 option. Estimates were adjusted with survey weights that account for sampling design, including the oversampling of households with children 17 years or younger.

^b Respondents were not asked to specify the type of entertainment media.

^c Mixing with, for example, coffee grounds.

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A National Study of the Prevalence of Life-Threatening Diagnoses in Patients With Chest Pain

Nontraumatic chest pain is the second most frequent cause of emergency department (ED) visits among adults, resulting in more than 8 million visits annually in the United States.¹ Although the predictive value of many signs, symptoms, and diagnostic tests have been defined for life-threatening diagnoses, to our knowledge, the frequency of these diagnoses has not been determined in a nationally representative sample. The pretest probability of a given condition is critical to drive Bayesian analysis and help determine posttest probability when known predictive values of findings from the history, physical examination, and any laboratory, electrocardiographic, or radiologic testing are applied.

Methods | We analyzed the National Hospital Ambulatory Medical Care Survey database, a national probability sample of visits to nonfederal, general, acute care hospitals in the United States conducted by the National Center for Health Statistics.² We included all ED visits from January 1, 2005, to December 31, 2011, for adults 18 years and older with the chief concern of nontraumatic chest pain. Data analysis was conducted from September 22, 2014, to September 30, 2015. We calculated the overall frequency of each diagnosis as a percentage of all included visits and for age-based subgroups. We identified 6 life-threatening conditions that are traditionally taught to be considered in patients who present with chest pain: acute coronary syndrome, aortic dissection, pulmonary embolism, tension pneumothorax, esophageal rupture, and perforated peptic ulcer.^{3,4} The University of California, San Francisco, Institutional Review Board waived review of this study. Patient data from the National Hospital Ambulatory Medical Care Survey database were deidentified.

Results | We analyzed 10 907 patient records, representing 42 579 676 patient visits to the ED with a primary symptom of chest pain; these visits represented 4.7% of all sampled ED visits. **Table 1** provides descriptive characteristics and weighted percentages of these visits. Most patients were aged 18 to 64 years (8215 [75.6%]), female (5685 [52.7%]), non-Hispanic white (6904 [64.5%]), and treated in an urban area (9519 [84.4%]). Private insurance, Medicare, and Medicaid rates were 45.1% (n = 4914), 13.6% (n = 1443), and 18.8% (n = 2132), respectively. In terms of visit disposition,



ORIGINAL ARTICLE

From dispensed to disposed: evaluating the effectiveness of disposal programs through a comparison with prescription drug monitoring program data

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ABSTRACT

Background: Organized disposal of controlled medications, such as take-back events and permanent drug donation boxes, is a prevention strategy that has been widely used to reduce the availability of controlled medications for diversion or abuse. However, little is known as to whether this strategy actually reduces the overall availability of these medications for the purposes of diversion or abuse. **Objectives:** The objective of this study was to compare the number and types of controlled medications that were disposed through organized efforts to the number dispensed in local communities. **Methods:** The quantity and type of controlled medication collected from three take-back events and permanent drug donation boxes over 4-week-long periods in five counties in south-central Kentucky was measured and compared to the number of controlled medications dispensed, as reported by Kentucky All Schedule Prescription Electronic Reporting system. **Results:** In 2013, 21,121,658 controlled medications units were dispensed in the participating counties. Of those, 46.9% were opioid analgesics, 13.1% tranquilizers, and 37.3% “other.” During the assessment periods, a total of 21,503 controlled medication units were collected. Of those, 39.9% were opioid analgesics, 2.7% tranquilizers, and 57.4% “other.” Annually, controlled medications disposed were estimated to account for 0.3% of those dispensed. **Conclusion:** Controlled medications collected by take-back events and permanent drug donation boxes constituted a miniscule proportion of the numbers dispensed. Our findings suggest that organized drug disposal efforts may have a minimal impact on reducing the availability of unused controlled medications at a community level.

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Introduction

Nonmedical use of controlled (Schedule II–V) medications continues to be a serious public health problem in the United States. Nonmedical use of controlled medications is the second most common form of substance abuse, following marijuana (1,2), with 52 million people estimated to have used controlled medications nonmedically at least once in their lifetime (3). Of the 6.5 million (2.5%) individuals 12 and older who reported current nonmedical use of controlled medications in 2013, 69.2% reported use of controlled opioid analgesics, 2.6% reported use of tranquilizers, and 2.2% reported use of stimulants (1). Prescription medication abuse is associated with adverse consequences, including emergency department (ED) visits (4) and overdose deaths (5,6).

Rates of prescribing opioid analgesics mirror trends in overdose deaths (7). In 2013, retail pharmacies in the United States filled just under 3.9 billion controlled medications (7). About 70% of these controlled medications are not used which has resulted in a large surplus of controlled

medications with the potential to be diverted or abused (8,9). The most commonly reported sources of controlled medications for nonmedical use are friends or family for free, followed by purchase from a friend or family member, theft from a family member, and purchase from a drug dealer or stranger (1,10,11). Because most individuals who have used controlled medications nonmedically obtained them from friends or family, personal medicine cabinets may be a primary source of controlled medications for nonmedical use, knowingly or unknowingly to the prescription holder (8). Thus, organized and secure disposal of unused medications is one strategy to reduce the availability of controlled medications for diversion or abuse after they have been dispensed into the community.

The Secure and Responsible Drug Disposal Act of 2010 provides national guidelines for organized and secure controlled medication disposal (12). Included in the Secure and Responsible Drug Disposal Act of 2010 are the two most commonly utilized organized and secure disposal strategies: take-back events and

permanent drug donation boxes. Take-back events typically occur biannually for 1–2 days at a time and can be held at various locations. Permanent drug donation boxes are available year-round and, prior to October 9, 2014, must have been located at law enforcement offices under 24–7 surveillance (12,13).

The DEA initiated take-back events in local communities across the nation in September 2010. Over 4000 communities in all 50 states participated in the first take-back event, which resulted in the return of over 242,000 pounds of over-the-counter (noncontrolled) and controlled medications (14). The DEA continued to sponsor these events through spring of 2016; 11 DEA-sponsored take-back events were conducted over 5 years. Over six million pounds of over-the-counter and controlled medication were collected from all the events (15,16).

Although local communities widely implement take-back events, to our knowledge, there are only three published peer-reviewed studies that have examined the quantity and type of medications collected at take-back events (8,17,18). In two of these studies, there were 11,406 (17)–50,549 (8) controlled medication units (1 unit = 1 pill, 1 milliliter, or 1 patch) collected from 6 and 11 take-back events, respectively. For all three studies, opioid analgesics were the most common controlled medication collected (8,17,18). However, controlled medications consisted of only 9–10% of the total collections (8,18), indicating that the majority of the collection consisted of noncontrolled medications.

In addition to take-back events, law enforcement agencies, often partnering with local substance abuse prevention coalitions, have installed permanent drug donation boxes in their offices. These drug donation boxes provide opportunities for community members to securely dispose of medications throughout the year. At this time, there is one published study that has examined the effectiveness of permanent drug donation boxes. The study took place over 2 years in a region of northeast Tennessee (19). With eight permanent drug donation boxes, 4841 pounds of controlled and non-controlled medications were collected over 2 years. Of that, 238.5 pounds (106,464 doses) were controlled medications (19).

While organized disposal efforts are widely implemented in communities across the United States, no studies to date have compared the amounts of controlled medications collected from permanent drop boxes and from take back events. More importantly, there have been no reports in the published literature that compare the volume of controlled substances collected to the volume dispensed. Our study expands upon the small number of previous studies by

examining the potential impact that organized disposal efforts—both take-back events and permanent drug donation boxes—have on reducing the availability of controlled medications that could be used for abuse or diversion in communities. In order to assess the impact on availability, we compare the number of controlled medications disposed to the number of controlled medications dispensed using Kentucky's prescription drug monitoring program.

Methods

Community recruitment and collection

Local law enforcement agencies (Police Departments and Sheriff Offices) in 10 counties in south-central Kentucky were invited to participate in the research study. Agencies from five counties elected to participate. The counties that participated in the study varied in size, with populations ranging from 42,173 to 113,792 (Table 1) (20). The Wake Forest School of Medicine Institutional Review Board deemed the study exempt from review because there were no human subjects and no personal health information was collected.

Dispensing data collection procedure and analysis

Pharmacies and other providers are required to report controlled medications (Schedules II–V) that are dispensed to Kentucky's prescription drug monitoring program (Kentucky All Schedule Prescription Electronic

Table 1. County characteristics and participation in disposal study.

	County				
	A	B	C	D	E
<i>County characteristics</i>					
Population size ^a	113,792	42,173	19,956	17,327	10,963
Population density/mi ² of land area ^a	210.1	86.5	58.0	74.0	33.3
Median age ^a	32.7	39.7	39.2	39.1	42.1
% Completed high school, but not college ^a	26.3	44.1	40.6	48.6	36.8
% College graduates ^a	8.5	7.6	7.3	1.3	0.9
% White ^a	83.6	92.5	97.0	87.3	95.1
% African-American ^a	9.1	3.9	0.8	9.4	2.1
% Hispanic ^a	4.5	2.6	1.5	1.9	2.6
% Persons in poverty ^a	19.1	20.3	19.6	25.8	19.5
% <65 years old without insurance ^b	18.8	19.2	19.6	18.1	23.8
<i>Participation in disposal study</i>					
Take-back events (n = 3 events)	3	3	0	0	0
Permanent drug donation box assessments (n = 4 week long assessments)	4	4	3	4	3

^aBureau of Census, 2010; ^bBureau of Census, Small Area Health Insurance Estimates, 2010.

Reporting, or KASPER) (21–24). Using these reports, the Kentucky Cabinet for Health and Family Services published data on the total units of controlled medications dispensed, by county and several generic types, quarterly on their website. The total units (1 unit = 1 pill, 1 milliliter, or 1 patch) of controlled medications (e.g., hydrocodone, oxycodone, tramadol, oxymorphone, alprazolam, and diazepam) dispensed in 2013 were obtained for the five counties that participated in the study. Data on hydrocodone, oxycodone, tramadol, and oxymorphone were combined to form an “opioid analgesic” group; alprazolam and diazepam were combined to form a “tranquilizer” group, and the remaining controlled medications whose classification was not reported formed an “other” group. The number of medication units was determined by county, individually, and all five participating counties combined.

Disposal data collection procedure and analysis

Take-back events

Three DEA-sponsored take-back events (October 2013, April 2014, and September 2014) were held by law enforcement agencies in two counties (Counties A and B) over the study period. County A participated in all three events and County B participated in two events. Law enforcement agencies conducted DEA-sponsored take-back events according to the dates, times, and guidelines specified by the DEA (12). The events were held at police departments and a high school parking lot and were advertised by the law enforcement agencies that hosted the events. The weather for all three take-back events was mild and there was no rain or snow that would have adversely impacted attendance at the events.

Permanent drug donation boxes

Permanent drug donation boxes were located at law enforcement agency offices, primarily outside, and were accessible to all community members 24 h, 7 days a week. Ongoing efforts to market the permanent drug donation boxes consisted of periodic advertisements in local newspapers, inserts within pharmacy bags at checkout, and printed labels on controlled substances. While marketing occurred during the study period, efforts were not increased during the week-long assessment periods.

Four week-long assessments of permanent drug donation boxes were conducted over 9 months. Counties A, B, and D participated in all four permanent drug donation box assessments and Counties C and E participated in three assessments. To prepare for the assessments, law enforcement agencies emptied and discarded the contents of their collection receptacles

at 12 pm on a specified Friday. One week later, at 12 pm, law enforcement agencies removed and secured the contents of their donation boxes. Each disposal sample was transported by the law enforcement agency that collected the medications to a centralized law enforcement agency for analysis on the Sunday following the end of each collection period.

Analysis

Analysis consisted of identifying and weighing noncontrolled and controlled medications and counting controlled medications. An initial safety screening for dangerous materials (i.e., sharp objects, hazardous materials, etc.) was conducted by the supervising law enforcement officer and the study supervisor using magnets and search gloves rated to withstand needle punctures. This stage also served as the first stage for trash removal from the sample. Medications were left in bottles to expedite identification by the pharmacist/technicians. Homogenous blister packs were left intact, while packs of mixed medications were emptied and remaining packaging included with the trash. All other nonmedication-related materials were considered trash. Pharmacists sorted the medications by drug type (noncontrolled and controlled). Controlled medications were counted and recorded by generic name and classification (opioid analgesic, tranquilizer, stimulant, muscle relaxer, other).

All trash and noncontrolled and controlled medications were transferred back to the assessment supervisor for final weight measurement. To ensure accuracy of measurement for small samples, all samples that were two pounds or less were weighed using an Acculab Vi-1200 scale; samples greater than two pounds were weighed using a Royal DG200 scale. Trash and noncontrolled substances were measured by weight (lb) only. The overall sample of controlled pills was measured by weight (lb), categorized by their generic name, and counted by pill. Controlled liquids were measured by weight (lb) and volume (ml). Controlled patches (e.g., fentanyl) were measured based on the patch count. Controlled pills, liquids, and patches were converted into units, with one unit constituting a single pill/capsule, milliliter of liquid, or patch (8). To be consistent with the data on dispensed controlled medications, data on hydrocodone, oxycodone, tramadol, and oxymorphone were combined to form an “opioid analgesic” group; alprazolam and diazepam were combined to form a “tranquilizer” group; and the remaining controlled medications formed an “other” group. All measurements were recorded and certified by the assessment supervisor. After final certification, the samples were returned to the original transporting containers and

transferred back to the original transporting law enforcement agencies for return to their respective communities for disposal.

Analysis of dispensed vs. disposed

To compare the quantity of controlled medications disposed through organized disposal methods to the number dispensed, the analysis was restricted to the two counties that participated in all permanent drug donation box assessments and two of the three take-back events (Counties A and B, Table 1). The primary outcome of the study was the estimated percentage of controlled medications dispensed that would be disposed annually through take-back events and permanent drug donation boxes. The estimate of total units disposed over a year was calculated based on the following assumptions: (1) two take-back events would occur annually and (2) permanent drug donation boxes would be accessible 52 weeks out of the year. In order to estimate the number of units disposed at two take-back events per year, an average was taken of the actual number of units collected and multiplied by two. Since permanent drug donation boxes were assessed in 1-week increments, the four collections were averaged by county and then multiplied by 52 to extrapolate the number of controlled medications that would be collected annually. The annual estimated collection from two take-back events and permanent drug donation boxes was added together to get an annual estimate of units disposed. In order to determine the percentage of dispensed controlled medications that are disposed through organized disposal efforts annually, the estimate of annual controlled medication units disposed was divided by the total number of dispensed controlled medicine in 2013.

Results

Dispensed controlled medications

Quantity and type of controlled medication, by unit

In 2013, a total of 26,121,658 (117,064 per 1000 residents) controlled medication units were dispensed in the five counties that participated in the study. The number of controlled medication units dispensed per county ranged from 2215,859 (202,122 per 1000 residents) to 13,288,979 (116,784 per 1000 residents). As shown in Table 2, the majority were opioid analgesics, specifically hydrocodone, oxycodone, tramadol, and oxymorphone (12,257,869; 46.9%), followed by tranquilizers (3425,713; 13.1%), and other controlled medications (10,438,076; 40.0%).

Table 2. Units of controlled medication dispensed, by county and classification.

County	Total controlled No.	Total controlled (rate/1000 residents)	Opioid analgesic ^a No. (%)	Opioid analgesic ^a (rate/1000 residents)	Tranquillizer ^b No. (%)	Tranquillizer ^b (rate/1000 residents)	Other ^c No. (%)	Other ^c (rate/1000 residents)
A	13,288,949	116,783	6013,616 (45.3)	52,847 (45.3)	1473,411 (11.1)	13,130 (11.2)	5801,922 (43.7)	50,807 (43.5)
B	5318,516	126,112	2553,750 (48.0)	60,554 (48.0)	707,214 (13.3)	16,769 (13.3)	2057,552 (38.7)	48,789 (38.7)
C	3083,601	154,520	1626,617 (52.8)	80,512 (52.1)	538,243 (17.5)	26,971 (17.5)	918,741 (29.8)	47,037 (30.4)
D	2214,703	127,819	1072,925 (48.4)	61,987 (48.5)	346,851 (15.7)	20,019 (15.7)	794,927 (35.8)	45,813 (35.8)
E	2215,859	202,122	990,961 (44.7)	90,391 (44.7)	359,964 (16.2)	32,835 (16.2)	864,934 (30.0)	78,896 (39.0)
Total	26,121,628	117,064	12,257,869 (46.9)	60,026 (51.3)	3,425,713 (13.1)	16,775 (14.3)	10,438,076 (40.0)	51,114 (43.7)

^aHydrocodone, oxycodone, tramadol, and oxymorphone; ^bAlprazolam, diazepam; ^cOther Schedule II–V controlled medications.

Disposed medications

Actual quantity and type of medication collected, by weight

Between the two collection strategies, the total weight of the collections was 802 lbs, and of that, 25 lbs (3.1%) were controlled medications. The collection from the three take-back events weighed 581 lbs, and consisted of 175 lbs (30%) of trash (pill bottles, a cell phone, and other non-medication items), 206 lbs (66%) of noncontrolled medications, and 21 lbs (4%) of controlled medications. The total weight of the four permanent drug donation box assessments was 222 lbs. There were 84 lbs (38%) of trash, 78 lbs (61%) of noncontrolled medications, and 4 lbs. (1%) of controlled medications.

Actual quantity and type of controlled medication collected, by unit

As shown in Table 3, between the two collection strategies, a total of 21,503 controlled medication units were collected. Of those, there were 8582 (39.9%) opioid analgesics (hydrocodone, oxycodone, tramadol, and oxymorphone), 573 (2.7%) tranquilizers (alprazolam and diazepam), and 12,349 (57.4%) other controlled medications. Among the “other” category of disposed medications, 5059 (41.0%) were tranquilizers other than alprazolam and diazepam, 3389 (27.4%) were other opioid analgesics (i.e., not hydrocodone, oxycodone, tramadol, and oxymorphone), 3157 (25.6%) were stimulants, 180 (1.5%) were muscle relaxers, and 564 (4.6%) were other controlled medications (e.g., testosterone). Specific to the take-back events, there were 18,069 units of controlled medications collected in the five counties. Of those, 6465

units (35.8%) were opioid analgesics (hydrocodone, oxycodone, tramadol, and oxymorphone); 386 (2.1%) were tranquilizers (alprazolam and diazepam); and 2864 (50.9%) were other controlled medications. From the four permanent drug donation box assessments, there were 3435 units of controlled medications collected. Opioid analgesics (hydrocodone, oxycodone, tramadol, and oxymorphone) were the most common (2118; 61.7%) followed by alprazolam and diazepam (187; 5.4%), and other controlled medications (386; 27.6%). The number and type of disposed controlled medication units varied by county (Table 3).

Dispensed vs. disposed

In 2013, a total of 18,607,495 units of controlled medications were dispensed in Counties A and B (Table 2). Based on the actual number of medication units collected, and the assumptions that there would be two take-back events annually and permanent drug donation boxes would be accessible 52 weeks out of the year, 56,085 were estimated to be disposed through organized disposal efforts annually (see Table 4 for estimates by classification and disposal method), which accounts for approximately 0.30% of the controlled medications dispensed (Table 5). Of the 9467,366 units of opioid analgesics dispensed in Counties A and B in 2013 (Table 2), only 0.31% were estimated to be disposed through organized disposal. Additionally, only 0.13% of tranquilizers and 0.30% of other controlled medications dispensed in both counties were estimated to be disposed through organized disposal efforts (Table 5).

Table 3. Actual units of controlled medication disposed, by county and classification.

	County	Total controlled	Opioid analgesic ^a	Tranquilizer ^b	Other ^c
		No.	No. (% total controlled)	No. (% total controlled)	No. (% total controlled)
Total	All	21,503	8582 (39.9)	573 (2.7)	12,349 (57.4)
Take-back events ^d		18,069	6465 (35.8)	386 (2.1)	2864 (50.9)
Permanent drug donation box ^e		3435	2118 (61.7)	187 (5.4)	386 (27.6)
	A	7019	3455 (49.2)	315 (4.5)	3250 (46.3)
		5623	2619 (46.6)	140 (2.5)	2864 (50.9)
		1397	836 (59.9)	12 (0.7)	677 (40.5)
	B	14,118	4830 (34.2)	258 (1.8)	9031 (64.0)
		12,446	3846 (30.9)	246 (2.0)	8345 (67.1)
		1672	984 (58.8)	12 (0.7)	677 (40.5)
	C	84	84 (100)	0 (0.0)	0 (0.0)
		—	—	—	—
		84	84 (100)	0 (0.0)	0 (0.0)
	D	272	214 (78.7)	0 (0.0)	58 (21.3)
		—	—	—	—
		272	214 (78.7)	0 (0.0)	58 (21.3)
	E	10	0 (0.0)	0 (0.0)	10 (100)
		—	—	—	—
		10	0 (0.0)	0 (0.0)	10 (100)

^aHydrocodone, oxycodone, tramadol, buprenorphine, and oxymorphone; ^balprazolam, diazepam; ^cother Schedule II–V controlled medications;

^dthree take-back events that lasted 4 h each; ^efour permanent drug donation box assessments that lasted 1 week each.

Table 4. Estimated annual units of controlled medication disposed, by county and classification.

	County	Total controlled No.	Opioid analgesic ^a No. (% total controlled)	Tranquilizer ^b No. (% total controlled)	Other ^c No. (% total controlled)
Total	All	56,085	29,245 (52.1)	2764 (4.9)	23,504 (41.9)
Take-back events ^d		16,194	5592 (34.5)	339 (2.1)	10,263 (63.4)
Permanent drug donation box ^e		39,891	23,654 (59.3)	2425 (6.1)	13,241 (33.2)
	A	21,903	12,614 (57.6)	2368 (10.8)	6349 (29.0)
		3748	1746 (46.6)	93 (2.5)	1909 (50.9)
		18,155	10,868 (59.9)	2275 (12.5)	4440 (24.5)
	B	34,182	16,632 (48.7)	396 (1.2)	17,155 (50.2)
		12,446	3846 (30.9)	246 (2.0)	8345 (67.1)
		21,736	12,786 (58.8)	150 (0.7)	8801 (40.5)

^aHydrocodone, oxycodone, tramadol, buprenorphine, and oxymorphone; ^balprazolam, diazepam; ^cother Schedule II–V controlled medications; ^dassume two take-back events per year; ^eassume permanent drug donation boxes would be accessible 52 weeks out of the year.

Table 5. Estimated percentage of controlled medications dispensed that would be disposed annually through take-back events and permanent drug donation boxes, by county and classification.

		Total controlled	Opioid analgesic ^a	Tranquilizer ^b	Other ^c
	County	%	%	%	%
Total	All	0.30	0.31	0.13	0.30
	A	0.16	0.21	0.16	0.11
	B	0.64	0.65	0.06	0.83

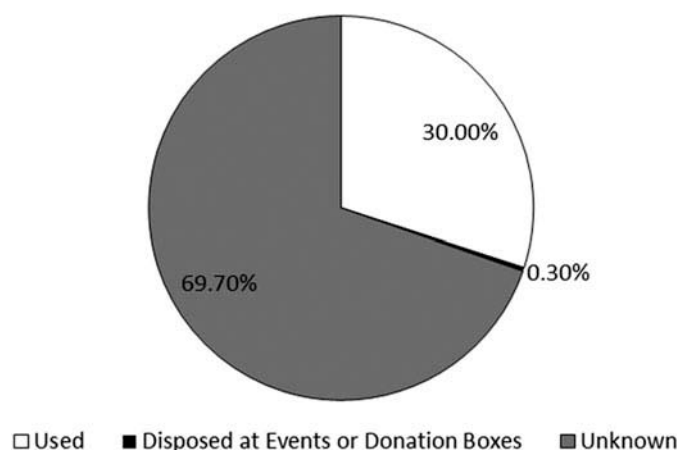
^aHydrocodone, oxycodone, tramadol, buprenorphine, and oxymorphone; ^balprazolam, diazepam; ^cother Schedule II–V controlled medications.

Discussion

To our knowledge, this is the first study to compare the number of controlled medications dispensed in a community to the number of controlled medications disposed through safe and secure organized efforts, such as take-back events and permanent drug donation boxes. We found that bi-annual take-back events and annual permanent drug donation boxes were estimated to account for 0.3% of the prescription medications dispensed in the participating counties within a single year (Table 5). These findings, in conjunction with previous research reporting that approximately 30% of controlled medications are used (8,9), suggest that 69%

of controlled medications are unused and unaccounted for in communities (Figure 1). Some of these unused medications are disposed through unorganized methods (e.g., flushing and throwing away in the trash) (18,21,22) and some are retained in homes even after treatment had ceased or the medication had expired (18,23). However, it is not known what percentage of the unused medication can be accounted for by these practices.

Controlled medications, with abuse potential (i.e., opioid analgesics and tranquilizers) (24), consisted of over 60% of the controlled medications dispensed in 2013. Of the controlled medications dispensed, 46.9% were opioid analgesics, specifically hydrocodone, oxycodone, tramadol, and oxymorphone, and 13.1% were tranquilizers (alprazolam and diazepam). The remaining 40.0% likely consisted of less frequently dispensed opioid analgesics (e.g., fentanyl and codeine) and tranquilizers (e.g., lorazepam and clonazepam) as well as prescription stimulants (e.g., amphetamine and methylphenidate); all of which also have a high abuse potential (24). The types of controlled medications disposed were slightly different from the types of controlled medications dispensed. Of the controlled medications

**Figure 1.** Estimated status of controlled medications dispensed.

disposed, 39.9% (compared to 46.9% dispensed) were opioid analgesics (hydrocodone, oxycodone, tramadol, and oxymorphone) and 57.4% (compared to 40.0%) were “other” medications. Only 2.7% of the disposed medications were tranquilizers compared to 13.1% that were dispensed. Although we are not able to ascertain the specific controlled medications within the “other” category of dispensed medications, among the “other” category of disposed medications, 41.0% were tranquilizers, 27.4% were opioid analgesics, 25.6% were stimulants, 1.5% were muscle relaxers, and 4.6% were other controlled medications (e.g., testosterone). These comparisons suggest that there is a similar but slightly different profile of controlled prescription medications dispensed than disposed.

Our findings corroborate previous research on take-back events and permanent drug donation boxes. We collected 18,069 controlled medication units at 3 DEA-sponsored take-back events in 2 counties compared to 11,406 units from 6 events in rural Appalachia (17), and 50,549 units from 6 take-back events in 11 counties in Maine (8). Specific to permanent drug donation boxes, the percentage of controlled medications disposed (1.8%) was slightly lower than the number that Gray et al. found (4.9%) (19). Although it appears that we may have collected slightly less controlled medications than previous studies, it is difficult to make direct comparisons given the difference in the number of events, length of assessments, and number of participating communities. It is important that future research describes the context (number, length, and geographic boundaries) of disposal efforts in order to better compare the effectiveness of the strategy.

Participating counties varied in both the number of controlled medication units dispensed and disposed. Rates of controlled medication units dispensed were higher in smaller counties which was inconsistent with national data on opioid prescriptions (25). In contrast, disposal rates were not related to population-size; restricted to disposal via permanent drug donation boxes, County B had the highest rate of controlled medication units disposed followed by Counties D, A, C, and E. The homogeneity of the counties (as seen in Table 1) suggests that the variability in dispensing and disposing rates may be due to factors beyond the presented characteristics of community. Given that organized disposal is a key strategy outlined in The Office of National Drug Control Policy’s 2011 Prescription Drug Abuse Prevention Plan (26), it is important that we understand how organized disposal can be improved to maximize its impact.

In September 2014, the Drug Enforcement Agency established the Secure and Responsible Drug Disposal

Act of 2010 final rule (12). The final rule expanded the current opportunities for the collection of controlled substances from ultimate users (take-back events, mail-back programs, and collection receptacles controlled by law enforcement agencies) by authorizing manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles (12). Opportunities for community members to dispose of unused medications at a venue that they frequent, such as a retail pharmacy, may increase the number of unused controlled medications that are disposed (27,28). Further research is needed to determine uptake of collection activities by newly authorized collectors and the results of these collections, as well as to monitor possible adverse consequences, such as pharmacy theft. The cost-benefit of disposal efforts should also be assessed.

Additionally, the impact of organized and secure disposal may expand beyond availability of prescription medications to affect community norms and behaviors involving storage, disposal, and abuse of controlled medications. Future research should examine how disposal efforts influence norms and behaviors to gain a better understanding of their impact on medication abuse and diversion.

Within County A and B, there were a total of 18,607,495 controlled medication units (13,288,979 and 5318,516,117 per county, respectively) dispensed in 2013 alone, which translates to 117 and 126 controlled medication units per community member, respectively. Given the sheer number of prescription medications dispensed, it is important to consider whether it is realistic to expect organized disposal to shift the needle of controlled medications available for abuse and diversion alone.

Limitations

There were several limitations to the study design. The study was conducted over a limited timeframe in several counties in a region of Kentucky, which limits its generalizability. Only 2013 dispensing data were utilized since it was the first year that the number of doses/units was published rather than the number of prescriptions dispensed, making it comparable to the disposal data. Utilizing only a single year of dispensing data is a conservative approach given that people likely hold on to controlled prescription medications for more than a year (18). Additionally, KASPER only reported a selected, albeit the most prevalently dispensed, generic names of medications rather than a

more inclusive list which were used to create the classifications (i.e., opioid analgesic, etc.) of both dispensed and disposed medications. Thus, the number of opioid analgesics and tranquilizers dispensed are likely to be larger than reported here. There may have been slightly more units collected than reported due to inability to assess medications that were congealed and not in their original form. Although the number of units dispensed and disposed was assessed by county, it is likely that prescription medications may not remain within the county in which they are dispensed, even for legitimate use (29). The assessment of permanent drug donation boxes consisted of 4-week-long assessments due to feasibility issues (i.e., cost and human resources) rather than assessment continuously throughout the study period. In order to account for potential seasonal differences, the assessments were taken at different times throughout the study, and an average across the assessments was taken in order to extrapolate the data. Our results from the donation box disposal were similar, albeit slightly lower, than previous research. However, even if the number of disposed units were double what we had found, the percentage of controlled medications dispensed versus disposed would still be less than 1%.

Conclusion

This was the first study to assess the impact of take-back events and permanent drug donation boxes on availability of controlled medications at a population level. Bi-annual take-back events and annual permanent drug donation boxes were estimated to account for 0.3% of the controlled medications dispensed within a single year. While our findings suggest that organized drug disposal efforts may have a minimal impact on reducing the availability of unused controlled medications at a community level, additional research is needed to examine its effect on community norms and behaviors involving storage, disposal, and abuse of controlled medications. In order to reduce the availability of controlled medications for abuse and diversion, a comprehensive approach that addresses both prescribing and disposal is recommended.

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Behavioral Intervention and Disposal of Leftover Opioids: A Randomized Trial

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abstract

OBJECTIVES: Leftover prescription opioids pose risks to children and adolescents, yet many parents keep these medications in the home. Our objective in this study was to determine if providing a behavioral disposal method (ie, Nudge) with or without a Scenario-Tailored Opioid Messaging Program (STOMP) (risk-enhancement education) improves parents' opioid-disposal behavior after their children's use.

METHODS: Parents whose children were prescribed a short course of opioids were recruited and randomly assigned to the Nudge or control groups with or without STOMP. Parents completed surveys at baseline and 7 and 14 days. Main outcomes were (1) prompt disposal (ie, immediate disposal of leftovers after use) and (2) planned retention (intention to keep leftovers).

RESULTS: There were 517 parents who took part, and 93% had leftovers after use. Prompt disposal behavior was higher for parents who received both the STOMP and Nudge interventions (38.5%), Nudge alone (33.3%), or STOMP alone (31%) compared with controls (19.2%; $P \leq .02$). Furthermore, the STOMP intervention independently decreased planned retention rates (5.6% vs 12.5% no STOMP; adjusted odds ratio [aOR] 0.40 [95% confidence interval (CI) 0.19–0.85]). Higher risk perception lowered the odds of planned retention (aOR 0.87 [95% CI 0.79–0.96]), whereas parental past opioid misuse increased those odds (aOR 4.44 [95% CI 1.67–11.79]).

CONCLUSIONS: Providing a disposal method nudged parents to dispose of their children's leftover opioids promptly after use, whereas STOMP boosted prompt disposal and reduced planned retention. Such strategies can reduce the presence of risky leftover medications in the home and decrease the risks posed to children and adolescents.



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Deidentified individual participant data will not be made available at this time.

Dr Voepel-Lewis developed the interventions, designed the study and methods, supervised the recruitment and data collection, ensured the ethical conduct of the study, guided the analyses, interpreted data, and drafted the manuscript; Drs Farley and Grant contributed to the risk education intervention and research design, facilitated the recruitment of the surgical population, interpreted the data, and edited the final manuscript; Dr Tait assisted with the research design and methods, conducted the statistical analyses, assisted with data interpretation, and edited the final manuscript; Drs Boyd and McCabe assisted with the research methods and surveys, interpreted data, and edited the final manuscript; Ms Weber assisted with survey methodology, supervised all subject recruitment, data collection, and database management, and edited the final manuscript; Dr Harbaugh assisted with editing; Dr Zikmund-Fisher helped to develop the educational and behavioral interventions, designed the study and survey methodology, guided statistical (Continued)

WHAT'S KNOWN ON THIS SUBJECT: Leftover prescription opioids pose significant risks of morbidity and mortality to children and adolescents, yet many parents keep these and other leftover medications in the home.

WHAT THIS STUDY ADDS: In this randomized trial, we showed that providing scenario-tailored risk information improved parents' prompt disposal of their children's leftover opioids and reduced their planned retention rates. Providing a disposal method enhanced prompt disposal but did not affect planned retention.

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Over the course of 2 decades, opioid-related emergency department, hospital, and ICU admission rates doubled and opioid-related mortality nearly tripled for children and adolescents.^{1–3} Exposure to prescribed opioids accounted for large majorities of these opioid-related pediatric hospital and critical care admissions³ and deaths,² and 96% of exposures occurred in private residences.⁴ Therapeutic error (ie, unintentionally given a wrong dose or someone else's medication) was found to account for only 1 in 5 pediatric exposures in 1 report, leaving the majority due to accidental or intentional access by children and adolescents.⁴ Retention and easy access to leftover prescription opioids is considered to be a major source of accidental and intentional pediatric exposures, posing significant risks of morbidity and mortality. Half to 90% of prescribed opioid doses are left over after acute pain treatment in children,^{5–9} and 3 out of 4 middle school children have reported unsupervised access to risky medications in the home.¹⁰ Moreover, up to 40% of adolescents who reported opioid misuse accessed their own past prescription, and more than half accessed that of a friend or family member.^{11–13} Importantly, most parents have admitted to keeping their children's leftover opioids,¹⁴ and 10% to 20% of adults report sharing their children's or their own leftovers between family and friends.^{14–16}

Interventions such as providing disposal information, giving store credit, and expanded availability of community take-back programs have increased opioid disposal to some degree, but up to two-thirds of those with leftovers retain them despite intervention.^{6,8,17} Indeed, a majority of adults who acknowledge the hazard and who have been given disposal information have reported an intention to retain their own or their children's leftover opioids.^{6,14,15} Thus, lack of knowledge about safe

disposal may not fully explain drug retention. Instead, there may be real or perceived barriers to disposal that factor into behavior. Recent data support this notion, showing that perceived barriers were associated with parents' poor opioid storage and retention practices.⁹ Additionally, drug take-back programs have been estimated to remove only a tiny portion of what is known to be leftover, suggesting barriers to action.⁸

Behavioral theorists recognize that people often fail to change behavior in a way that reduces risk even when they have relevant information about risks.¹⁸ They emphasize the importance of shaping the choice architecture to make preferred risk-reduction actions more salient and easier to perform and the implied default or expected behavior.^{19,20} Nudges are designed tactics meant to shape the choice architecture to prompt better decisions.¹⁸ Providing a disposal method at the time of prescribing is a type of nudge strategy that could prompt or motivate disposal rates over and above what other, less convenient methods have achieved because it minimizes the steps needed and enhances the perception that disposal is the expected behavior (subjective norm).

Another solution is to provide enhanced education about the real risks that leftover opioids pose to children and adolescents. Data suggest that to best reduce risky decision-making, educational interventions must enhance the perceived riskiness of the behavior rather than inform risk awareness alone.²¹ We previously showed how our Scenario-Tailored Opioid Messaging Program (STOMP) enhanced parents' opioid risk perceptions, shifted their preferences toward risk avoidance, and improved safe analgesic decision-making.²² To date, there are limited data about whether behavioral or educational

strategies are most effective and efficient in prodding early and safe disposal of leftover prescribed opioids.

Our purpose in this randomized, controlled trial was to examine whether provision of a disposal method with or without enhanced risk information at the time of prescribing would improve parents' leftover disposal behavior after short-term use. Specifically, we hypothesized that when controlled for child and parent pain-related factors in a factorial design, the following would occur.

1. Providing a take-home disposal packet at the time of prescribing (ie, Nudge) would independently increase parents' timely disposal behavior compared with parents who were randomly assigned to the no packet group (control).
2. STOMP risk information will increase timely disposal rates and lower planned retention of leftover opioids compared with routine information.

METHODS

Interventions

Nudge is a cost-efficient disposal kit with illustrated instructions (ie, Ziploc of coffee grounds, a US Food and Drug Administration-sanctioned method for leftover drug disposal).²³ The Nudge intervention provides a how-to-dispose kit that eliminates uncertainty, makes the required steps concrete, and creates an injunctive norm that use of the kit is expected behavior. The Nudge intervention was meant to boost response efficacy by putting the risk-reduction behavior within parents' immediate control.

STOMP is an interactive Web-based program that presents descriptive, clinically relevant pain and risk situations in which parents consider common scenarios and make intentional analgesic use and handling decisions.^{21,24,25} Each

decision prompts immediate feedback about the risk portrayed along with behavioral advice about what to do to reduce the risk. Parsimonious messages serve to heighten risk perception and build behavioral response efficacy.²⁶ Similar feedback strategies have been shown to enhance health behaviors and outcomes compared with provider interactions alone.²⁷ We hypothesized that STOMP information would improve disposal behavior and intentions by enhancing parents' risk perceptions.

Main Outcome Measure

The main outcomes were prompt disposal (parents' self-reported disposal immediately after the children's course of treatment) and intention to retain (parents will keep after use). Self-report is the primary method used to ascertain opioid storage and disposal behavior.^{9,28,29} Meta-analyses show that health intentions correlate moderately with actual behavior and that this association increases when the risk behavior is within the control of the subject and when expected behavior change is <5 weeks postintervention.³⁰ We used recent recommendations to optimize the validity of self-report,³¹ including computer survey of outcomes (instead of face-to-face assessment, which could increase social desirability), brief recall period, and inclusion of nonjudgmental wording (eg, "people often keep their leftover medications for various reasons"). We also asked parents to submit a photograph of the disposal as a secondary validation of the self-report.

Other Measures

The Parents' Postoperative Pain Measure–Short Form³² measured the children's pain (scored 0–10; 10 = most pain interference). This tool has excellent internal consistency ($\alpha = .85$)³² and agreement with self-reported pain intensity in children.³³

Risk perception was measured by several questions derived from a validated survey assessing parental concerns about prescription opioid storage in the home.⁹ Scores on the composite measure ranged from –6 to +6, where lower scores indicate strong disagreement and higher scores indicate strong agreement about the riskiness of opioid retention and misuse in the home.

Procedure

With approval from the institutional review board (Institutional Review Board, Medicine Human Subjects No. 127009), we consecutively recruited and consented parents whose children (aged 5–17 years) were scheduled to undergo a short-stay surgical procedure with a typical need for prescribed opioids. All recruitment occurred between October 2017 and December 2018, and follow-up was completed by January 31, 2019. We excluded non-English-speaking parents and those whose children were undergoing emergency procedures, those who could not self-report their pain, and those who had chronic pain or opioid use (≥ 3 months in the past year).

Trained assistants used computer-generated randomization to assign parents a priori to either the control group (no disposal Ziploc) versus the Nudge group (ie, received the disposal Ziploc) and to the STOMP versus routine information. Parents (blinded to assignment) completed baseline surveys using a Qualtrics link via iPad for consistency, completeness, and privacy. Parents entered their assigned, unique identification number and recorded their demographics, their own and their children's past pain and opioid use, analgesics stored in the home, and whether they had ever taken a prescribed opioid in greater amounts or more frequently than prescribed, taken someone else's prescribed opioid, or shared their

opioid with a friend or family member (together coded as past opioid misuse). Parents' health literacy was assessed by using the Rapid Estimate of Adult Literacy in Medicine–Short Form, which has established reliability and validity in adults (score range 0–7; scores <3 indicate less than a sixth-grade reading level).³⁴ Parents assigned to the STOMP feedback received this information (embedded into the Qualtrics survey platform) immediately after the baseline survey.

On days 7 and 14 postdischarge, parents received follow-up Qualtrics survey links via e-mail to record pain interference scores, analgesic use, discontinuation, leftover opioid amounts, and disposal behavior and retention intentions. Parents who intended to retain leftovers were asked to provide reasons for retention (semistructured and open-ended options). Those who indicated disposal intention were asked how they disposed or planned to dispose and to e-mail or text a picture of the disposal process if possible. Parents recorded all opioid doses administered in diaries, which they returned in a prestamped envelope after analgesic discontinuation. These data were used to check the reliability of parental reports of leftover opioid amounts. Parents received \$50 for completion of all surveys and diaries. We obtained prescription and surgical procedure data from the children's electronic medical record. All surveys and child data were linked by using the parents' unique identifier to maintain privacy and enhance honest disclosure.

Statistical Analyses

Data were analyzed by using SPSS (version 24; IBM SPSS Statistics, IBM Corporation) and are presented as *n* (%) and mean $\pm$ SD with odds ratios (ORs) or mean differences and 95% confidence intervals (CIs) when appropriate. No missing data were imputed. Univariate comparisons of

group characteristics were conducted by using χ^2 with Fisher's exact tests or unpaired t tests with Levene's tests for equality of variance. Logistic regression models assessed the effects of our interventions on the outcomes (1) prompt disposal and (2) intention to retain. In both models, we included our interventions and controlled for relevant pain and analgesic factors, including child procedure, pain interference, past opioid (parent and child), parental opioid misuse, and opioid storage in the home at baseline. We report adjusted odds ratios (aORs) for all factors and accepted significance at $P < .05$.

Sample Size Determination

We based our sample size on an expected disposal rate of 30% in our control group.¹⁴ To detect a small effect of the Nudge on disposal behavior (OR 1.5) with 95% confidence and a relative precision of 50%, we needed 196 parents in the Nudge and control groups. We recruited 640 parents to account for potential loss to follow-up and missing data (30%) and to ensure a sufficient sample to detect small effects of the interventions in a factorial model with up to 10 covariates (sample needed = 333).

RESULTS

Our analytical sample derivation ($n = 517$) is depicted in Fig 1. There were no significant differences in baseline characteristics between the study groups at baseline (Table 1). Of note, 61 parents (11.8%) reported past prescription opioid misuse (31% for pain relief, 11% for sleep, and 5% to relax or for another effect), and the balance provided no motivation.

There were no differences between the groups in the children's opioid and analgesic prescriptions or their use after hospital discharge (Table 2). Overall, 59% of children took opioids for ≤ 2 days, and 84% took them for < 6 days. Most parents reported

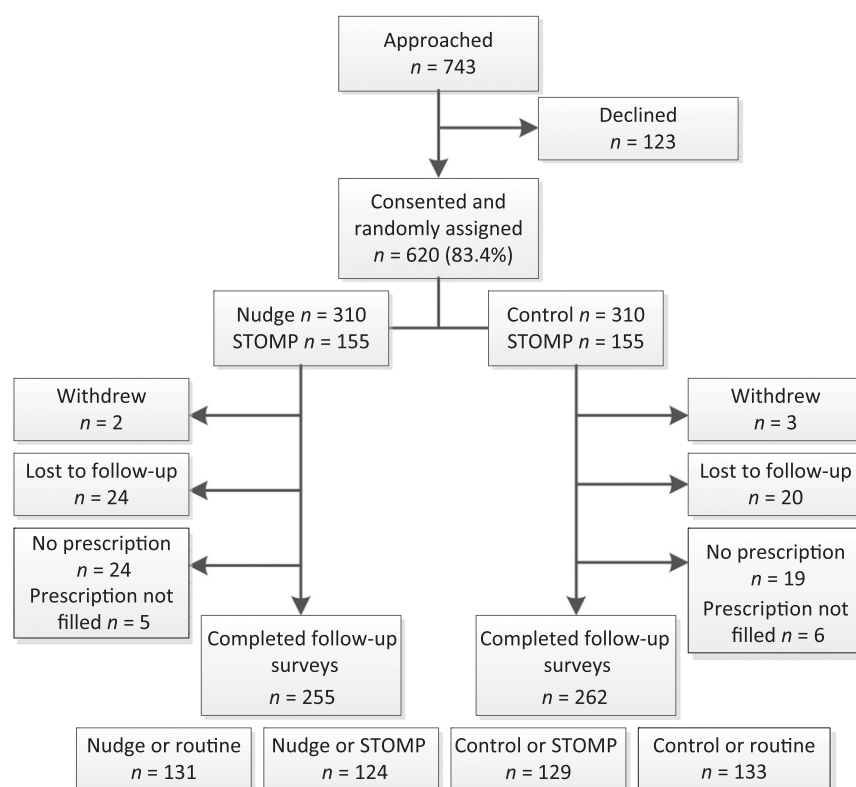


FIGURE 1

Consolidated Standards of Reporting Trials diagram depicting sample derivation: prompt disposal.

leftover opioids; 99 (19%) estimated that $> 50\%$ to 100% of doses remained, 146 (28%) had one-quarter to half of the doses left, and 101 (20%) had only a few doses leftover. Comparisons between parents' diary dose recordings and dispensed volume validated parental leftover estimates.

At the final survey, disposal rates were significantly higher for all intervention groups (Fig 2). Prompt disposal was highest for the STOMP and Nudge group (38.5%) and lowest for the control and routine information group (19.2%; OR 2.64 [95% CI 1.46–4.80]). Disposal confirmation by e-mailed image validated 56 (40%) early disposal cases.

Most parents reported an intention to eventually dispose of leftover opioids, but 44 (9%) intended to retain them. Planned retention was significantly lower for parents who received the

STOMP intervention (5.6% vs 12.5% for parents without STOMP; OR 0.41 [95% CI 0.21–0.81]). Reasons for planned retention included concern for future child need ($n = 34$ [77%]), future family need ($n = 3$ [7%]), paid for the drug ($n = 5$ [11%]), and do not know how to dispose or not easy to get rid of ($n = 6$ [14%]). There was no association between intention to retain and doses administered at home or number of doses dispensed (ρ 0.071 and -0.004 , respectively). Of those planning retention, 7 parents (64%) who had received STOMP planned to store the retained opioid in a locked cabinet or drawer compared with 11 (38%) who received standard information ($P = .17$).

Our hypotheses were supported by logistic regression analyses, showing that both the Nudge and STOMP interventions had significant effects on prompt disposal behavior when

TABLE 1 Description of Baseline Characteristics of the Groups

	Control		Nudge	
	STOMP (n = 129)	Routine (n = 133)	STOMP (n = 124)	Routine (n = 131)
Female parent, n (%)	111 (86)	103 (77)	105 (85)	106 (81)
High school diploma or less, n (%)	18 (14)	14 (11)	16 (13)	10 (8)
Parent health literacy, ^a mean ± SD	6.95 ± 0.21	6.83 ± 0.69	6.89 ± 0.37	6.86 ± 0.59
White race, n (%)	116 (90)	115 (87)	105 (85)	116 (89)
Hispanic, n (%)	2 (2)	6 (5)	5 (4)	3 (2)
Child previous surgery, n (%)	85 (66)	81 (61)	84 (68)	78 (60)
Female child, n (%)	47 (36)	59 (44)	50 (40)	60 (46)
Child age, mean ± SD	12.76 ± 3.72	12.79 ± 3.86	13.52 ± 3.40	12.36 ± 3.72
Child procedure type, n (%)				
Orthopedic or sports medicine	79 (61)	78 (59)	69 (56)	74 (57)
General surgery or urology	25 (19)	26 (20)	21 (17)	28 (21)
Otology	11 (9)	16 (12)	13 (11)	20 (15)
Other	14 (11)	13 (10)	21 (17)	9 (7)
Child past opioid use, n (%)	30 (23)	35 (26)	40 (32)	34 (26)
Parent past opioid use, n (%)	78 (61)	50 (38)	60 (48)	72 (55)
Opioid kept in home, n (%)	28 (22)	22 (17)	24 (19)	36 (27)
Past opioid misuse, any, n (%)	18 (14)	8 (6)	11 (9)	24 (18)
Took more	8 (6)	3 (2)	7 (6)	12 (9)
Shared their opioid	10 (8)	4 (3)	3 (2)	14 (11)
Took someone else's	7 (5)	3 (2)	8 (7)	17 (13)

^a Measured by using Rapid Estimate of Adult Literacy in Medicine–Brief, scored 0 to 7.

controlled for child and parent factors (Table 3). The STOMP significantly reduced parents' intention to retain, whereas the Nudge had no independent effect on planned retention (Table 3). Importantly, higher parental risk perception lowered the odds of planned retention, whereas their past prescription opioid misuse behavior

increased the odds of planned retention.

DISCUSSION

In this randomized controlled study, the Nudge intervention significantly enhanced parents' timely disposal of leftover prescribed opioids after their children's short-term use. Despite this important finding, the Nudge

intervention had no effect on planned retention rates. In contrast, the STOMP intervention had significant effects on both prompt disposal behavior and planned retention. These findings suggest that provision of a handy disposal method can nudge immediate risk-reduction behavior but has little effect on future planning. To further reduce parents' retention of leftover opioids, clear

TABLE 2 Details of Prescribed Analgesics, Use After Discharge, and Opioid Leftovers in the Groups

	Control		Nudge	
	STOMP (n = 129)	Routine (n = 133)	STOMP (n = 124)	Routine (n = 131)
Oxycodone prescription, n (%)	112 (87)	120 (90)	113 (91)	126 (96)
Hydrocodone prescription, n (%)	17 (13)	13 (10)	15 (12)	7 (5)
Doses dispensed, n (median [IQR])	27.91 (24.39 [23.07–32.74])	25.59 (21.43 [21.77–29.41])	23.09 (20.00 [19.55–26.64])	22.77 (20.00 [19.47–26.06])
Other analgesics ordered, n (%)				
Acetaminophen	92 (74)	95 (74)	92 (76)	93 (71)
Ibuprofen	61 (50)	66 (51)	55 (45)	67 (54)
Diazepam	10 (8)	7 (5)	11 (9)	7 (5)
Gabapentin	4 (3)	6 (5)	6 (5)	5 (4)
Magnesium	17 (13)	12 (9)	16 (13)	16 (12)
Opioid given after discharge	106 (82)	109 (83)	101 (82)	103 (79)
Total opioid doses given after discharge, range (median [IQR])	0–41 (5 [1–11])	0–36 (5 [1–10])	0–61 (4 [1–9.25])	0–39 (6 [1–10])
Nonopioid given after discharge, n (%)	122 (95)	126 (98)	115 (94)	124 (97)
Ongoing nonopioid use (d 14), n (%)	35 (27)	31 (23)	45 (36)	29 (22)
Ongoing opioid use (d 14), n (%)	8 (6)	2 (2)	4 (3)	3 (2)
Pain interference score (d 14), mean ± SD	1.14 ± 2.18	0.80 ± 1.43	1.05 ± 1.83	1.00 ± 2.03
Leftover opioids, n (%)	120 (93)	122 (92)	113 (91)	126 (96)

IQR, interquartile range.

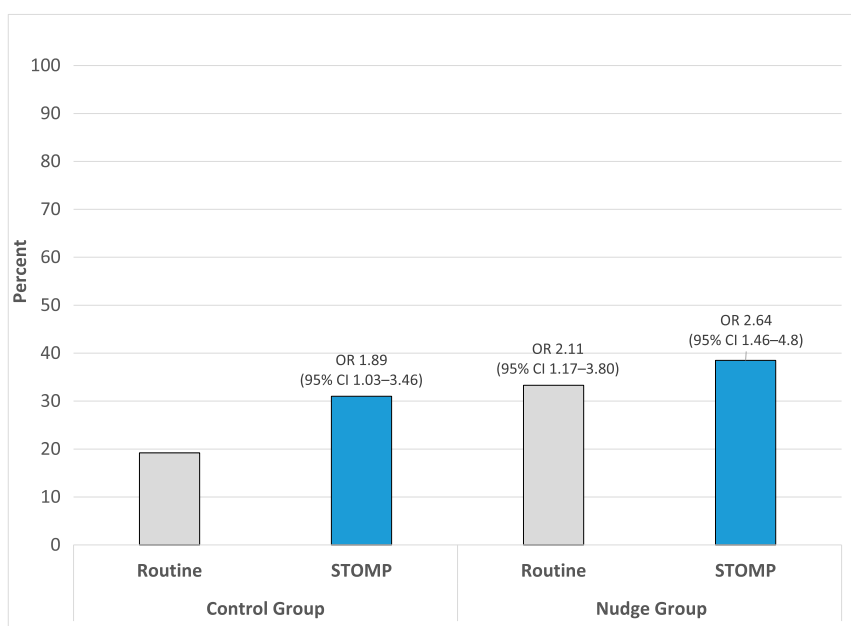


FIGURE 2

Prompt leftover prescription opioid-disposal rates between the study groups. Presented are ORs (95% CIs) versus control (no nudge) without the STOMP (routine) group.

messaging about the risks posed to children and adolescents in the home is required.

We considered prompt disposal to be the best risk-reduction behavior because storage in the home, even for

short periods, poses increased risk to family members and others. Good intentions to dispose, which the majority of our parents reported, may wane over time as parents get busy with other more pressing family activities. Furthermore, several parents in our study anecdotally described barriers in finding appropriate take-back programs, particularly for liquid medications. Many parents with disposal intentions planned to take their children's leftover opioids back to a pharmacy or to their children's clinic where appropriate disposal capability was unclear.

Our findings have important implications for promoting parental disposal of leftover prescription opioids. Nudge interventions aim to enhance behavior at the time of decision-making. In contrast, our STOMP intervention is meant to enhance opioid risk perceptions in addition to guiding risk-reduction

TABLE 3 Results of Hypotheses Tests: Effects of Nudge and STOMP on Parental Disposal Behavior and Planned Retention

Factor	aOR (95% CI)
Outcome: prompt opioid disposal (children with ongoing opioid use at final survey excluded); model χ^2 28.54 (df 11); $P = .003$; Hosmer-Lemeshow test 0.447	
Child age	0.95 (0.90–1.01)
Child past opioid use	1.29 (0.76–2.18)
Pain interference score	0.92 (0.80–1.06)
Orthopedic or SM procedure	0.66 (0.43–1.02)
Opioid kept in home baseline	0.82 (0.47–1.45)
Parent past opioid use	0.78 (0.49–1.23)
Parent misused opioid	1.06 (0.51–2.19)
Total opioid doses dispensed	0.99 (0.98–1.01)
Nudge intervention	1.78 (1.16–2.73)
STOMP intervention	1.68 (1.10–2.58)
Perceived opioid risk	1.02 (0.96–1.10)
Outcome: parental intention to retain leftover opioid (included all parents); model χ^2 43.96 (df 11); $P < .001$; Hosmer-Lemeshow test 0.815	
Child age	1.02 (0.92–1.12)
Child past opioid use	1.03 (0.44–2.39)
Pain interference score	0.96 (0.79–1.17)
Orthopedic or SM procedure	2.45 (1.09–5.51)
Opioid kept in home baseline	2.13 (0.96–4.71)
Parent past opioid use	0.63 (0.27–1.50)
Parent misused opioid	4.44 (1.67–11.79)
Total opioid doses dispensed	1.00 (0.99–1.02)
Nudge intervention	1.04 (0.51–2.12)
STOMP intervention	0.40 (0.19–0.85)
Perceived opioid risk	0.87 (0.79–0.96)

df, degrees of freedom; SM, sports medicine.

behavior. STOMP provides parents with simple but blunt risk messages (eg, “Younger children have been poisoned, and some have died. ... Overdose and death have occurred in teenagers who took leftover opioids”) paired with recommended behaviors (eg, “...get rid of all leftovers right away by 1 of these approved ways. ...Getting rid of all leftover prescribed pain relievers is the only way to keep children and teenagers from potentially causing themselves harm”). That STOMP improved the rates of timely disposal and also reduced retention intentions supports this strategy. Notably, our messages have not, to date, diminished parents’ pain management behavior. That is, parents who receive scenario-tailored risk information have been found to make better decisions about when it is safe to use opioids to manage their children’s pain and when it is unsafe to do so.²² Thus, scenario-tailored messaging achieves a more balanced risk/benefit understanding that can improve pain outcomes while reducing risk. A balanced approach to education is imperative because parents’ primary motivation for retaining opioids is the anticipated future pain relief needs of their children.

Importantly, parents’ past prescription opioid misuse behavior quadrupled the risk of planned retention. Parents who have misused a prescribed opioid are likely to perceive the risks to be low, particularly if they or their families experienced no adverse problems. Assessing parents’ past behaviors and enhancing their perceptions of the real risks posed to children are important targets for risk reduction. This is particularly germane given

new data showing that maternal prescription opioid misuse increases the risk for adolescent misuse (aOR 1.62 [95% CI 1.28–2.05]), whereas higher parental risk perceptions decrease this risk (aOR 0.93 [95% CI 0.87–1.00]).³⁵ Additionally, mothers have been found to strongly influence their teenagers’ analgesic use and information.^{36,37} To interrupt the modeled pattern of medication misuse, assessments and interventions must first target parents.

Despite our rigorous randomized controlled trial design, our ability to generalize findings is somewhat limited. Firstly, we cannot reject the possibility of a social desirability bias because parents may want to appear to be doing the right thing for their children and household. We minimized the potential for social desirability bias by including nonjudgmental statements in our survey and using computerized surveys (versus face to face). Although use of self-reported outcomes may have overestimated disposal behavior, evidence from adherence studies suggests their correlation with other observational methods and their good predictive validity.³¹ Next, our sample consisted of mostly white, well-educated parents in a state and community that has been heavily impacted by the opioid epidemic and related deaths. Thus, parents’ baseline opioid risk perceptions may be higher than those in other less-impacted communities. Finally, our intervention was particularly low cost, thus meeting the definition of a nudge intervention. Although commercially available drug disposal pouches are available, it is unclear how their cost would impact use and implementation across

settings. Even if policies mandated their distribution with scheduled drugs, it is likely that the cost would be passed along to consumers, thus creating a potential barrier to use. Despite these limitations, our findings have relevance to inform future interventions aimed at reducing the retention of leftover, high-risk prescription medications.

CONCLUSIONS

In summary, we found that providing a disposal method at the time of opioid prescribing effectively nudged more parents to do the right thing and promptly dispose of their children’s leftovers after short-term use. Heightening risk perceptions with tailored risk information had an additive effect on parental behavior and reduced their intention to retain prescription opioid leftovers. It will be important to determine if such interventions have longer-lasting impacts on opioid misuse and adverse events among children, teenagers, families, and communities.

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ABBREVIATIONS

aOR: adjusted odds ratio
CI: confidence interval
OR: odds ratio
STOMP: Scenario-Tailored Opioid Messaging Program

analyses and interpretation of data, and helped to draft the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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CO-MORBID PAIN & SUBSTANCE USE DISORDERS

Effect of Drug Disposal Kits and Fact Sheets on Elimination of Leftover Prescription Opioids: The DISPOSE Multi-Arm Randomized Controlled Trial

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Abstract

Objective. To determine how passively providing informational handouts and/or drug disposal kits affects rates of leftover prescription opioid disposal. **Design.** A multi-arm parallel-group randomized controlled trial with masked outcome assessment and computer-guided randomization. **Setting.** Johns Hopkins Health System outpatient pharmacies. **Subjects.** Individuals who filled ≥ 1 short-term prescription for an immediate-release opioid for themselves or a family member. **Methods.** In June 2019, 499 individuals were randomized to receive an informational handout detailing U.S. Food and Drug Administration–recommended ways to properly dispose of leftover opioids ($n = 188$), the informational handout and a drug disposal kit with instructions on its use ($n = 170$), or no intervention ($n = 141$) at prescription pickup. Subjects were subsequently contacted by telephone, and outcomes were assessed by a standardized survey. The primary outcome was the use of a safe opioid disposal method. **Results.** By 6 weeks after prescription pickup, 227 eligible individuals reported they had stopped taking prescription opioids to treat pain and had leftover medication. No difference in safe disposal was observed between the non-intervention group (10% [6/63]) and the group that received disposal kits (14% [10/73]) (risk ratio = 1.44; 95% confidence interval: 0.55 to 3.74) or the group that received a fact sheet (11% [10/91]) (risk ratio = 1.15; 95% confidence interval: 0.44 to 3.01). **Conclusions.** These findings suggest that passive provision of a drug disposal kit at prescription pickup did not increase rates of leftover opioid disposal when compared with provision of a fact sheet alone or no intervention. Active interventions may deserve further investigation.

Key Words: Pain; Acute; Analgesics; Opioid; Prescription Drug Misuse; Medical Waste Disposal; Opioid Stewardship

Introduction

Leftover prescription opioids in the home create a significant health risk that, despite recent decreases in U.S. opioid prescribing, contribute to the rising rates of nonfatal and fatal opioid overdoses [1]. Misuse of unused opioids has also contributed to the escalating rates of overdose in children and teens and served as a common initial exposure among many of the more than 2 million Americans who suffer from an opioid use disorder [2–4].

National guidelines and federal agencies recommend that patients receive information describing how to dispose of leftover prescription medication, but little evidence has shown how this information affects disposal rates [5–8]. Guidelines from the U.S. Food and Drug Administration (FDA), the U.S. Environmental Protection Agency (EPA), and the U.S. Drug Enforcement Agency (DEA) for disposal of household medicines recommend the use of secure medicine take-back programs as the best disposal option. This recommendation has led to implementation of these programs in hospitals, pharmacies, and police stations throughout the United States. If no take-back program is available, though, the FDA recommends that many commonly prescribed opioids be flushed down the toilet, which is based on the belief that the benefits of immediate disposal outweigh any potential risks to humans or the environment. However, the FDA's "flush list" is not aligned with the disposal guidance of many local jurisdictions across the country that advise against flushing [9].

Over the past few years, a number of commercial products have been developed that claim to provide a means for safe and convenient in-home disposal of waste medicines. Although these drug disposal kits cost more than informational handouts, major retailers and the U.S. Department of Veterans Affairs have begun dispensing the kits at reduced or no cost to patients who fill an opioid prescription in an effort to combat the opioid epidemic [10, 11]. Recent studies suggest that providing postoperative patients with these kits along with personalized discharge teaching increases the rate of leftover opioid disposal [12–14]. However, it is not known whether the simple provision of a drug disposal kit without teaching influences an individual to properly dispose of leftover opioids among a broader patient population.

The Disposal Interventions for Safe Prescription Opioid Surplus Elimination (DISPOSE) trial was a randomized trial designed to establish whether passively supplying a drug disposal kit with an instructional fact sheet to individuals who pick up a short-term opioid prescription at a pharmacy would increase the rate at which they dispose of leftover prescription opioids at 6 weeks, as compared with provision of the fact sheet alone. The secondary objective was to determine whether either intervention was better than no intervention.

Methods

The Johns Hopkins institutional review board approved the protocol for this multi-arm parallel-group trial.

Participants were studied under a waiver of consent until they provided oral informed consent at the time of the first study assessment (see trial protocol and statistical analysis plan in [Supplementary Data](#) Document 1).

Participants

Participants were recruited from two Johns Hopkins Health System outpatient pharmacies located at the Johns Hopkins Hospital, an urban academic medical center located in Baltimore, Maryland, USA. The hospital and health system provide care to inner-city residents and individuals from surrounding communities. One pharmacy is located in the outpatient center, which houses general internal medicine and specialty clinics and an ambulatory surgery center. The second pharmacy is located in the inpatient portion of the hospital and dispenses prescriptions to the majority of patients discharged from the hospital and emergency department. During 2019, the two pharmacies dispensed more than 200,000 prescriptions to more than 35,000 individuals, with approximately 53% of prescriptions being dispensed to Baltimore residents, 31% to Maryland residents residing outside of the city, and 9% to residents of the surrounding states of Delaware, Pennsylvania, Virginia, West Virginia, and the District of Columbia. Eligible patients were identified by pharmacists who screened opioid prescriptions being filled daily from June 5 to June 28, 2019 ([Supplementary Figure 1](#)). To be eligible for randomization, individuals had to fill ≥ 1 prescription provided by a medical or surgical provider for an immediate-release opioid product with ≤ 7 days' supply on a weekday (i.e., Monday to Friday). Adults (age ≥ 18 years) who picked up an opioid prescription for either themselves or a family member, regardless of age, were included.

To minimize the enrollment of individuals receiving chronic opioid analgesia, who would not be expected to dispose of opioids within the study's time frame, individuals were excluded if they filled a prescription with ≥ 8 days' supply of opioid, filled a prescription for an extended-release or long-acting opioid, or had a history of opioid medication listed on their active medication list. Those with an address or phone number outside the United States and those who did not speak English were also excluded.

Randomization, Allocation, and Blinding

For logistical reasons, randomization was based on the day of prescription drop-off. The RANDOMIZE package in STATA (version 15.2, StataCorp LLC, College Station, TX) was used to create a computerized randomization table. It applied a simple randomization pattern of 1:1:1 allocation to the drug disposal kit, fact sheet, and control group [15]. The lead pharmacist concealed assignments from this table until they were communicated electronically the evening before implementation. On the basis of the assignment, pharmacists placed the

intervention in the bag that contained the opioid prescription. Outcome assessors were masked to group assignment.

Interventions

Individuals were provided with one of three interventions along with their opioid prescription. The control group received no specific disposal information, which was standard of care. The second group received an informational sheet detailing safe use, storage, and disposal of opioids, including the methods recommended by the FDA to properly dispose of leftover opioids [16]. The third group received the same information sheet as the fact-sheet group, plus a DisposeRx[®] drug disposal kit (DisposeRx, Inc., Sanford, NC) and instructions on its use [17]. When DisposeRx powder and water are mixed with leftover drug in the prescription bottle, DisposeRx chemically and physically sequesters the medication in a polymer gel that can then be safely disposed of in household trash.

Documents for the two active intervention arms were created by the Johns Hopkins Health System Opioid Stewardship Clinical Community's Patient Education workgroup to have accessible readability scores and availability in multiple languages (Supplementary Data Documents 2 and 3). The pharmacist coordinating the study provided the intervention for each day, removed any interventions from previous days, and reviewed the process and intervention with the pharmacist on duty that morning. The on-duty pharmacist was responsible for checking each filled opioid prescription, logging prescriptions that met inclusion criteria, and confirming that the appropriate intervention was placed in the bag with the medication based on the day. To be consistent with current pharmacy practice, pharmacists and pharmacy technicians provided no additional planned verbal education to individuals in any group.

Data Collection and Quality

A member of the study team made up to three attempts to contact individuals by telephone at 3 weeks after they obtained their opioid prescriptions to assess outcomes through the use of a standardized survey (Supplementary Data Document 4). At the first successful phone contact, the study team member obtained oral consent. A previously tested standardized survey designed to query prescription opioid use, storage, and disposal after surgery was adapted for use at 3 and 6 weeks' follow-up [18]. Individuals who at 3 weeks were continuing to use opioid analgesic therapy, as well as those who did not respond to three telephone call attempts, were re-contacted at 6 weeks. Individuals who filled a subsequent opioid prescription were not re-contacted and were excluded from primary and secondary outcome analyses.

Patient, prescriber, and prescription data were collected through the electronic health record and included

age, sex, race/ethnicity, opioid prescription characteristics, and insurance status. Missing data elements were supplemented by reports from individuals who consented to participate. Oral morphine milligram equivalents for prescriptions were calculated by standard conversion methods [5]. Prescriber credentials were obtained from the National Provider Identifier Registry Public Search. Data collection occurred via Research Electronic Data Capture (REDCap) [19]. Random checks on 10% samples of data suggested high rates of concordance.

Main Outcome Measure

The primary outcome was safe drug disposal, which the interviewer assessed by asking participants whether they had disposed of leftover prescription opioid medications by using an FDA-recommended method of disposal (e.g., a drug take-back program, a drug disposal kit, or flushing down the toilet) up to 6 weeks after they had received an opioid prescription [7]. Because use of a disposal intervention applies only to those individuals who have stopped their course of therapy, the a priori plan was to analyze individuals who reported having stopped taking prescription opioids and who had leftover opioids at the time of follow-up.

Secondary Outcomes

Secondary outcomes included opioid disposal by any method, which was assessed by asking whether any method of disposal had been used; the safe storage of prescription opioids, assessed by asking whether individuals stored opioids in a locked location; and discontinuation of prescription opioid therapy, assessed by asking whether individuals had stopped taking opioids. Similar to the primary outcome, the analysis plan for opioid disposal by any method was to examine only individuals who reported both stopping opioid therapy and having leftover opioids.

Statistical Analysis

Assuming 80% power with an alpha of 0.05, 126 individuals per group were required to detect a difference between the group given the drug disposal kit (estimated safe disposal rate of 33%) and the group given the fact sheet (estimated safe disposal rate of 17%). With the inclusion of the control group (estimated safe disposal rate of 5%) [20, 21], the initial target was 499 eligible randomized individuals.

Preliminary analyses were based on intent to treat and included patients as assigned to their intervention group. Fisher's exact tests were used in unadjusted comparisons of primary and secondary outcomes. In regression models, log-binomial models were used to determine the risk ratios for the independent variables of safe drug disposal and other secondary outcomes by comparing the two groups with active intervention to the control group, with the dependent variable of treatment group.

Sensitivity analyses were conducted by using Poisson models with robust error variance. Outcome measures are presented with 95% confidence intervals (CIs), and P values <0.05 were considered statistically significant. No adjustments for multiplicity were applied. STATA (StataCorp LLC, version 15.2) was used for statistical analysis.

Results

Between June 5 and July 3, 2019, 499 individuals were randomized and received the intended intervention. Among this group, 227 individuals (45%) reported having leftovers after stopping the use of prescription opioids and were included in the primary analysis (73 in the drug disposal kit group, 91 in the fact sheet group, and 63 in the control group; [Supplementary Figure 1](#)). Seventy-one participants (14%) used all opioids, and 46 (9%) continued taking opioids. Among the remaining participants, 100 (20%) were unable to be reached for follow-up assessment, 46 (9%) were reached but declined to participate, and 9 (2%) did not speak English.

Among those who stopped using prescription opioids and had leftovers, the median patient age was 34 years (interquartile range [IQR]: 16–56), and 125 (55%) were women ([Table 1](#)). The most commonly prescribed opioid was oxycodone (88% of all prescriptions). The median daily and total oral morphine equivalents prescribed were 45 mg (IQR: 30–45) and 112.5 mg (IQR: 75–187.5), respectively. Values were similar when we examined all randomized individuals ([Supplementary Table 1](#)).

Safe Opioid Disposal

At 6 weeks, we found no significant difference in safe opioid disposal between the group that received the drug disposal kit (14%) and the group that received the fact sheet (11%) (risk ratio = 1.25; 95% CI: 0.55 to 2.83; [Tables 2 and 3](#)). Furthermore, safe opioid disposal rates did not differ significantly between the control group (10%) and either the drug-disposal-kit group (risk ratio = 1.44; 95% CI: 0.55 to 3.74) or the fact-sheet group (risk ratio = 1.15; 95% CI: 0.44 to 3.01; [Table 4](#)). These findings were unchanged when we examined all patients in sensitivity analyses ([Supplementary Table 2](#)). In all three groups, the most commonly used method for safe disposal among those who had leftovers was flushing the remaining medication down the toilet ($n = 14$), followed by dropping off leftovers at a take-back location ($n = 7$). Furthermore, five respondents (four given a drug disposal kit and one given the fact sheet but no kit) reported using a kit to dispose of leftover medication ([Supplementary Table 3](#)).

Other Outcomes

The likelihood of drug disposal by any method did not differ significantly among the three groups. At 6 weeks,

21% of those who had received a disposal kit and 23% of those who had received a fact sheet reported opioid disposal by any means (risk ratio = 0.89; 95% CI: 0.50 to 1.60). The control group exhibited a similar likelihood of drug disposal by any method (24%). Among the respondents who disposed of unused opioid in a non-FDA-approved fashion ($n = 25$), the most common methods were placing the medication in the trash ($n = 12$) and washing it down the sink ($n = 11$).

Among all individuals who reported where and how their prescription opioids were stored, safe storage in a locked location was reported at similar levels among all groups. The proportion of individuals reporting safe storage ranged from 8% in the control (7/88) and drug disposal-kit groups (8/97) to 14% (15/107) in the fact-sheet group ($P = 0.32$). Similarly, the proportion of individuals who stopped using prescription opioids did not differ between the control group (85%, 89/105) and either the fact-sheet group (88%, 110/125) or drug-disposal-kit group (87%, 99/114) ($P = 0.78$).

Individuals reported receiving disposal information from their health care team at similarly low rates in all groups (range: 10% to 15%; $P = 0.57$). However, reports of receiving disposal information from the pharmacy did differ among groups and were highest in the group that received drug disposal kits (48%; $P = 0.002$; [Supplementary Table 4](#)). Thirty-five percent of participants in the drug-disposal-kit group reported being aware that they had received a kit from the pharmacy. Among individuals in that group, participants who reported being aware of receiving the kit had rates of safe opioid disposal and opioid disposal by any method similar to those of participants who reported being unaware of having received the kit (safe disposal: 17% vs. 13%; Fisher's exact, $P = 0.72$; any disposal: 25% vs. 19%; Fisher's exact, $P = 0.55$). The most common explanation provided by individuals in all study arms for not discarding their leftover opioids was a desire to keep the medication in case it was needed in the future (61% to 63% across groups; [Supplementary Table 5](#)).

Discussion

In this randomized clinical trial of individuals taking a brief course of immediate-release opioid therapy, the passive provision of a drug disposal kit did not increase the disposal rate of leftover opioid as compared with provision of a fact sheet alone. Furthermore, when compared with no intervention, neither the drug disposal kit nor the fact sheet changed the frequency of disposal by any method. Similar proportions of individuals in all three groups reported both safely storing and stopping opioid therapy. Overall, the act of passively providing drug disposal kits or fact sheets did not in and of itself produce a meaningful change in either the safe disposal or any disposal of prescription opioids.

Table 1. Baseline characteristics of eligible individuals who were randomized to a drug disposal kit, fact sheet, or no intervention and had leftover opioids

Characteristic	No Intervention (n = 63)	Fact Sheet (n = 91)	Drug Disposal Kit (n = 73)	P Value
Age, y, median (IQR)	49 (20–59)	33 (14–56)	30 (15–55)	0.08
Age, y				0.41
0 to 17	13 (21)	32 (35)	22 (30)	
18 to 24	5 (8)	6 (7)	10 (14)	
25 to 44	12 (19)	20 (22)	18 (25)	
45 to 64	22 (35)	19 (21)	14 (19)	
65 to 74	7 (11)	9 (10)	6 (8)	
≥75	4 (6)	5 (5)	3 (4)	
Female	37 (59)	43 (47)	45 (62)	0.15
Race/ethnicity				0.94
White	36 (57)	58 (64)	41 (56)	
Black	10 (16)	14 (15)	12 (16)	
Other	13 (21)	16 (18)	16 (22)	
Not reported	4 (6)	3 (3)	4 (5)	
Primary insurance or payer				0.49
Private insurance	41 (65)	55 (60)	45 (62)	
Medicare	6 (10)	6 (7)	4 (5)	
Medicaid	9 (14)	24 (26)	15 (21)	
Cash	6 (10)	6 (7)	9 (12)	
Other	1 (2)	0 (0)	0 (0)	
Prescriber type				0.87
Surgical	57 (90)	83 (91)	68 (93)	
Medical	6 (10)	8 (9)	5 (7)	
Prescriber credentials*				0.21
Physician	47 (75)	60 (66)	59 (81)	
PA	10 (16)	19 (21)	11 (15)	
NP	6 (10)	12 (13)	3 (4)	
Number of opioid prescriptions†				0.34
One	63 (100)	89 (98)	73 (100)	
Two	0 (0)	2 (2)	0 (0)	
Opioid product†				0.34
Oxycodone	58 (92)	78 (84)	65 (89)	
Hydrocodone	0 (0)	4 (4)	1 (1)	
Hydromorphone	2 (3)	2 (2)	3 (4)	
Codeine	1 (2)	0 (0)	1 (1)	
Tramadol	2 (3)	9 (10)	3 (4)	
Opioid formulation†				0.07
Tablet	55 (87)	67 (72)	59 (81)	
Liquid	8 (13)	26 (28)	14 (19)	
Opioids prescribed in total				0.94
OME				
<100	24 (38)	37 (41)	31 (42)	
100 to <200	22 (35)	33 (36)	27 (37)	
≥200	17 (27)	21 (23)	15 (21)	
Opioids prescribed in OME/day				0.24
<30	9 (14)	27 (30)	13 (18)	
30 to <50	48 (76)	52 (57)	53 (73)	
50 to <90	3 (5)	5 (5)	3 (4)	
≥90	3 (5)	7 (8)	4 (5)	

All data are presented as n (%) unless otherwise indicated.

IQR=interquartile range; NP=nurse practitioner; OME=oral morphine equivalents; PA=physician assistant.

*Credentials were identified from a National Provider Identifier Registry Public Search.

†Percentages were calculated on the basis of the number of opioid prescriptions per treatment arm.

The proportion of individuals in this study who reported disposing of leftover opioid medications by any method, though relatively low at 21% to 24%, represents an increase from 4% to 9% in prior years at our

institution [18, 21, 22] and appears to be in line with findings from past studies on patient-reported disposal [20]. However, more recent randomized controlled trials have suggested that providing individuals with drug

Table 2. Outcomes among individuals receiving an opioid prescription who were randomized to receive a drug disposal kit, fact sheet, or no intervention

Parameter	No Intervention	Fact Sheet	Drug Disposal Kit
Drug disposal, n	63	91	73
Safe drug disposal among individuals who stopped using opioids	10 (2 to 17)	11 (5 to 17)	14 (6 to 22)
Any drug disposal among individuals who stopped using opioids	24 (13 to 34)	23 (14 to 32)	21 (11 to 30)
Opioid storage, n	88	107	97
Safe storage of prescription opioids	8 (2 to 14)	14 (7 to 21)	8 (3 to 14)
Opioid usage, n	105	125	114
Stopped use of prescription opioids	85 (78 to 92)	88 (82 to 94)	87 (81 to 93)

Unadjusted between-group comparisons of percentages. Results are shown as percent difference (95% confidence interval); $P > 0.05$ for all differences.

Table 3. Between-group differences for individuals randomized to receive a drug disposal kit, fact sheet, or no intervention (control)

Parameter	Fact Sheet vs. Control	Drug Disposal Kit vs. Control	Drug Disposal Kit vs. Fact Sheet
Drug disposal, n	63	91	73
Safe drug disposal among individuals who stopped using opioids	1 (−8 to 11)	4 (−7 to 15)	3 (−7 to 13)
Any drug disposal among individuals who stopped using opioids	−1 (−13 to 14)	−3 (−17 to 11)	−3 (−15 to 10)
Opioid storage, n	88	107	97
Safe storage of prescription opioids	6 (−3 to 15)	0 (−8 to 8)	−6 (−14 to 3)
Opioid usage, n	105	125	114
Stopped use of prescription opioids	3 (−6 to 12)	2 (−7 to 11)	−1 (−10 to 7)

Unadjusted between-group comparisons of percentages. Results are shown as percent difference (95% confidence interval); $P > 0.05$ for all differences.

disposal kits may lead to further increases in the disposal of prescription opioids. Brummett et al. [12] reported that adult surgical patients who received a drug disposal kit were 3.8 times more likely to dispose of leftover opioids than were those who received usual care. In pediatric studies, Lawrence et al. [13] observed a 20% increase in proper disposal of excess opioids among families of children prescribed opioids after outpatient surgery, whereas Voepel-Lewis and colleagues [13] found that provision of a noncommercial drug disposal kit increased disposal rates by almost 13% from baseline.

The ability of these studies to demonstrate significant and clinically meaningful improvements in the rate of excess opioid disposal by issuing drug disposal kits stands in sharp contrast to our findings of no difference. Although those trials and our present study had many similarities, a number of characteristics distinguish them. First, in our trial, disposal information was provided passively in the form of written handouts at the time of prescription pickup. Neither

the pharmacist nor pharmacy technician spoke with the individual picking up the prescription about its contents, an approach that is consistent with current practice across the Johns Hopkins Health System. In contrast, other clinical trials have included interactive discussions with study subjects about drug disposal kits. In the study by Brummett et al. [12], the intervention was actively delivered to the patient by a nurse who described the disposal kit, showed the subject the disposal product, and reviewed instructions on how to use it before patient discharge. Similarly, families in the study by Lawrence et al. [13] reviewed instructions about kit use with a study team member before patient discharge. In the study by Voepel-Lewis et al. [13], information was not provided in person but instead by way of a scenario-tailored opioid messaging program that study subjects viewed online. In addition to this active educational approach, the awareness of participants that they were enrolled in a study focusing on pain management [12] or opioid therapy [13] may also have altered their behavior

Table 4. Primary and secondary outcomes among individuals receiving an opioid prescription randomized to a drug disposal kit, fact sheet, or no intervention

Characteristic	Risk Ratio (95% CI)	P Value
Primary outcome		
Safe drug disposal among individuals who stopped using opioids (n = 227)		
Control	1 (referent)	
Fact sheet	1.15 (0.44 to 3.01)	0.77
Drug disposal kit	1.44 (0.55 to 3.74)	0.46
Secondary outcomes		
Any drug disposal among individuals who stopped using opioids (n = 227)		
Control	1 (referent)	
Fact sheet	0.97 (0.54 to 1.73)	0.92
Drug disposal kit	0.86 (0.46 to 1.62)	0.64
Safe storage of prescription opioids among all individuals (n = 292)		
Control	1 (referent)	
Fact sheet	1.76 (0.75 to 4.13)	0.19
Drug disposal kit	1.04 (0.39 to 2.74)	0.94
Stopped use of prescription opioids among all individuals (n = 344)		
Control	1 (referent)	
Fact sheet	1.04 (0.94 to 1.15)	0.48
Drug disposal kit	1.02 (0.92 to 1.14)	0.66

CI=confidence interval; ratios estimated using log-binomial models.

and made them more likely to dispose of leftover opioids, in line with the Hawthorne effect [23]. Unlike the passive approach that we used, the active approach, including patient-specific verbal or electronic messaging about analgesic use and disposal kits, aligns well with techniques to enhance patient adherence to desired health care outcomes and represents a likely explanation for why investigators in these past trials observed meaningful improvements in disposal that we did not [24, 25].

Beyond differences in presentation of and instructions about drug disposal kits, other factors may have also played a role in generating divergent findings. First, participants in previous trials consisted solely of postoperative patients. Our provider demographics suggest that many of our subjects were prescribed opioids by a surgical provider to treat procedure-related pain. However, almost 20% received an opioid prescription from a medical provider. Postoperative patients may differ from medical patients in how they receive and follow instructions from members of their health care team after a procedure, a factor that may have enhanced their use of drug disposal kits as reported in other studies [26]. Second, our investigation differed from prior studies with regard to the demographic representation and primary insurance for the patient population, as well as with regard to characteristics of the opioid prescriptions, such as type of opioid and formulation dispensed. Of note, studies by both Lawrence et al. [13] and Voepel-Lewis et al. [13] focused solely on patients less than 18 years of age, whereas Brummett and colleagues [12] studied adults (≥ 18 years) only. Our enrollees included patients of all ages prescribed opioid prescriptions, with rates of Medicare or

Medicaid insurance falling between those of prior studies [12, 13]. Finally, the trials by Brummett et al., Lawrence et al., and Voepel-Lewis et al. all provided study subjects with a different type of drug disposal system than the one provided here. Although each system provided requires individuals to complete only a handful of straightforward steps to safely dispose of unused medication, we do not know whether study subjects may have been more likely to use one drug disposal system than another.

Although our results may appear to suggest that drug disposal kits and fact sheets will make no difference in promoting appropriate disposal of unused opioids, the more likely explanation is that both tools need to be routinely coupled with active patient and caregiver engagement and education. The need for active education seems further warranted if we consider the most commonly cited reason for not disposing of leftover medication—the desire to keep it in case of a future need. That concern may need to be addressed proactively at the time prescriptions are provided. Simply providing drug disposal kits without active education may ultimately contribute little to enhancing opioid disposal while at the same time increasing the cost to patients and insurers [10, 11]. The individual cost of one drug disposal kit is relatively low, but it makes little sense to incur this added expense without actively engaging individuals about appropriate opioid use and disposal. As such, it is important to underscore that findings from the present study should not dissuade clinicians from advocating the use of drug disposal kits, pharmacists from stocking them and promoting their use, health systems from implementing strategies to promote their uptake, and payers from adopting policies that encourage safe drug disposal. Rather, this study calls attention to the need for policies and

programs to support the active engagement of health care professionals involved in all aspects of patient care to work with patients toward the safer stewardship of opioids.

Limitations

Findings from this study should be considered in the context of several limitations. First, participants and pharmacists were not masked to the study intervention, as doing so could not be practically accomplished. Second, primary and other outcomes depended on patient reporting, which could predispose the findings to reporting bias favoring the disposal of opioids; however, bias seems unlikely, as we found no difference in the primary outcome. As in similar prior studies, we did not verify use, storage, or disposal methods. Third, though all individuals in the intervention arms were provided with opioid disposal information, we do not know whether participants read the study materials once home. Fourth, the accrued sample size came close to or lagged that of the calculated sample size among the three intervention groups, which slightly diminished the ability to discern differences between groups. The requisite number of individuals needed to adequately power the study was amplified by similar proportions of safe opioid disposal observed in all arms. Furthermore, participant characteristics may differ from those in the population at large, given that this study was conducted in a single, urban academic health system. Although determinants of health care in our population likely vary from those in other environments, our investigation captures well a mixture of patient demographics, private and other payer coverages, and opioid prescribing practices.

Finally, it should be noted that take-back programs remain the recommended disposal method of the FDA and DEA, whereas the use of in-home drug disposal products, including the one used in this study, has not been endorsed by these agencies. Federal agencies do not have specific performance standards or guidelines for medicine disposal products, and no products have been reviewed or approved. In addition, testing has not convincingly demonstrated that any home medicine disposal products meet the DEA's non-retrievable standard for disposal of controlled substances [9]. These important limitations require consideration, irrespective of the impact of drug disposal kits on rates of home opioid disposal.

Conclusions

The simple provision of a drug disposal kit did not improve the rate of safe opioid disposal or any opioid disposal better than provision of a fact sheet, and neither intervention appeared to differ from no intervention. These results support the need to further investigate active interventions to improve the rates at which individuals safely dispose of leftover prescription opioids.

Supplementary Data

Supplementary data may be found online at <http://pain-medicine.oxfordjournals.org>.

Authors' Contributions

MCB conducted the study and is responsible for the data analysis, had full access to all the data in the study, and takes responsibility for the integrity of the data and the accuracy of the data analysis. MCB, DF, MDS, EW, SAN, and CLM contributed to the concept and design. Acquisition, analysis, and interpretation of data were performed by MCB, DF, EW, MDS and CLM. MCB and CLM drafted the manuscript. All authors contributed to critical revision of the manuscript for important intellectual content. Statistical analysis was performed by MCB. MCB and MDS obtained funding.

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RESEARCH

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Community-based medication disposal pilot initiative in southwest tribal communities

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Abstract

Background: Misuse and abuse of prescription drugs including opioids has been a driving force behind the drug overdose epidemic plaguing communities across the USA for more than two decades. Medication accumulation in the home environment can contribute to this issue. However, research on proper disposal in rural communities is limited. For this project, an applied public health approach was used to raise awareness and improve prescription drug disposal practices by pilot testing prescription drug disposal systems in participating communities.

Methods: A community-based disposal project was facilitated with assistance from community partners. The project centered on distribution of drug deactivation bags in homes and medication drop boxes at multiple healthcare facilities.

Results: The team distributed 215 drug deactivation bags to 162 community households resulting in destruction of 8011 pills, 8 medicated dermal patches and 777 mL of liquid medication. A total of 4684 pounds of medication were collected and disposed of through healthcare facility drop boxes.

Conclusion: The strategies identified are scalable and easy to replicate to meet any community's needs in reducing potential challenges of medication diversion.

Keywords: Behavior change, Interventions, Public health, Poisoning, Medication disposal, Community, Opioids, Tribal

Background

Misuse and abuse of prescription drugs, including opioids, has been a driving force behind the overdose epidemic plaguing communities across the nation for more than two decades. As the leading cause of injury-related death, drug overdose claimed the lives of more than 70,000 individuals in 2019 (National Institutes of Health 2020). The impact of prescription drug abuse/misuse

has been felt across all racial and ethnic groups; however, American Indian/Alaskan Natives (AI/AN) have felt the magnitude of the crisis. In 2018, AI/AN population had the second-highest drug overdose death rate (14.2 deaths/100,000 people) in the USA (Wilson et al. 2020).

Published literature suggests medication left unsecured in the home contributes to an increased risk of intentional medication abuse, theft, diversion by individuals and unintentional poisoning due to ingestion by small children or pets (McCance-Katz 2019).

The US Food and Drug Administration (FDA) provides guidance for proper medication disposal, which includes disposal at drug take-back sites (e.g., retail pharmacies,

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police departments), flushing in a domestic sewer system if listed on the FDA approved “Flush List,” which includes some medications sought after for their misuse and/or abuse potential, or other types of medications that can be discarded in the domestic trash (Center for Drug Evaluation and Research n.d.).

Due to the remote setting of many tribal communities, literature is limited on barriers and access to proper medication disposal. This often results in stockpiling medications in the home environment or improperly discarding in the trash or toilet. From a previous project survey conducted by the Indian Health Service (IHS) Injury Prevention Program (IPP), only one out of every five individuals who had been prescribed medications disposed of them properly. To address this issue, IHS introduced strategies to improve disposal.

IHS is the principal healthcare provider and health advocate for AI/AN communities, which includes preventative services offered by IPP. IHS consists of 12 geographical areas across the USA; each area supports a unique group of tribes (Service, I. H. 2020). Within IHS Division of Environmental Health Service, IPP is designed to assist tribal communities to reduce injury-related risk factors. As of 2018, injuries were the leading cause of AI/AN death among those ages 1–54 (National Center for Injury Prevention and Control, C. n.d.). Through collaborative efforts, IPP utilized an applied public health approach to raise awareness, provide education and improve prescription drug disposal practices by pilot testing two drug disposal systems.

Methods

The project’s goal was to determine if the distribution of drug deactivation bags and medication drop boxes would serve as acceptable options for medication disposal in tribal communities. Both methods met US Drug Enforcement Administration (DEA) requirements. Tribal leadership in participating communities and the appropriate IHS Institutional Review Board formally approved the project.

Baseline assessment

During routine home safety assessments, medications were frequently observed stockpiled and unsecured throughout the residence. Anecdotal comments were received from tribal elders and other community members expressing the need for education and access to proper medication disposal options. In addition, telephone interviews were conducted by IPP staff to document IHS and tribally operated healthcare facility pharmacy department perspectives to better understand community disposal options.

During interviews, the following were asked:

1. Is education provided to the community regarding proper disposal of expired/unused medications?
2. Is there a location within the healthcare facility for community members to dispose of medications?
3. If there is no system in place, would the facility participate in a project focused on safe medication disposal?

Responses indicated that none of the healthcare facilities had an openly accessible system for collecting and disposing of unused or expired medications. Baseline information suggested accessible options for medication disposal would reduce unused/excess prescription medications in the home environment.

Drug deactivation bags

Drug deactivation bags were provided to IPP at no additional cost as part of a statewide response to the opioid epidemic; however, there is an average cost of \$3.90 per bag. Over 1700 bags were received for distribution among tribal communities across Arizona. This initiative was piloted within six communities over a three-month period.

Product description

Drug deactivation bags selected for this project contained carbon-activated powder that neutralizes medication. Medium-size bags were distributed, which allow for destruction of 45 pills, six fluid ounces of liquid medication, and six dermal patches. Deactivation bags work by depositing medications, adding warm water, sealing, and shaking the bag to mix contents. After 30 s, contents are deactivated and safe for deposit in the domestic trash.

Tools development

An educational flyer was created to promote participation and provide step-by-step instructions of deactivation bags.

A community partner distributed the flyer and bags along with an in-person overview. A data collection form was developed for use during distribution. The forms gathered the following information: patient’s age and quantity of unused/expired medication (whether pills, patches, liquid or other); quantity and medication type being disposed; reason for disposal (i.e., discontinued, expired, unused, or other); and whether medication was prescribed for pain relief. Discontinued medications were classified as: medical provider, original prescriber, instructed individuals to discontinue use; expired medications were those beyond the use-by or expiration date; unused medications were defined as medications individuals elected to stop taking. An individual completing the form could select multiple options as reasons for

medication disposal, such as expired and discontinued, or unused and expired. Space was provided for both community partners and community members to initial and verify the destruction of medications. A master data collection spreadsheet was created to track usage for all pilot sites.

Distribution

Pharmacists and community partners distributed drug deactivation bags using multiple methods: (1) during community events, (2) during home or provider office visits, and (3) through door-to-door campaigns. Community partners included Community Health Representatives (CHR) Program and Public Health Nurses (PHN) that provide home health services to community members. The CHR/PHN program is a primary healthcare program that provides services geared toward health promotion, disease prevention, and reducing health risks at the community level for elderly or disabled patients. As part of their role, they advocate for public health at the local level and assist community members with medication distribution.

Prior to implementation, a brief kick-off meeting was held with the community partners to discuss the project goals and deliverables. This meeting also served as a training session to review the project materials, to view a 2-min “how-to” video by the manufacturer, and as an opportunity for hands-on training.

Medication drop boxes

Baseline assessments revealed IHS and tribally operated healthcare facilities did not have drop boxes for community medication disposal. Although they offered periodic take-back events, they were interested in obtaining a box to expand disposal options for their patients. Twenty-six (26) of the 29 participating sites were in rural setting. This was defined using Rural–Urban Commuting Area (RUCA) code methodology (Defining rural population 2021). This portion of the project included healthcare facilities in Arizona, Minnesota, Nevada and Oklahoma.

Product description

Stainless-steel collection drop boxes with the capacity to hold 18 to 36 gallons were selected for the project. The box secures to the floor or wall and is equipped with two locks on the main door and a one-way medicine drop. Each box included a removable, prepaid, ship-back liner. When full, liners must be sealed and returned to the vendor via common carrier to undergo proper destruction. Boxes for this project were purchased through approved government vendors and cost between \$1300 and \$1450 per unit. Annual maintenance, which included liner and common carrier fee, ranged from \$465 to \$675. Drop box

site installations were in accordance with Title 21 Code of Federal Regulation Part 1317 Subpart B enforced by DEA. Requirements included: (1) a DEA license, (2) 24-h monitoring and (3) bolted/secured to floor or wall.

Tools development

A flyer was developed and provided to points of contact (POC) highlighting the importance of the medication drop box, benefits to the community and the facility, and DEA requirements for collection sites. A centralized tracking spreadsheet was developed to analyze disposal data made available by the manufacturer through an online portal.

Distribution

Funding for drop boxes was site-specific. Chief Pharmacists were the facility POCs and were responsible for obtaining funding for the drop box and its maintenance.

Results

Key findings from this pilot project included the widespread distribution of medication deactivation bags in conjunction with increased public knowledge and awareness of medication drop box locations.

Drug deactivation bags

In May 2019, the IPP collaborated with five Arizona tribal communities and distributed 215 drug deactivation bags to 162 community households. These bags were used to destroy 8011 pills, 777 mL (mL) of liquid, and eight medicated dermal patches (Table 1).

Unused medications were the leading reason for disposal, followed by discontinued medications. Of the 8011 pills destroyed, 1054 were unused; 862 were discontinued; 221 were disposed due to being expired; 359 were a combination of being discontinued, expired, or unused; and, 246 were due to “other” reasons not listed. Of the 777 mL liquids, 713 mL were neutralized due to discontinued use, and 64 mL were disposed of for varied reasons (e.g., discontinued and expired). All eight patches were destroyed due to discontinued use (Fig. 1).

Table 1 Forms of medications disposed of using the deactivation bags

Types of medications disposed	Number of medications disposed
Pills	8011
Patches	8
Liquid	777 mL

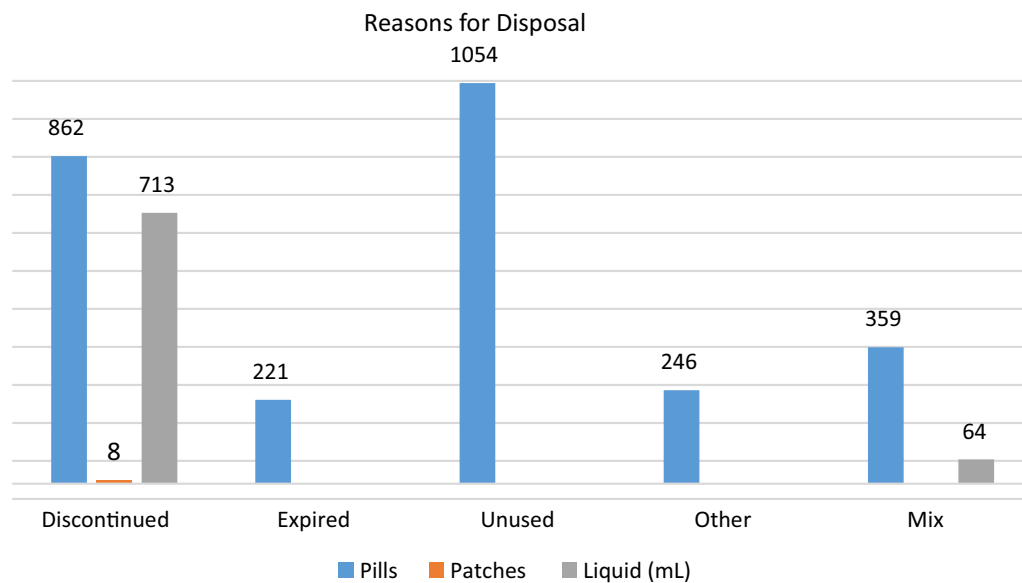


Fig. 1 Reasons for medication disposal. Reasons for medication disposal. Participant self-identified reasons for disposing medication which included: discontinued use, expired medication, unused medication, for other reasons, or mixed reasons. Unused medication was the leading reason for disposal

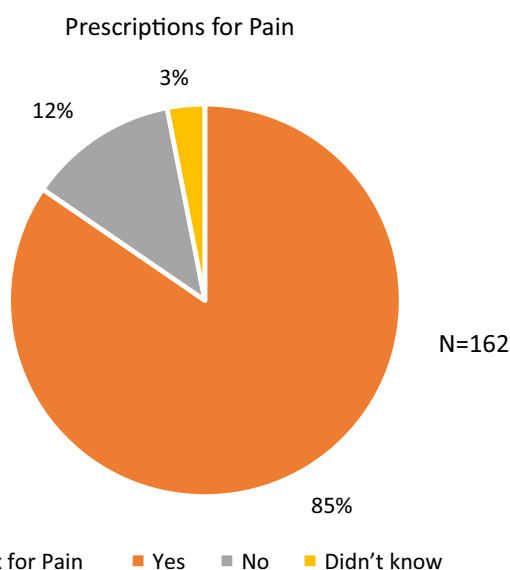


Fig. 2 Prescriptions for pain. Prescriptions for pain. Participants self-identified the nature of prescription was pain medication. Majority of the prescription were identified as not for pain

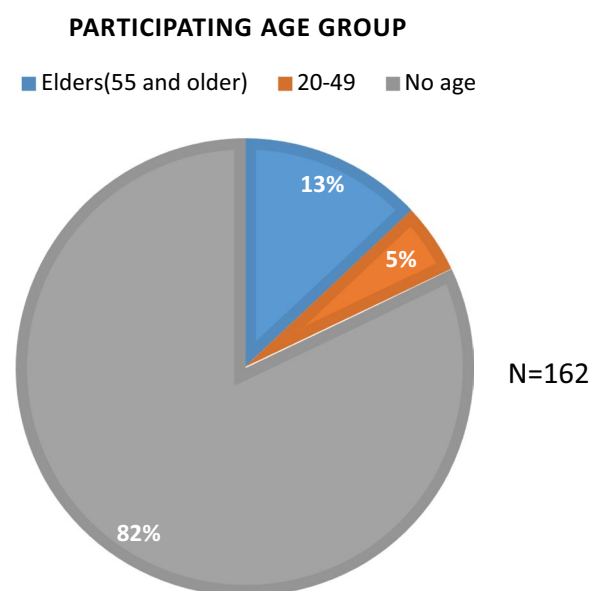


Fig. 3 Participants by age. Participants by age. Age of participants that disposed of medication using drug deactivation bags. Elders 55 and older, overwhelming participated in this medication disposal project

Eighty-five percent ($n = 137$) of households reported “Yes” that they were disposing of prescription pain medication, while 12% ($n = 20$) reported “No” to disposing of pain medication; and 3% ($n = 5$) reported, “Didn’t Know” if they were disposing of pain medication (Fig. 2).

Of persons in the participating 162 households, 82% ($n = 133$) did not self-report their age; 13% ($n = 21$) identified as elders (i.e., 55 and above age group); and 5% ($n = 8$) identified as adults (i.e., 20–49 age group) (Fig. 3).

Table 2 Forms of medications disposed of using the deactivation

Setting	Number of sites	Number of drop boxes	Pounds disposed FY19	Pounds disposed FY20	Total pounds disposed
Rural	26	31	1506.73	2506.05	4012.78
Urban	3	3	297.8	373.45	671.25
Grand total	29	34	1804.53	2879.5	4684.03

Table 3 Forms of medications disposed of using the deactivation

Site	Number of sites	Number of drop box	Pounds disposed FY19	Pounds disposed FY20	Total pounds disposed
Federal	17	20	1636.43	1730.1	3366.53
Tribal	12	14	168.1	1149.4	1317.5
Grand total	29	34	1804.53	2879.5	4684.03

Medication drop boxes

From October 1, 2018, to September 30, 2020 data were collected from 34 drop boxes located in 29 healthcare facilities. A total of 4684 pounds of medication were collected and disposed of through healthcare facility drop boxes. Ninety percent of the boxes were located in rural settings (Table 2).

Federal healthcare facilities disposed of 3367 pounds of medication during the project period (Table 3).

Discussion

Based on findings from this project, limited knowledge and access to medication disposal can lead to stockpiling medications in the home, potentially leading to increased diversion, theft or abuse. Many communities in rural settings do not have the same access as those in urban settings. Collection differences in rural communities may also be attributed to lack of access to retail pharmacies or other limitations such as lack of available resources for medication disposal.

The two interventions selected for this project were a result of the community engagement process. This led to increased acceptance and participation. Prior to the project, medication disposal options were limited. At completion of the project, multiple options were available and used. Partnering with healthcare facilities contributed to the success of this project due to their convenience and visitation frequency by the community members. Access to disposal in the home environment was also a convenient alternative for rural tribal communities. This project benefited from the multiple partnerships that exist in

tribal communities. The CHR and PHN programs that conduct home health services were critical to the implementation of the drug deactivation bags in the home environment. These programs were instrumental in providing education for proper medication disposal in addition to identifying recipients of resources made available by state partners.

Limitation

Data collection instruments designed for this project were not end user friendly. As a result, there were gaps in collecting information regarding types of medications disposed. Moreover, to further validate the findings of this project, additional marketing would be needed to expand the number of participants. Lastly, materials used for this project required external funding and future projects would have to identify funding sources. An additional barrier to replicate this project on a larger scale is to identify community partners to distribute and market project interventions.

Conclusion

The project assessed distribution of drug deactivation bags and medication drop boxes, which proved to be acceptable options for medication disposal in tribal communities. Community education coupled with access to effective disposal options in the home environment and local healthcare facilities resulted in collection of unused/expired medications and reduced diversion risk. The strategies identified in this project are scalable and easy to replicate to address safe medication disposal.

Abbreviations

AI/AN: American Indians/Alaska Natives; CHR: Community Health Representatives; DEA: Drug Enforcement Administration; FDA: Food and Drug Administration; FY: Fiscal Year; IHS: Indian Health Services; IPP: Injury Prevention Program; PHN: Public Health Nurses; POC: Point of Contact.

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About this supplement

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Authors' contributions

IA, AT, RM, LA and MS provided substantial contributions to the conception and design of the work; or the acquisition, analysis or interpretation of data for the work; and drafting the work or revising it critically for important intellectual content. DB and WC provided contributions by revising the work critically for important intellectual content. All authors provided final approval of the version to be published and are in agreement to be accountable for

all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Although no personal identifying information was collected during this project, the authors voluntarily elected to obtain written permission from each tribal government to implement, evaluate, and publish the findings of the project. The Phoenix Area Indian Health Service IRB determined no review was necessary and provided a written waiver.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Prescription Opioid Analgesics Commonly Unused After Surgery

A Systematic Review

Mark C. Bicket, MD; Jane J. Long, BS; Peter J. Pronovost, MD, PhD;
G. Caleb Alexander, MD, MS; Christopher L. Wu, MD

IMPORTANCE Prescription opioid analgesics play an important role in the treatment of postoperative pain; however, unused opioids may be diverted for nonmedical use and contribute to opioid-related injuries and deaths.

OBJECTIVE To quantify how commonly postoperative prescription opioids are unused, why they remain unused, and what practices are followed regarding their storage and disposal.

EVIDENCE REVIEW MEDLINE, EMBASE, and Cochrane Central Register of Controlled Trials were searched from database inception to October 18, 2016, for studies describing opioid oversupply for adults after a surgical procedure. The primary outcome—opioid oversupply—was defined as the number of patients with either filled but unused opioid prescriptions or unfilled opioid prescriptions. Two reviewers independently screened studies for inclusion, extracted data, and assessed the study quality.

FINDINGS Six eligible studies reported on a total of 810 unique patients (range, 30-250 patients) who underwent 7 different types of surgical procedures. Across the 6 studies, 67% to 92% of patients reported unused opioids. Of all the opioid tablets obtained by surgical patients, 42% to 71% went unused. Most patients stopped or used no opioids owing to adequate pain control, and 16% to 29% of patients reported opioid-induced adverse effects. In 2 studies examining storage safety, 73% to 77% of patients reported that their prescription opioids were not stored in locked containers. All studies reported low rates of anticipated or actual disposal, but no study reported US Food and Drug Administration–recommended disposal methods in more than 9% of patients.

CONCLUSIONS AND RELEVANCE Postoperative prescription opioids often go unused, unlocked, and undisposed, suggesting an important reservoir of opioids contributing to nonmedical use of these products, which could cause injuries or even deaths.

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Opioid analgesics play an important role as a safe and effective method for pain relief when used appropriately. Despite this role, the benefits of opioids in treating pain have to be balanced with their risks, including tolerance, dependence, and respiratory depression. *Nonmedical use* of opioids, defined as taking medication for a purpose other than as prescribed, often leads to more serious harms, such as abuse, addiction, or life-threatening overdose. To address the opioid epidemic, efforts have largely focused on opioid prescribing among those with chronic non-cancer pain.¹ In contrast, the risks for and evidence of patients with acute pain following surgery are less well characterized.²

Surgery often serves as the inaugural event for many patients to obtain a prescription for opioids, fill it at the pharmacy, and take opioid medications on a frequent basis. Prescriptions may go

unfilled for several reasons, including adequate pain control after surgery. When prescriptions are filled, opioid-naïve patients may inadvertently transition into long-term opioid users.^{3,4} Low-risk surgical procedures give rise to most opioid-naïve patients receiving and filling prescriptions for oxycodone, hydrocodone, or another opioid.⁵ Patients may fill the prescription but not use all of the medication, leading to a reservoir of pills that can potentially contribute to the nonmedical use of opioids.

Given the lack of data-driven approaches to opioid prescribing after surgery, we conducted a systematic review to examine the prevalence of unused prescription opioids among home-going adults following inpatient or outpatient surgery. We defined our primary outcome—*opioid oversupply*—as the number of patients who either elected to not fill an opioid prescription or filled the

opioid prescription but did not use the medication following surgery. We also examined the volume of unused opioids, reasons for not taking the medication, and storage and disposal practices.

Methods

Data Sources and Search

We adhered to the Preferred Reporting Items for Systematic reviews and Meta-Analyses guidelines, including protocol registration with PROSPERO on June 9, 2016.⁶ We searched MEDLINE, EMBASE, and the Cochrane Central Register of Controlled Trials without language restriction from database inception to July 20, 2016, and updated our search on October 18, 2016. For studies fulfilling the inclusion criteria, we used Web of Science to search citation lists and cite studies from database inception to July 20, 2016. We created a search strategy using a controlled vocabulary of known studies meeting the inclusion criteria and focused on specific terms associated with the concepts of adults (population), opioids (intervention), surgery or procedure (intervention), and medication use and prescription (outcome; eMethods in the [Supplement](#)).

Inclusion Criteria and Outcome Definition

We included cross-sectional and cohort studies and randomized clinical trials of adult surgical patients who were prescribed an oral opioid medication by a medical professional at the time of postsurgical discharge. We included both inpatient and outpatient procedures and did not apply any restrictions regarding surgery type. We required studies to report on *unused opioid medication*, defined as unfilled prescriptions or unused tablets. We excluded retrospective studies, those that described nonsurgical or pediatric (age <18 years) patients, and those that did not report the outcome of unused opioids.

We calculated the percentage of patients who had an oversupply of a prescription opioid as the sum of patients not filling opioid prescriptions and patients filling opioid prescriptions but reporting unused opioids. For the denominator, we used the number of patients provided an opioid prescription after surgery. Secondary outcomes included the number of opioid tablets (or volume of solution) unused by the patient, morphine equivalents of prescription opioid medication unused by the patient, reasons for not using or stopping opioid therapy, and opioid storage and disposal characteristics.

Two reviewers (M.C.B. and J.J.L.) independently assessed 2419 nonduplicate studies, with 2324 studies failing title and abstract screening. Of the 95 studies retrieved and assessed by the 2 reviewers, 6 (6%) fulfilled the inclusion criteria (κ statistic = 0.78) (eFigure in the [Supplement](#)).

Data Extraction and Quality Assessment

Two of us (M.C.B. and J.J.L.) independently extracted relevant study characteristics using a data extraction template. Data included study design, setting, patient population, type of surgery, opioid prescription characteristics, unused opioid tablets, reasons for stopping or not using opioid therapy, and opioid storage and disposal characteristics. Storage characteristics included the location and use of a lock to secure opioids according to the guidelines of the US Food and Drug Administration and the Centers for Disease Control and Prevention.^{1,7} For disposal, Food and Drug Administration-

Key Points

Question How commonly are prescription opioid analgesics unused among adult patients after a surgical procedure?

Findings In this review of 6 studies involving 810 unique patients who underwent orthopedic, thoracic, obstetric, and general surgical procedures, 67% to 92% of patients reported unused opioids. Rates of safe storage and/or disposal of unused prescription opioids were low.

Meaning Unused opioids prescribed for patients after surgery are an important reservoir of opioids available for nonmedical use and could cause injuries or even deaths.

recommended methods included returning the medication to the pharmacy or a drug take-back program or flushing the medication down the sink or toilet. Two reviewers (M.C.B. and J.J.L.) assessed the quality of studies and the potential bias using the Newcastle-Ottawa Scale⁸ adapted for observational studies or the Cochrane Risk of Bias Tool⁹ for clinical trials. Disagreements between the reviewers regarding data extraction and quality assessment ratings were resolved by discussion and consensus.

Data Synthesis

We aggregated extracted data by type of surgery, reporting on study characteristics, opioid use, reasons for opioid therapy cessation, and opioid storage and disposal characteristics. We qualitatively summarized outcomes across surgery type because of differences in patient populations, which precluded quantitative data pooling.

Results

After full-text review, 6 studies met our prespecified inclusion criteria, with all studies describing populations in the United States (Table 1 and eTable 1 in the [Supplement](#)).¹⁰⁻¹⁵ Among the prospective studies considered for this review, 1 study was identified as having duplicate reports^{14,16} and 3 were excluded¹⁷⁻¹⁹ for inability to distinguish surgical from nonsurgical reports of unused opioid medications.

Six eligible studies prospectively evaluated the oversupply of opioids after 7 types of surgery, including obstetric, thoracic, orthopedic, and urologic. Practice settings described surgeons employed by 4 institutions and 1 private practice between January 1, 2011, and December 31, 2016. Studies primarily evaluated outpatient procedures ($n = 4$), with fewer reports of inpatient ($n = 2$) or mixed ($n = 1$) procedures. In all, 810 unique patients received at least 1 opioid prescription after surgery. Patient samples ranged in size from 30 for cesarean delivery to 250 for orthopedic surgery. Follow-up most commonly ranged in duration from 1 to 5 weeks after surgery.

All 6 studies were rated as having intermediate quality. Reporting of baseline characteristics important for comparability, such as preprocedural use of opioid medications, varied among the studies: 3 studies excluded patients because of preprocedural opioid use (within 7 or 30 days),^{13,15,16} 1 study assessed and reported preprocedural use via self-report,¹⁰ and 2 studies neither excluded such patients nor recorded this characteristic.^{11,12}

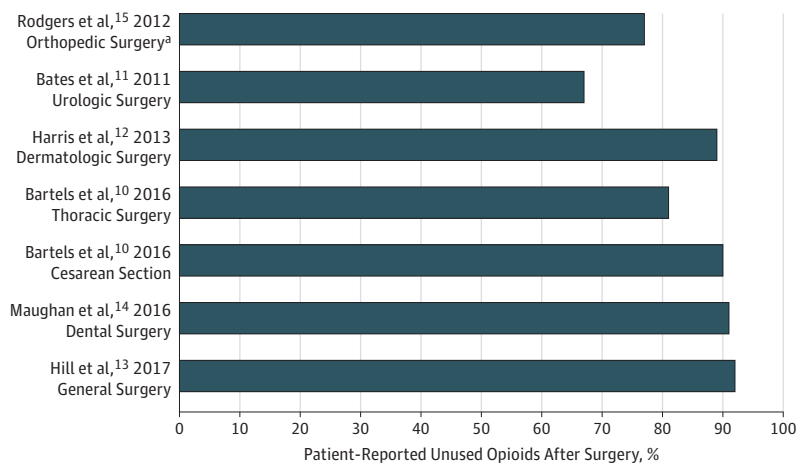
Table 1. Characteristics of Studies Assessing Unused Opioids After Surgery

Source	Study Design	Study Setting	Procedure Type	Study Population	All Patients, No.	Female, No. (%)	Study Length, Mean (SD), d
Bartels et al, ¹⁰ 2016 ^a	Cross-section	University of Colorado	Cesarean delivery	Inpatient	30	30 (100)	30 (12)
Bartels et al, ¹⁰ 2016 ^a	Cross-section	University of Colorado	Thoracic surgery	Inpatient	31	16 (52)	32 (14)
Bates et al, ¹¹ 2011	Cross-section	University of Utah	Urologic surgery	Mixed	226	NR	NR (14 to 28)
Harris et al, ¹² 2013	Prospective cohort	University of Utah	Dermatologic surgery	Outpatient	72	20 (28)	NR (3 to 4)
Hill et al, ¹³ 2017	Cross-section	Dartmouth Medical Center	General surgery	Outpatient	127	NR	NR (NR to 180)
Maughan et al, ¹⁴ 2016	RCT	University of Pennsylvania	Dental surgery	Outpatient	74	NR	21 (NR)
Rodgers et al, ¹⁵ 2012	Cross-section	Iowa private practice	Orthopedic surgery	Outpatient	250	167 (67)	11 (7 to 14)

Abbreviations: NR, data not reported; RCT, randomized clinical trial.

^a Bartels et al report on 2 distinct surgical populations—cesarean delivery and thoracic surgery.

Figure. Prevalence of Unused Opioids Prescribed After Surgery



^a Percentage of patients reporting use of 15 tablets or fewer.

Table 2. Utilization in Studies Assessing Unused Opioids After Surgery

Source	Patients Reporting, No. (%)			Unused Opioid Tablets	
	Any Unused Opioid	Unfilled Opioid Prescription	Filled Prescription Without Opioid Use	No. Unused/Used (%)	Mean (SD) ^a
Bartels et al, ¹⁰ 2016 ^b	27/30 (90)	4/30 (13)	2/30 (7)	NR	NR
Bartels et al, ¹⁰ 2016 ^b	25/31 (81)	0/31 (0)	3/31 (10)	NR	NR
Bates et al, ¹¹ 2011	NR (67)	13/226 (6)	NR	NR (42)	NR
Harris et al, ¹² 2013	64/72 (89)	15/72 (21)	10/72 (14)	NR (68)	5 (4)
Hill et al, ¹³ 2017	117/127 (92)	NR	NR	2527/3545 (71)	20 (NR)
Maughan et al, ¹⁴ 2016	67/74 (91)	2/74 (3)	NR	1102/2051 (54)	15 (NR)
Rodgers et al, ¹⁵ 2012	193/250 (77) ^c	NR	NR	4639/NR	19 (NR)

Abbreviation: NR, data not reported.

^a Mean unused opioid tablets per patient.

^b Bartels et al report on 2 distinct surgical populations—cesarean delivery and thoracic surgery.

^c Percentage of patients reporting use of 15 tablets or fewer.

Opioid Oversupply

The prevalence of unused opioids after surgery was high for all 7 procedures examined, with 67% to 92% of patients reporting unused opioids (Figure). Table 2 highlights the primary outcome and associated secondary outcomes. Patients reported large amounts of unused opioids following both outpatient surgery (77%-92%) and inpatient surgery (67%-90%). In 5 of the 7 surgical settings examined, more than 80% of patients reported unused opioids. Three studies examined patient reports of filling

a prescription but no opioid use and patient reports of not filling the opioid prescription, and 2 studies examined only the latter outcome. A small number of patients either did not fill their opioid prescription (0%-21%) or filled the prescription but did not take any opioids (7%-14%). A significant number of opioid tablets went unused after surgery, ranging from 42% to 71% of pills dispensed.

Reasons for not consuming opioid medications were reported for 3 types of procedures (eTable 2 in the Supplement). Most patients

Table 3. Storage and Disposal Characteristics for Unused Opioids After Surgery

Study	Patients Reporting, No. (%)					
	Storage			Disposal		
	Locked or Unlocked Location		Unlocked Storage	Performed or Planned	FDA-Recommended Method Used	No Disposal Instructions
Bartels et al, ¹⁰ 2016 ^a	6/23 (26)	Cupboard/wardrobe	17/22 (77)	1/23 (4)	1/23 (4)	NR
	16/23 (70)	Medicine cabinet/other box				
Bartels et al, ¹⁰ 2016 ^a	5/24 (21)	Cupboard/wardrobe	16/22 (73)	2/24 (8)	1/24 (4)	NR
	13/24 (54)	Medicine cabinet/other box				
Bates et al, ¹¹ 2011	NR	NR	NR	15/164 (9)	5/164 (3)	213/231 (92)
Harris et al, ¹² 2013	NR	NR	NR	9/49 (18)	2/49 (4)	NR
Hill et al, ¹³ 2017	NR	NR	NR	NR (26)	NR (9)	NR
Maughan et al, ¹⁴ 2016	NR	NR	NR	8/27 (30) ^b	NR	NR

Abbreviation: FDA, Food and Drug Administration; NR, data or descriptive text not reported.

^a Bartels et al report on 2 distinct surgical populations—cesarean delivery and thoracic surgery.

^b Based on control group.

(71%- 83%) described not taking opioids because of adequate pain control, and fewer patients (16%-29%) reported concern for adverse effects induced by opioids. Only 1 study examined patients' concern about addiction: 8% of patients who underwent thoracic surgery avoided opioids for this reason.¹⁰

Storage and Disposal

Patients' storage of prescription opioids was characterized for 2 types of surgery, focusing on cesarean delivery and thoracic surgery (Table 3). Most patients stored opioids in a medicine cabinet or another box (54% to 70%), and some used a cupboard or wardrobe (21% to 26%). Notably, a high percentage (73% to 77%) of patients stored opioids in unlocked locations. Five studies examined patients' opioid disposal practices: few patients (4% to 30%) planned to or actually disposed of their unused prescription opioids, and even fewer patients (4% to 9%) considered or used a disposal method recommended by the Food and Drug Administration.

Discussion

In this systematic review, more than two-thirds of patients reported unused prescription opioids following surgery. These findings were consistent across several studies of general, orthopedic, thoracic, and obstetric inpatient and outpatient surgeries. Of the 5 studies examining storage and disposal practices, 3 of 4 patients reported failing to store opioids in a locked location, and planned or actual safe disposal of opioids rarely occurred. These findings are important because of the magnitude of injuries and deaths attributable to the nonmedical use of prescription opioids in the United States, and oversupply of these products contributes to this epidemic.

Several factors likely contribute to how commonly patients report unused opioid medications. Health care professionals may not be aware of how commonly opioids go unused,² and heterogeneous patient populations and procedure types complicate the development of evidence-based prescribing guidelines in these settings. However, some patient-reported outcomes and psychological

profiles may inform pain intensity and subsequent analgesic use after surgery. For example, Thomazeau et al²⁰ correlated postoperative pain for total knee arthroplasty with preoperative pain at rest, anxiety levels, and symptoms of neuropathic pain. In another example, Carvalho et al²¹ associated pain scores and analgesic use for women after cesarean delivery with psychological questionnaires and simple patient-reported ratings.

We recommend a data-driven approach to prescribing opioids after surgery. An inappropriate response to the problem of unused opioids would be to pursue a reflexive one-size-fits-all tactic that indiscriminately curtails opioid prescribing after invasive procedures given the critical consequences of pain undertreatment, the possibility of inducing drug-seeking behavior, and the important role that opioid medications serve in controlling postoperative pain.^{2,22} As health care professionals encounter new regulations, such as prescription drug monitoring programs in most states and electronic prescribing requirements in New York,²³ the evidence associated with these interventions continues to evolve.²⁴ At a national level, guidelines emphasize the importance of nonopioid analgesics, such as acetaminophen, nonsteroidal anti-inflammatory drugs, and gabapentinoids, as well as nonpharmacologic approaches, such as exercise, cold, and heat.^{2,25}

In addition, we found that opioids were seldom stored and disposed of correctly. Safe storage practices mitigate risks for other household members, such as adolescents at risk of misusing medication accessible in the house.^{26,27} The failure to properly dispose of opioids highlights the role of stockpiling as an important contributor to their nonmedical use. Stockpiling is common given the time and energy involved in properly disposing medicine. Patients may perceive a future utility for keeping opioids besides saving money: pain medication will relieve acute pain should it return in the future. Medication take-back programs help to address the oversupply of tablets sitting around the house.²⁸ Pharmacies and health systems facilitate the capture of an enormous amount of drug products during US Drug Enforcement Agency-sanctioned take-back days, community-based collection events,²⁹ and coordinated programs, such as National Prescription Drug Drop-off Day in Canada.³⁰ However, these events secure only a small fraction of

opioids available for nonmedical use and remain in rudimentary stages of implementation.²⁹ Pharmacies appear as one possible solution but assume unwanted costs and liabilities in taking back scheduled medications. Few commercial solutions (eg, disposal bags) exist, relegating patients to flushing opioids down the sink or toilet, which may reduce individual risk at the expense of the environment.

The combination of unused opioids, poor storage practices, and lack of disposal sets the stage for the diversion of opioids for nonmedical use. Based on the 2015 National Survey on Drug Use and Health, an estimated 3.8 million Americans engage in the nonmedical use of opioids every month.³¹ More than half of people (54%) who misused an opioid medication in 2014 obtained opioids from a friend or relative.³² Most of these pills were either given for free, bought, or taken without asking. The second largest source of misused opioids (36%) was a prescription from 1 or more physicians and other clinicians.³² Because more than 90% of opioids originate from medical practitioners, family, or friends, the oversupply of opioids in health care environments that appear otherwise innocuous deserves additional scrutiny.

Limitations

Despite the importance of our findings, our review had several limitations. First, the studies we examined were of intermediate rather than high methodological quality, and the questionnaires completed by patients varied in form, structure, phrasing, and timing across the studies. Many studies also failed to ascertain a history of opioid use among respondents and did not describe essential fea-

tures for cross-sectional and cohort studies, such as nonrespondents and missing data. Evidence gaps also exist for surgical subspecialties as well as for individual surgical operations aside from the 7 types reported here. Second, we were not able to estimate leftover morphine equivalents for these patients because this information was not reported in any of the studies examined or to examine more granular data regarding unused opioid pill counts to determine a consistent, clinically relevant definition of unused opioids. Data on additional surgical subspecialties would enhance the generalizability of these findings, which largely agree with most estimates of nonsurgical opioid prescribing in acute, chronic, or both types of pain. For example, Porucznik et al¹⁸ showed similarly high rates of leftover pills among adults prescribed opioids. Regarding storage, Reddy et al¹⁹ showed similar rates of unlocked medication in cancer patients prescribed opioids. Finally, heterogeneity across the studies precluded any quantitative pooling of the results.

Conclusions

Most patients who underwent surgery in these studies had unused prescription opioids, and safe storage and disposal of unused medications rarely occurred. Increased efforts are needed to develop and disseminate best practices to reduce the oversupply of opioids after surgery, especially given how commonly opioid analgesics prescribed by clinicians are diverted for nonmedical use and may contribute to opioid-associated injuries and deaths.

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Study concept and design: Bicket, Pronovost, Wu.
Acquisition, analysis, or interpretation of data: Bicket, Long, Alexander.

Drafting of the manuscript: Bicket, Long, Wu.
Critical revision of the manuscript for important intellectual content: Bicket, Pronovost, Alexander.
Statistical analysis: Bicket.

Administrative, technical, or material support: Bicket.

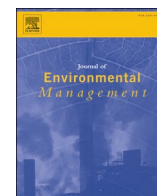
Study supervision: Bicket, Pronovost, Alexander, Wu.

Conflict of Interest Disclosures: Dr Alexander reported being chair of the US Food and Drug Administration's Peripheral and Central Nervous System Advisory Committee and serving as a paid consultant to PainNavigator, a mobile startup to improve patients' pain management; as a paid consultant to QuintilesIMS; and on a scientific advisory board of QuintilesIMS Health. This arrangement has been reviewed and approved by The Johns Hopkins University according to its conflict-of-interest policies. No other disclosures were reported.

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Research article

Pharmaceutical pollution sources and solutions: Survey of human and veterinary medication purchasing, use, and disposal

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ABSTRACT

Human and veterinary pharmaceuticals offer many benefits, but they also pose risks to both the environment and public health. Life-cycle stewardship of medications offers multiple strategies for minimizing the risks posed by pharmaceuticals, and further insight is required for developing best practices for pharmaceutical management. The goal of this study was to clarify points of intervention for minimizing environmental and public health risks associated with pharmaceuticals. Specifically, our objectives were to provide insight on purchasing, use, and disposal behaviors associated with human and veterinary medications. This study used a state-wide representative sample of Vermont adults ($n = 421$) to survey both human and veterinary pharmaceuticals as potential sources of the unintended consequences of prescribed and over-the-counter (OTC) medications. The majority (93%) of respondents had purchased some form of medication within the past twelve months, including OTC (85%), prescription (74%), and veterinary (41%) drugs. Leftover drugs of any kind were reported by 59% of respondents. While 56% of people were aware of drug take-back programs, the majority reported never being told what to do with leftover medications by their physician (78%), pharmacist (76%), or veterinarian (53%). Among all respondents, take-back programs were the most common disposal method (22%), followed by trash (19%), and flushing (9%), while 26% of respondents reported keeping unused drugs. Awareness of pharmaceutical pollution in the environment and having received information about proper disposal were both significantly associated with participation in take-back programs. These findings indicate that a large volume of drugs are going unused annually, and that only a portion of leftover medications are returned to take-back programs where they can be appropriately disposed. Our results warrant further investigation of clinical interventions that support lower dose prescribing and dispensing practices in order to reduce the unintended environmental and public health consequences of pharmaceuticals within the consumer sphere. In addition, our findings suggest that directed efforts to raise awareness of proper disposal may be more effective than broad awareness campaigns, and we recommend research on the efficacy of providing disposal instructions on drug packaging.

1. Introduction

Pharmaceuticals provide tremendous benefit by curing disease, alleviating symptoms, and improving quality of life—but in so doing, they also pose a number of unintended consequences to public health and the environment. Over the past century, Americans in particular have increasingly relied upon medications, filling 4.38 billion prescriptions in 2019 alone (Shahbandeh 2019). Similarly, veterinary care for pets increasingly relies upon medications with \$19.2 billion USD

spent on purchasing animals, supplies, and medication in 2019 (American Pet Products Association, 2020). Evidence from across the U.S. and around the world suggests that many drugs go unused, leading to concerns about diversion and the related public health crisis of opioid addiction (Neill et al., 2020; Seth et al., 2018), and environmental pollution from improper disposal (Lam et al., 2018; Tong et al., 2011). The primary concern of this article is to provide insight into consumer behaviors, from point-of-contact with medical providers to practices regarding leftover medications.

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1.1. Pharmaceuticals in the environment

The global occurrence of pharmaceuticals in the environment is now well-established (aus der Beek et al., 2016; Hughes et al., 2013; Sui et al., 2015). Pharmaceutical contaminants have been identified globally in surface waters (Deo 2014; Fekadu et al., 2019) including freshwater ecosystems (Fekadu et al., 2019; Pal et al., 2010), estuaries (Letsinger et al., 2019; Reis-Santos et al., 2018), and marine environments (Ojemaye and Petrik 2019), as well as groundwater (Fram and Belitz 2011; Zainab et al., 2020), and drinking water (Furlong et al., 2017; Khan and Nicell 2015). Sources of pharmaceuticals in the environment include drug manufacturing facilities (Scott et al., 2018), intensive livestock production (Jaffrézic et al., 2017), landfill leachate (Lu et al., 2016), sewage sludge biosolids (García-Santiago et al., 2016), municipal wastewater treatment facilities (Yang et al., 2017), and atmospheric deposition (Deere et al., 2020).

The pharmacokinetics and continuous flow (i.e. pseudo-persistence) of the active ingredients and metabolites of various medications into the environment is of concern to the health of aquatic species and ecosystems (Tijani et al., 2016). Pharmaceuticals are known to impact a wide variety of non-target biota including zooplankton, fish, mammals, and plants (Klimaszynski and Rzymiski 2017; Sarma et al., 2017; Sathishkumar et al., 2020). Evidence of physiological (Arnold et al., 2014; Brooks 2014), behavioral (Brodin et al., 2014; Valenti et al., 2012), and reproductive failure (Bringolf et al., 2010; Fursdon et al., 2019) associated with pharmaceutical pollutants among numerous aquatic species is well-documented.

1.2. Identifying pathways and interventions for minimizing pharmaceutical pollution

Several points of intervention for minimizing pharmaceutical pollution have been identified including wastewater treatment to remove pharmaceutical residues from effluent (Couto et al., 2019; Yang et al., 2017). While some treatment technologies show promise in their capacity to remove drug compounds from wastewater (Shi et al., 2017), the cost of implementing such processes can be a barrier (Kosek et al., 2020). As a result, various forms of source reduction are considered more feasible options for removing environmental pharmaceutical residues, including life-cycle stewardship of medications (Daughton and Ruhoy 2011), lower-dose prescribing (Daughton and Ruhoy 2013), and improved consumer disposal behaviors (Kusturica et al., 2016).

Increasing consumer participation in appropriate disposal practices is considered a promising avenue for reducing the volume of medications entering the environment. For over a decade, drug take-back programs have been offered as one option for diverting unused medications from landfills and wastewater (Lubick 2010) and are currently the preferred disposal method for unused and expired medications (Environmental Protection Agency, 2019), but reports suggest that participation varies widely. An early review of pharmaceutical disposal practices from eight countries found that returning unused drugs to pharmacies ranged from a low of 1% in the United States to a high of 58% in the Netherlands (Tong et al., 2011). Recent studies have shown similar results from around the world, ranging from drug take-back participation of 4% in Lebanon (Massoud et al., 2016), to 21% in Kabul (Bashaar et al., 2017). In the United States, despite concerted efforts by the federal government to develop safe disposal mechanisms for consumers through the creation of the Drug Enforcement Administration's National Drug Takeback Initiative and the implementation of the Safe and Secure Drug Disposal Act of 2010, few take-back programs have been successful at increasing consumer awareness and participation in these initiatives (Stoddard and Huggett 2012). In previous work in Vermont, only 24% of university students were aware of take-back programs, and 4% had ever used take-back services (Vatovec et al., 2017). Regarding veterinary drug disposal, the American Veterinary Medicine Association and National Sea Grant Office

developed a Memorandum of Understanding for proper disposal of veterinary medications in 2011 (American Veterinary Medicine Association, 2011), though even veterinarians themselves tend to dispose of unused drugs via municipal trash (Lam et al., 2018). More work is needed for increasing awareness and participation in appropriate disposal of unused medications.

An area that is increasingly cited as a key point of intervention for minimizing pharmaceutical pollution is reduction of the volume of unused medications (West et al., 2014) resulting from patient non-adherence, adverse drug effects, modification in dosage, drug expiration, and prescribing and dispensing practices (Ruhoy and Daughton 2008; Seehusen and Edwards 2006). A study in California found that up to 67% of prescribed human medications go unused (Law et al., 2015). Several opportunities exist to prevent leftover drugs from being generated through clinical practices, including addressing over-prescribing and overdispensing (Boxall et al., 2012).

Two particular cases of global concern provide some insight into the potential for clinical actions to minimize the risks associated with unused pharmaceuticals: opioids and antibiotics. In the case of opioid misuse and addiction, overprescribing is a well-established contributor to this global public health crisis (Degenhardt et al., 2019; Makary et al., 2017). One recent study of over 7600 elective surgery patients in the U. S. showed that 81% of patients received more than the recommended narcotic prescription at hospital discharge (Thiels et al., 2017). In the E. U., suggested interventions to minimize opioid-related deaths focus in part on primary care strategies to minimize demand for opioid prescriptions (Alho et al., 2020). Similarly, a quality improvement project in the U.S. that implemented provider education, accountability, and oversight led to a 38% reduction in opioid prescriptions (Meisenberg et al., 2018). In the case of antibiotic resistance in the environment, clinical practices have long been associated with this global concern, and several provider-focused strategies for reducing antibiotic over-prescription have been identified (Bertollo et al., 2018; Rodrigues et al., 2013). Programs designed to educate patients and providers about antibiotic over-prescription show effectiveness, though interventions that focus on patient-clinician communication have been identified as most effective at decreasing unnecessary antibiotic prescriptions (Hu et al., 2016). Antibiotic resistance is of major concern within the global veterinary community, and a survey of clinicians at a U.S. veterinary teaching hospital found that 88% felt that antibiotics were over-prescribed at the hospital, and 91% reported that at least one class of antibiotics should be restricted from use in companion animals because of the public health concerns of resistance (Jacob et al., 2015). These insights provide evidence in support of interventions to modify clinical prescribing and dispensing practices in both human and veterinary health care.

To the authors' knowledge, the present study is the first of its kind to use a representative sample of adults to survey both human and veterinary prescription and OTC medications as potential sources of pharmaceutical pollution. Building upon earlier work that offered a snapshot of pharmaceutical behaviors among a young adult population in Vermont, the goals of the present study were to 1) expand current understanding of state-wide pharmaceutical behaviors by using a representative sample of the Vermont population and including both human and veterinary medications, 2) provide a baseline for measuring the success of future interventions targeted at minimizing pharmaceutical pollution, and 3) provide insight into purchasing, use, and disposal behaviors associated with both human and veterinary medications in order to support evidence-based approaches to minimizing the environmental and public health risks associated with pharmaceuticals.

2. Materials & methods

This study reports data from a survey of a representative sample of Vermont residents conducted during the fall of 2016, and was approved by the University of Vermont Institutional Review Board (CHRB)

14–612). The survey instrument was based on our previous survey of university students (Vatovec et al., 2017), and questions were pre-tested with research associates and students. The survey tool included questions on demographics, purchasing, use, and disposal of OTC, prescription, and veterinary medications, and respondent's knowledge of pharmaceutical pollution and participation in drug take-back programs (see Supplemental Material).

Data were collected by the Center for Rural Studies at the University of Vermont as part of the 2016 Vermonter Poll. The survey was conducted between the hours of 12:00 p.m. and 8:30 p.m. in October and November 2016. Telephone polling was conducted from the University of Vermont using computer-aided telephone interviewing (CATI). A random sample for the poll was drawn from lists of Vermont landline and cellular telephone numbers. Only Vermont residents over the age of eighteen were interviewed.

A total of 421 Vermont residents over the age of 18 agreed to participate and completed the survey. Based upon 421 valid responses, the overall study results have a margin of error of plus or minus 5 percent with a confidence level of 95 percent. Consistent with current phone surveys, 61% of respondents were reached by cell phone, 51% of whom did not have a landline (Marken 2018).

2.1. Statistical analysis

Descriptive statistics were used to characterize participant demographics, and behaviors related to pharmaceutical purchasing, use, and disposal. Chi-square tests were used to evaluate whether respondent characteristics were associated with pharmaceutical disposal behaviors. Any p values less than 0.05 were considered statistically significant. All analyses were conducted using the Statistical Package for Social Science version 26.

3. Results & discussion

3.1. Survey demographics

The overall demographics of the survey population were representative of the Vermont population in terms of gender, race, income, and locality (Table 1). The survey population was relatively older and more educated than Vermont's general population, a finding that is typical of phone surveys (Marlar et al., 2018).

3.2. Pharmaceutical purchasing and use behaviors

The majority (93%) of respondents had obtained some form of human or veterinary medication within the past twelve months, including OTC and prescription drugs (Table 2). Sixty-three percent of respondents reported animal ownership ($n = 264$), which is just below the national rate of pet ownership at 67% (National Pet Owners Association, 2020). Veterinary medications were purchased by 41% of all respondents (66% of animal owners). The average number of veterinary medications purchased in the past year was 2.4 per animal owner. The most common animals reported were dogs (42% of all respondents) and cats (38%).

Human OTC and prescription pharmaceutical use varied from daily use to rare use of a few times in the past year (Table 2). These numbers are higher than national statistics of prescription drug use between 2013 and 2016 which reported 48% of the U.S. population had used at least one prescription medication in the past 30 days (Centers for Disease Control 2017). One possible explanation for this difference is the fact that the median age of Vermonters (43 years) is older than that of the national median (38 years), and people tend to use more pharmaceuticals as they age (Department of Health 2018). In terms of the numbers of drugs being used by Vermonters, the present results follow national trends from the same time period with 48% of Americans using at least one prescription drug, 24% using three or more, and 13% using five or

Table 1

Demographic characteristics of respondents to pharmaceutical behavior telephone survey of Vermont residents aged 18 years or older ($n = 421$)^a.

Variable	Respondents n (%)	Vermont Population ^b (%)
Gender		
Female	219 (54)	(51)
Male	188 (46)	(49)
Race		
White or Caucasian	368 (95)	(94)
Black or African American	5 (1)	(1)
American Indian or Inuit	6 (2)	(<1)
Asian or Pacific Islander	2 (<1)	(2)
Other	7 (2)	(2)
Ethnicity		
Hispanic or Latino/a	6 (2)	(2)
Not Hispanic or Latino/a	382 (98)	(98)
Age (years)		
18–34	64 (16)	(19) ^c
35–44	48 (12)	(11)
45–54	75 (19)	(14)
55–64	88 (22)	(16)
65–74	72 (18)	(11)
75 +	48 (12)	(7)
Income		
<\$25,000	56 (16)	(21)
\$25 to \$50,000	74 (21)	(22)
\$50 to \$75,000	81 (23)	(19)
\$75 to \$100,000	67 (19)	(14)
>\$100,000	79 (22)	(24)
Education		
Less than high school	11 (3)	(8)
High school	65 (16)	(29)
Some college or Associate's degree	107 (27)	(27)
Bachelor's degree or higher	214 (54)	(36)
Locality		
Urban	60 (15)	(39) ^d
Suburban	88 (23)	na ^e
Rural	242 (62)	(61)
Health insurance		
Private insurance	214 (61)	(55)
Medicare/Medicaid	132 (38)	(39)
Uninsured	6 (2)	(4)

^a Data within each category may not equal 421 due to missing values.

^b Data from United States Census Bureau <https://data.census.gov/cedsci/>; Vermont total population estimate for the year the survey was completed (2016): 624,594.

^c U.S. Census Data is for adults aged 20–34 years for age category.

^d Urban/rural population data is from U.S. Census 2010; no suburban data available. https://www.census.gov/newsroom/releases/archives/2010_census/cb12-50.html.

^e na = Not available.

more prescription drug therapies (Centers for Disease Control 2017).

3.3. Leftover medications

Leftover drugs of any kind were reported by 59% of respondents (Table 2). This result supports concerns that a large volume of medications go unused, requiring appropriate disposal, and closely matches our previous finding that 61% of university students in Vermont reported leftover drugs (Vatovec et al., 2017) and echoes similar surveys of unused human medication from across the country (Law et al., 2015) and around the world (Nepal et al., 2020). In addition, the findings of this study reflect recent research examining unused veterinary medications in which between 46% and 74% of veterinary professionals reported leftovers (Lam et al., 2018). Several factors lead to unused medications, including low costs the result in bulk purchasing, insurance models that prefer dispensing in volume, and a lack of regulation on the production of waste (Wöhler et al., 2020). Our findings on the most common reasons reported for the occurrence of unused medications—discontinued use,

Table 2

Purchasing and use of human and veterinary over-the-counter (OTC) and prescription pharmaceuticals among Vermont residents (n = 421).

Variable	OTC drugs n (%)	Prescription drugs n (%)
Pharmaceutical purchasing behaviors ^a		
Obtained human medication in past 12 months.	359 (85)	313 (74)
Obtained veterinary medications in past 12 months.	96 (23)	123 (29)
Use of human medications in past 12 months.		
Never used medication in the past 12 months.	38 (9)	95 (23)
Used medication daily.	115 (27)	247 (59)
Used medication at least once a week, but not every day.	84 (20)	11 (3)
Used medication at least once a month, but not every week.	94 (22)	12 (3)
Used medication a few times in the past 12 months.	98 (23)	31 (7)
Quantity of human medications used in past 12 months.		
Used 1 to 3 different medications in the past 12 months.	287 (68)	188 (45)
Used 4 to 6 different medications in the past 12 months.	60 (14)	78 (19)
Used 7 or more different medications in the past 12 months.	11 (3)	44 (10)
Occurrence of leftover medications of any kind.		
Report leftover drugs	252 (59)	
Reason for leftover medications of any kind. ^a		
More came in the package than was needed.	104 (25)	
I used it until I felt better, then stopped using it.	105 (25)	
It didn't work for me so I stopped using it.	57 (13)	
The medication expired.	54 (13)	
Physician directed to stop using.	43 (10)	
Awareness of pharmaceutical take-back programs.		
Aware of National Drug Take-Back Day or local program.	235 (56)	
Sources of pharmaceutical disposal information. ^a		
The internet	100 (24)	
Pharmacist	71 (17)	
Physician	50 (12)	
Family and friends	47 (11)	
Drug packaging	41 (10)	
Veterinarian	21 (5)	
Have never received information	84 (20)	
Frequency of disposal information given by healthcare provider.	Every or most visits	Some visits
Physician	10 (2)	52 (12)
Pharmacist	23 (5)	50 (12)
Veterinarian	8 (2)	17 (4)
Status of leftover medications of any kind. ^a		
Report disposing of any leftover medications.	208 (49)	
Report keeping any leftover medications.	109 (26)	
Report giving any leftover medications to friends or family.	7 (2)	

^a Multiple responses possible.

more dispensed that required, expiration—provide further evidence in support of the concern of over-prescribing, over-purchasing, and over-dispensing (Vatovec et al., 2017). Together, these findings support long-standing concerns that a large volume of medications that are prescribed and dispensed are not medically required, and become sources of environmental and public health risks (Ruhoy and Daughton 2008). As a result, the authors argue that clinical prescribing and dispensing practices are a clear point for intervention to minimize the volume of medications that are purchased by consumers but will not be used.

3.4. Pharmaceutical disposal knowledge

The majority of respondents had never been told how to properly

dispose of unused medications by their physician, pharmacist, or veterinarian (53% of all respondents, 84% of pet owners; Table 2). These findings are consistent with previous studies of healthcare provider practices regarding drug disposal. In the U.S., a survey of pharmacists showed that the majority supported educating patients about proper drug disposal, but 68% actually provided this information to consumers once a month or less (Tai et al., 2016). Among veterinarians in the U.S., a survey study found that although the majority of these clinicians were concerned with pharmaceutical pollution, proper drug disposal was discussed with clients in only 19% of appointments (Lam et al., 2018). In India, a series of recent surveys among doctors, nurses, and pharmacists have found that while the majority of providers believed that proper disposal was everyone's responsibility, few actually knew appropriate protocols for drug disposal (Aditya and Rattan 2014; Bhayana et al., 2016; Raja et al., 2018). In Romania, 33% of surveyed pharmacists report having refused drugs returned by consumers, citing a lack of protocols among other concerns (Bungau et al., 2018). The growing evidence of the need for clear and consistent ways to educate consumers about proper drug disposal raises the question of what role clinicians including physicians, pharmacists, and veterinarians can play in increasing consumer awareness and participation in drug take-back programs (Abahussain et al., 2012; Gray-Winnett et al., 2010; Wilson et al., 2011).

Fifty four percent of respondents reported ever having looked for drug disposal information, with the internet being the primary source of information (Table 2). The authors were surprised by the result that few respondents (10%) indicated ever finding disposal information through drug packaging. The authors suggest that drug packaging is one area deserving of further attention since it is the most accessible form of information that consumers will have literally in-hand when they are questioning what to do with leftover medications. Limited research has investigated drug packaging as a source of disposal information, with a survey of patients using therapeutic opioid medications reporting that 30% of people had received proper disposal information on opioid packaging (Kennedy-Hendricks et al., 2016). Requiring proper disposal information on drug packaging may be a promising avenue for promoting take-back programs, and warrants further study.

3.5. Pharmaceutical disposal behaviors

Most respondents indicated that when they have leftover medications they dispose of them (Table 2). These results follow similar trends from previous studies conducted in the U.S. (Kotchen et al., 2009; Law et al., 2015; Seehusen and Edwards 2006), as well as more global reviews (Kusturica et al., 2016; Tong et al., 2011; Vollmer 2010). Drug take-back programs were the most commonly reported disposal behavior, of which police departments were most used for returning unused drugs (Table 3). While the number of people disposing of drugs via trash and flushing continue to because for concern, the relatively higher proportion of people reporting use of take-back programs is a positive outcome and supports the implementation of offering convenient, local take-back options through police departments and neighborhood pharmacies (Stoddard et al., 2017).

Over one quarter of respondents reported keeping leftover drugs, raising concern over the public health risks of accidental poisoning (Tadros et al., 2016), drug diversion (Schirle et al., 2020), and the environmental risks of future disposal behaviors as people continue to accumulate unused medications.

Disposal methods varied by medication type (Table 3), which provides some insight into which types of drugs require greater intervention in terms of consumer education about proper disposal. Opioids and antibiotics were among the five most commonly disposed types of both human and veterinary pharmaceuticals. These numbers relate to several public health concerns, including antibiotic resistance and the risk of narcotics diversion discussed above. One promising study from China suggests that directed programs to increase awareness of antibiotic take-

Table 3

Pharmaceutical disposal behaviors among Vermont residents who reported ever having leftover or unused medications of any type (n = 252).

Disposal of medications	n (%)		
Method of medication disposal used			
Returned to drug take-back program.	92 (37)		
Threw them out in the garbage.	80 (32)		
Flushed them down the drain.	31 (12)		
If take-back, type of program used			
Police department take-back	52 (21)		
Pharmacy take-back	37 (15)		
National Drug Take-Back Day	10 (4)		
Mail-in program	1 (0.4)		
Disposal behavior by medication type	Flush	Trash	Takeback
Liquids	50 (20)	46 (18)	22 (8)
Pills	22 (9)	77 (31)	87 (35)
Creams	1 (<1)	120 (48)	20 (8)
Aerosols	0 (0)	56 (22)	24 (10)
Type of medication disposed	Human (% of respondents who reported leftover medication)		Veterinary (% of respondents who reported having animals)
Cold medicine	50 (20)		na ^a
Antibiotic	46 (18)		12 (5)
Non-opioid pain reliever	35 (14)		4 (2)
Opioid	29 (12)		3 (1)
Allergy/antihistamine	26 (10)		2 (<1)

^a na = not applicable.

back programs can successfully encourage participation in safe disposal programs (Lin et al., 2020).

This survey did not distinguish between disposal methods of human versus veterinary medications, but given that the present results show that these two sources of unused medications may both contribute substantial volumes of pharmaceutical pollution, we believe it would be useful in future studies to ask specific questions regarding these drug types in order to design more targeted disposal interventions.

Age and gender were not associated with disposal behaviors. Awareness of both pharmaceutical pollution in the environment and take-back programs were significantly associated with use of take-back programs (Table 4). Awareness of environmental risks posed by pharmaceutical pollution has previously been found associated with disposal behaviors (Kusturica et al., 2016). However, our results also show that awareness is not enough to ensure participation in take-back programs, a finding that echoes recent studies in Afghanistan (Bashaar et al., 2017), Malaysia (Ariffin and Zakili 2019) and Poland (Rogowska et al., 2019).

The reasons given for not using a take-back program included not having medication to throw out (50%), not knowing the time or location to drop-off drugs (6%), wanting to keep the unused medications (6%), inconvenient time or location (5%), or not feeling comfortable returning drugs to a program (3%). Though limited research has been done on participation in take-back days, an intervention study in Texas found that while 73% of people surveyed said they would be willing to participate in a take-back day, more than half would not be willing to travel farther than 5 miles to do so (Stoddard et al., 2017). A survey of employees at a Turkish company found that 47% of respondents reported a change in their behaviors regarding unused drug disposal when the company implemented a drug take-back drop-box program on-site, indicating that convenience and awareness both play a role in

Table 4

Respondent characteristics associated with pharmaceutical disposal behaviors among people who reported ever having leftover or unused medications of any type (n = 252).

Variable	Return unused drugs to take-back program n (%) ^a	Keep unused medications n (%)	Dispose of unused medication in trash or flush down-the-drain n (%)	p value ^b
Awareness of pharmaceutical pollution in the environment				<0.001
Yes	52 (21.8)	81 (33.9)	106 (44.4)	
No	5 (9.1)	10 (18.2)	40 (72.7)	
Awareness of take-back programs				<0.001
Yes	57 (22.5)	91 (36.7)	105 (41.5)	
No	0 (0)	0 (0)	41 (100)	
Received information about proper drug disposal ^c				0.004
Yes	37 (22.8)	58 (35.8)	67 (41.4)	
No	21 (15.4)	33 (24.3)	82 (60.3)	
Number of sources of disposal information received ^d				0.84
One source	22 (22.2)	33 (33.3)	44 (44.4)	
Two sources	8 (24.2)	12 (36.4)	13 (39.4)	
Three or more sources	7 (23.3)	13 (43.3)	10 (33.3)	

^a Percentages within rows.

^b p values are from chi-square tests evaluating whether disposal behaviors varied by respondent characteristics.

^c Sources of pharmaceutical disposal information included drug packaging, healthcare providers, internet, and family/friends.

^d Analysis of number of sources of disposal information limited to only respondents who reported receiving any amount of information (n = 162).

encouraging preferred behavior (Akici et al., 2018). These results contribute to previous findings and further support the idea that continual local take-back programs may be better than individual take-back days for increasing participation in safe disposal behaviors (Kotchen et al., 2009).

People who reported having received information about proper disposal from any source (including the internet, healthcare providers, drug packaging, or family and friends) were significantly more likely to have participated in take-back programs (Table 4). However, receiving more than one source of information about proper disposal was not associated with increased participation in this preferred disposal method. While previous studies have called for identifying appropriate roles for clinicians and pharmacists to play in raising consumer awareness about appropriate drug disposal (Ehrhart et al., 2020; Hwang 2013), the present results suggest that identifying key points of intervention for concerted effort at increasing awareness of proper drug disposal may be more effective and efficient than a broader educational approach.

4. Conclusions

To our knowledge, this study offers the first representative state-wide survey of both human and veterinary pharmaceutical purchasing, use, and disposal. Our results indicate four primary outcomes: 1) leftover pharmaceuticals continue to occur at high rates which beg the question of their fate and impact on the environment and public health, 2) veterinary medications may represent a sizable portion of medications needing proper disposal, 3) awareness of both environmental risks of pharmaceutical pollution and take-back programs increases participation in preferred disposal behaviors, but that still only a portion of drugs are returned to take-back programs, and 4) several options exist for increasing awareness of appropriate disposal, but a concerted educational effort may be more effective than multiple interventions. The fact that a large proportion of consumers continue to report leftover prescription medications provides further evidence in support of lower volume prescribing and dispensing practices among physicians,

veterinarians, and pharmacists. Furthermore, the large volume of leftover OTC drugs supports the development of interventions to move away from bulk sales of such medications.

When leftover medications do occur, the present results suggest that further measures are needed to encourage appropriate disposal. While our findings show that more Vermonters are now returning drugs to take-back instead of disposing of them in the trash or down-the-drain, there is a long way to go in capturing the majority of unused drugs. The classic public health problem that awareness does not mean action appears as much a problem here in considering proper drug disposal as it does with the documented challenges of tobacco: people may report awareness, but that awareness does not equate to healthy behaviors. More needs to be done to nudge behavior than simply providing information to people. The fact that Vermonters are using local police station and pharmacy take-back programs rather than the less-convenient National Drug Take-back Day events supports the idea that medication disposal falls within the “make the healthy choice the easy choice” challenge. The authors recommend research on the efficacy of requiring disposal information directly on drug packaging, in addition to studying what specific roles physicians, pharmacists, and veterinarians could effectively play in promoting preferred drug disposal behaviors.

Credit author statement

Christine Vatovec, Conceptualization, Methodology, Formal analysis, Resources, Data curation, Writing – original draft, Writing – review & editing, Supervision. Jane Kolodinsky, Methodology, Investigation, Formal analysis, Writing – review & editing. Peter Callas, Methodology, Formal analysis, Writing – review & editing. Christine Hart, Investigation, Writing – review & editing. Kati Gallagher, Formal analysis, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jenvman.2021.112106>.

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September 2019

PRESCRIPTION OPIOIDS

Patient Options for Safe and Effective Disposal of Unused Opioids

Why GAO Did This Study

In 2017, an estimated 11.1 million Americans misused a prescription pain reliever, which included opioids. This misuse contributes to opioid abuse and death, which has quintupled from 1999 to 2017; about 17,000 people died from prescription opioid overdoses in 2017. Government agencies and stakeholders have attempted to address the potential for misuse and abuse by facilitating safe disposal of unused prescription opioids and other drugs.

The SUPPORT for Patients and Communities Act enacted in 2018 included a provision for GAO to review patient disposal of unused opioids, among other things. This report examines (1) federally recommended and other available methods patients may use to dispose of unused prescription opioids, and (2) what is known about patients' use of these methods.

To do this work, GAO examined peer-reviewed, academic literature on outcomes for prescription opioid disposal; reviewed federal agency documentation; interviewed federal agency officials, independent researchers, and stakeholder group representatives—such as those from the American Medical Association; and analyzed DEA data as of April 2019 on permanent drug collection sites. GAO also interviewed representatives of three companies that manufacture commercial in-home disposal products and reviewed publicly available documents about these products.

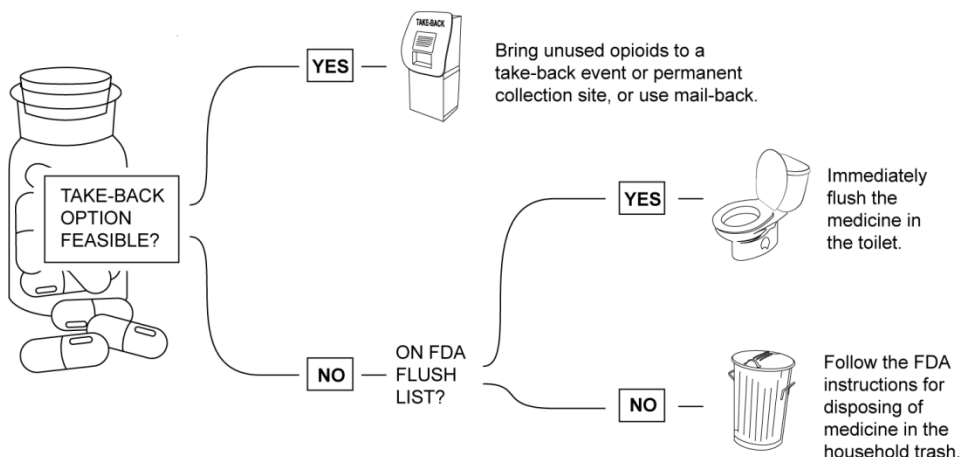
PRESCRIPTION OPIOIDS

Patient Options for Safe and Effective Disposal of Unused Opioids

What GAO Found

The Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), and Environmental Protection Agency (EPA) recommend that patients dispose of unused prescription opioids by bringing them to DEA-registered collection sites or a DEA take-back event, or using mail-back programs. As of April 2019, 70 percent of the U.S. population lived less than 5 miles from permanent collection sites, which are often located at pharmacies. If collection sites, take-back events, or mail-back programs are not feasible, FDA recommends quickly and permanently removing the most dangerous prescription opioids, such as hydrocodone and fentanyl, from the home by flushing them down the toilet. For all other prescription opioids, the agencies recommend disposal in the trash after mixing them with unpalatable substances, such as cat litter. Commercial products to facilitate in-home disposal also exist, and FDA is aware that patients may opt to use these products for disposal in the trash.

FDA Recommendations for Disposal of Unused Prescription Opioids



Source: GAO analysis of Food and Drug Administration (FDA) documents. | GAO-19-650

Available studies suggest that many patients are unaware of federally recommended disposal methods or choose not to dispose of unused prescription opioids. For example, five studies found that between one-quarter and three-quarters of patients stored unused opioids for future use or had misplaced their unused opioids. Further, federal data indicate that 85 percent of intentional misuse occurs with the patient's knowledge—for example, when a patient sells or gives away unused prescription opioids. To educate and motivate patients to dispose of unused opioids, FDA launched a public awareness campaign called "Remove the Risk" in April 2019. Also, FDA and other stakeholders have created educational materials for patients and providers on safe opioid disposal.

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Abbreviations

AMA	American Medical Association
CDC	Centers for Disease Control and Prevention
DEA	Drug Enforcement Administration
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
REMS	risk evaluation and mitigation strategy
RCRA	Resource Conservation and Recovery Act
SAMHSA	Substance Abuse and Mental Health Services Administration
SUPPORT Act	SUPPORT for Patients and Communities Act

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September 3, 2019

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Frank Pallone Jr.
Chairman
The Honorable Greg Walden
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Substance Abuse and Mental Health Services Administration (SAMHSA) estimates that in 2017, 11.1 million people aged 12 or older used a prescription pain reliever, which includes opioids, in a way not intended by the prescriber.¹ Health care providers prescribe opioids to treat chronic pain and after an acute medical event, such as a surgery, to help patients manage pain while they heal.² Because patients may not take all of the opioids that their providers prescribe, many possess excess opioids that could be misused by the patient or someone else. This misuse contributes to opioid abuse and can lead to overdoses. Overdoses involving prescription opioids—hereafter referred to as

¹SAMHSA. *Key Substance Use and Mental Health Indicators in the United States: Results from the 2017 National Survey on Drug Use and Health*, (2018). Misuse of prescription opioids includes taking opioids in a manner or dose other than prescribed or taking opioids for non-medical use. Abuse often starts as misuse of prescription opioids.

²For the purposes of this report, we use the term opioids to refer to prescription opioid pain relievers, such as hydrocodone or oxycodone, rather than illicit substances, such as heroin. SAMHSA reports that in 2017, 97.2 percent of an estimated 11.4 million people age 12 or older who misused opioids in the past year misused prescription opioids, and 2.8 percent of these people misused heroin only. Health care providers include physicians, dentists, and mid-level practitioners (e.g., nurse practitioners or physician assistants) who can be licensed, registered, or otherwise permitted to prescribe a controlled substance.

opioids—were five times higher in 2017 than in 1999, accounting for about 17,000 deaths in 2017.³

Federal, state and local government agencies, drug manufacturers, communities, and others have attempted to address the potential for misuse and abuse by identifying or providing safe, secure, and convenient methods for disposing of unused, unneeded, or expired opioids. However, there is no federal law or regulation imposing requirements for how patients are to dispose of unused opioids.

The SUPPORT for Patients and Communities Act (SUPPORT Act) included a provision for us to review options for patients to dispose of unused opioids, including products intended to facilitate in-home disposal.⁴ In this report we describe:

1. The federally recommended and other available methods patients may use to dispose of unused opioids, and
2. What is known about patients' use of these methods to dispose of unused opioids and examples of efforts to educate patients and providers about opioid disposal.

To describe the methods that federal agencies recommend patients use to dispose of unused opioids, we reviewed documentation and interviewed officials from the three federal agencies that have authorities related to the disposal of opioids—the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). We analyzed data from DEA as of April 2019 indicating the locations of permanent drug take-back collection sites in conjunction with data from the U.S. Census Bureau's population estimates through 2017. We used these data to estimate the percentage of the U.S. population living within varying distances of a permanent

³Centers for Disease Control and Prevention (CDC), *Prescription Opioid Data*, accessed June 13, 2019, <https://www.cdc.gov/drugoverdose/data/prescribing.html>.

⁴Pub. L. No. 115-271, § 3032(d), 132 Stat. 3894 (2018).

collection site.⁵ For all data used in these analyses, we reviewed related documentation and conducted electronic testing and, based on these steps, determined that the data were sufficiently reliable for our purposes. To describe other disposal methods, we reviewed documents and studies from vendors of three commercial in-home disposal products that patients can use to help them dispose of prescription and nonprescription medication in their home trash. We identified these products and documents through stakeholder interviews, a related study, a patent search using Google Patents, and a review of product websites.⁶ Additionally, we conducted interviews with other stakeholders—including researchers, a representative from the AmerisourceBergen Foundation, and representatives from three companies that manufacture in-home drug disposal products.⁷ We asked these stakeholders about the effectiveness of these other disposal methods at preventing misuse of opioids.⁸

To describe what is known about which methods patients use to dispose of unused opioids, we conducted interviews with stakeholders, such as the Association for Accessible Medicines and the American Medical Association (AMA), and reviewed results of SAMHSA's 2017 National

⁵We analyzed the most recent DEA and U.S. Census Bureau data available at the time of our analysis. The U.S. Census Bureau's American Community Survey 5-year estimates are updated annually and are based on data collected continuously from a sample of households during the entire 60-month period. We used the 5-year estimates rather than 1-year estimates because they are based on larger sample sizes and thus are more reliable. To conduct this analysis, we calculated the distance between the central point of each zip code and the nearest DEA-registered permanent collection site. For some zip codes, depending upon whether their central point is located just within the distance threshold or just beyond it, a portion of their population may be unintentionally included in or excluded from the population subtotal and total, thus introducing a small degree of error in the percentage calculation. The radius of each distance category was not limited by state boundaries, and we chose these distance thresholds based on a review of available information on convenient distances for accessing pharmacies.

⁶Community Environmental Health Strategies LLC, *Medicine Disposal Products: An Overview of Products and Performance Questions*, (2019). Community Environmental Health Strategies is a consulting firm that prepared this report for the San Francisco Department of the Environment.

⁷We selected manufacturers of two products that are distributed in retail outlets and one newer product that has not been broadly distributed.

⁸The AmerisourceBergen Foundation is an independent not-for-profit charitable giving organization established by the AmerisourceBergen Corporation to support health-related causes that enrich the global community, including by supporting distribution of in-home drug disposal products to communities.

Survey on Drug Use and Health.⁹ We also conducted a literature review. Specifically, we performed a structured search of research databases—such as Scopus, ProQuest, ProQuest Dialog, and Harvard Think Tank—to identify literature published from January 1, 2009 through February 2019. In our search, we used a combination of terms such as “controlled substance,” “disposal,” “drug,” and “prescription.” These searches retrieved 846 results, of which 191 studies were selected by a librarian based on general relevancy for further review. We selected 25 studies based on the following criteria: if the study was published after January 1, 2014 and (1) presented findings that assessed the effectiveness of certain methods for disposing of opioids and other medications, (2) documented the quantity of unused opioids in the community, (3) examined how patients disposed of unused opioids, or (4) evaluated patient attitudes toward opioid disposal.¹⁰ The findings from each individual study are limited by the studies’ overall lack of national representation and small patient populations; however, taken together, we found that the methods and conclusions were sufficient for our purposes. To describe examples of efforts to educate patients and providers about opioid disposal, we interviewed officials from FDA and the AMA and reviewed relevant documentation from each.

We conducted this performance audit from December 2018 to September 2019 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Opioids, such as hydrocodone and oxycodone, can be prescribed to treat both acute and chronic pain. Opioids can pose serious risks when they are misused. These risks include addiction, overdose, and death. As a

⁹The National Survey on Drug Use and Health collects data through interviews with U.S. civilians who are not institutionalized. In the survey, respondents are asked about their drug use, among other things. Based on these responses, SAMHSA estimates results for the U.S. population. Results from the 2017 survey were the most recent data available at the time of our analysis.

¹⁰We selected studies published after January 1, 2014 because DEA’s final rule governing disposal of controlled substances was released in 2014. See 79 Fed. Reg. 53,520, 53,548 (Sept. 9, 2014).

result, opioids are classified as controlled substances, which means that their use and disposal are subject to additional oversight by DEA.¹¹

Some studies suggest that the majority of patients who received prescriptions for opioids often do not use a large portion of the drugs dispensed. A study that surveyed U.S. adults who had received opioids found that approximately 60 percent of patients who were no longer using the medication had unused opioids.¹² Two studies reported that over one-half of patients did not use all of the opioids prescribed to them after surgery; these studies found that patients reported leaving 15 to 20 pills unused, representing 54 percent to 72 percent of the opioids they were prescribed.¹³ Another study on patient opioid use after a cesarean section and thoracic surgery found that most patients, 83 percent and 71 percent respectively, used less than half of the total opioids they were prescribed.¹⁴

Federal Authorities

There is no federal law or regulation imposing requirements for how patients are to dispose of unused opioids. However, DEA, FDA, and EPA all have authorities and initiatives related to patient disposal of opioids.

DEA

DEA regulations specify three take-back options that patients can opt to use to dispose of their unused controlled substances: take-back events, permanent collection sites, and mail-back programs. DEA hosts semi-annual events called National Prescription Drug Take-Back Days, where

¹¹Controlled substances are regulated under the Controlled Substances Act, which is enforced by DEA. See Pub. L. No. 91-513, tit. III, 84 Stat. 1236, 1242-84 (1970) (codified, as amended, at 21 U.S.C. § 801 et seq.).

¹²A. Kennedy-Hendricks et al., "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults," *JAMA Internal Medicine*, vol. 176, no. 7 (2016): p. 1027-1029.

¹³M. V. Hill et al., "Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures," *Annals of Surgery*, vol. 265, no. 4 (2017): p. 709-714 and B. C. Maughan et al., "Unused Opioid Analgesics and Drug Disposal Following Outpatient Dental Surgery: A Randomized Control Trial," *Drug and Alcohol Dependence*, vol. 168 (2016): p. 328-334.

¹⁴K. Bartels et al., "Opioid Use and Storage Patterns by Patients after Hospital Discharge following Surgery," *PLoS ONE*, vol. 11, no. 1 (2016).

temporary collection sites are set up in locations such as police stations.¹⁵ Advertisements encourage community participation in the events and educate the community on safe disposal of unused medications, including opioids. DEA also registers collectors and provides information to the public about the location of permanent collection sites for take-back, such as at local retail pharmacies or hospital pharmacies, and sets requirements for the provision of postage-paid envelopes that patients can use to mail unused drugs to a collector for destruction.¹⁶

DEA regulations establish a standard for the destruction of controlled substances that applies to DEA registrants, which can destroy opioids on patients' behalf.¹⁷ DEA registrants include pharmaceutical companies that manufacture controlled substances, health care providers who prescribe them, and pharmacies that dispense them. The standard for destruction requires that controlled substances maintained or collected by DEA registrants be rendered non-retrievable. This means that the physical and chemical conditions of the controlled substance must be permanently altered, thereby rendering the controlled substance unavailable and unusable for all practical purposes. According to DEA, as of May 2019, the only method currently used to meet this standard is incineration, and DEA rulemaking states that DEA will not evaluate, review, or approve methods used to render a controlled substance non-retrievable.¹⁸

FDA

FDA has broad authority under the Federal Food, Drug, and Cosmetic Act to evaluate whether a drug is safe and effective and ensure the benefits of drugs outweigh the risks. FDA may require manufacturers to develop a

¹⁵Federal, state, tribal, and local law enforcement may also collect unused controlled substances through other take-back events, mail-back programs, or collection receptacles located inside the law enforcement's premises. See 21 C.F.R. §§ 1317.35 and 1317.65 (2018).

¹⁶Under the Controlled Substances Act, all persons or entities that manufacture, distribute, or dispense controlled substances are required to register with DEA, unless specifically exempted. DEA regulates these entities to limit diversion and prevent abuse. DEA registrants must receive authorization from DEA to collect controlled substances for disposal. Authorized collectors may (1) receive and destroy mail-back packages; (2) install, manage, and maintain collection receptacles located at their collection locations; and (3) dispose of sealed inner liners from collection receptacles, including their contents. 21 C.F.R. § 1317.40(c) (2018).

¹⁷A patient who receives a prescription for a controlled substance is not a DEA registrant and therefore is not subject to this standard.

¹⁸79 Fed. Reg. 53,520, 53,548 (Sept. 9, 2014). DEA regulations do not specify a test for evaluating whether a method meets the non-retrievable standard.

risk evaluation and mitigation strategy (REMS) for drugs with serious safety risks, including the risk of abuse, to ensure that the benefits outweigh the risks.¹⁹ Under one REMS, for example, manufacturers of opioids intended for outpatient use must make training available to health care providers involved in the treatment and monitoring of patients who receive opioids. The training must contain certain elements, including how providers should counsel patients and caregivers about the safe use and disposal of these opioids, among other things.

In October 2018, the SUPPORT Act authorized FDA to, at its discretion, require specific packaging or disposal systems as a part of certain drugs' REMS.²⁰ For drugs with a serious risk of overdose or abuse, FDA may require the drug to be made available for dispensing to certain patients with "safe disposal packaging" or a "safe disposal system" for purposes of rendering the drug non-retrievable in accordance with DEA regulations.²¹ Before imposing these requirements, FDA must consider the potential burden on patient access to the drug and the health care delivery system. As of May 2019, FDA had not imposed any REMS requirements using the new SUPPORT Act authority.

EPA

Under the Resource Conservation and Recovery Act (RCRA), EPA has authority to regulate the generation, transportation, treatment, storage, and disposal of hazardous waste, including certain discarded opioids.²² However, hazardous waste pharmaceuticals generated by households are not regulated as hazardous waste even if the waste would otherwise

¹⁹GAO has forthcoming work that examines risk evaluation and mitigation strategies.

²⁰Pub. L. No. 115-271, § 3032(a), 132 Stat. 3894 (2018) (codified at 21 U.S.C. § 355-1(e)(4)).

²¹The SUPPORT Act also authorized FDA to require that certain drugs be made available for dispensing in unit dose packaging, packaging that provides a set duration, or another packaging system that FDA determines may mitigate serious risk of overdose or abuse. On May 31, 2019, FDA issued a notice in the Federal Register soliciting comments about unit dose packaging for opioids. 84 Fed. Reg. 25,283 (May 31, 2019).

²²A waste is "hazardous" under RCRA if EPA has specifically listed it as such by regulation, or if it exhibits one of four hazardous characteristics (ignitability, corrosivity, reactivity, or toxicity). See 40 C.F.R. § 261.3(a)(2)(2018). EPA may authorize states to implement their own hazardous waste management programs in lieu of the federal program as long as, among other things, the state programs are at least equivalent to the federal program. Authorized states may implement regulations that are more stringent or broader in scope than the federal regulations. 42 U.S.C. § 6926(b).

be considered hazardous.²³ Opioids and other household waste pharmaceuticals collected through a take-back option are also exempt from most hazardous waste regulations, provided certain conditions are met.²⁴ Some states and localities have imposed additional requirements for pharmaceutical disposal, such as requirements for drug manufacturers to manage or fund the disposal of collected household pharmaceuticals.

²³While a small percentage of pharmaceuticals discarded by households meet the definition of hazardous waste under RCRA, EPA regulations specify that solid waste generated by households, including pharmaceuticals, are not regulated as hazardous waste. 40 C.F.R. § 261.4(b)(1) (2018) and 84 Fed. Reg. 5,816, 5,941 (Feb. 22, 2019) (to be codified at 40 C.F.R. § 266.501(g)(7)). Household hazardous waste pharmaceuticals are allowed to be disposed of as municipal solid waste when discarded by individuals at their residences.

²⁴To meet the conditional exemption, collected household hazardous waste pharmaceuticals must be: (1) managed in compliance with EPA's prohibition on discharging hazardous waste pharmaceuticals to a sewer system that passes through to a public-owned treatment works; (2) collected, transported, stored, and disposed of in compliance with all applicable DEA regulations for controlled substances; and (3) destroyed by a method DEA has publicly deemed in writing to meet the non-retrievable standard of destruction or combusted at one of five permitted types of hazardous waste combustors. 84 Fed. Reg. 5,816, 5,945 (Feb. 22, 2019) (to be codified at 40 C.F.R. § 266.506). If these conditions are not met, it is the entity collecting the pharmaceuticals, and not the consumer, that is subject to EPA's hazardous waste regulations.

Federal Agencies Recommend Take-Back Options as the Preferred Disposal Method

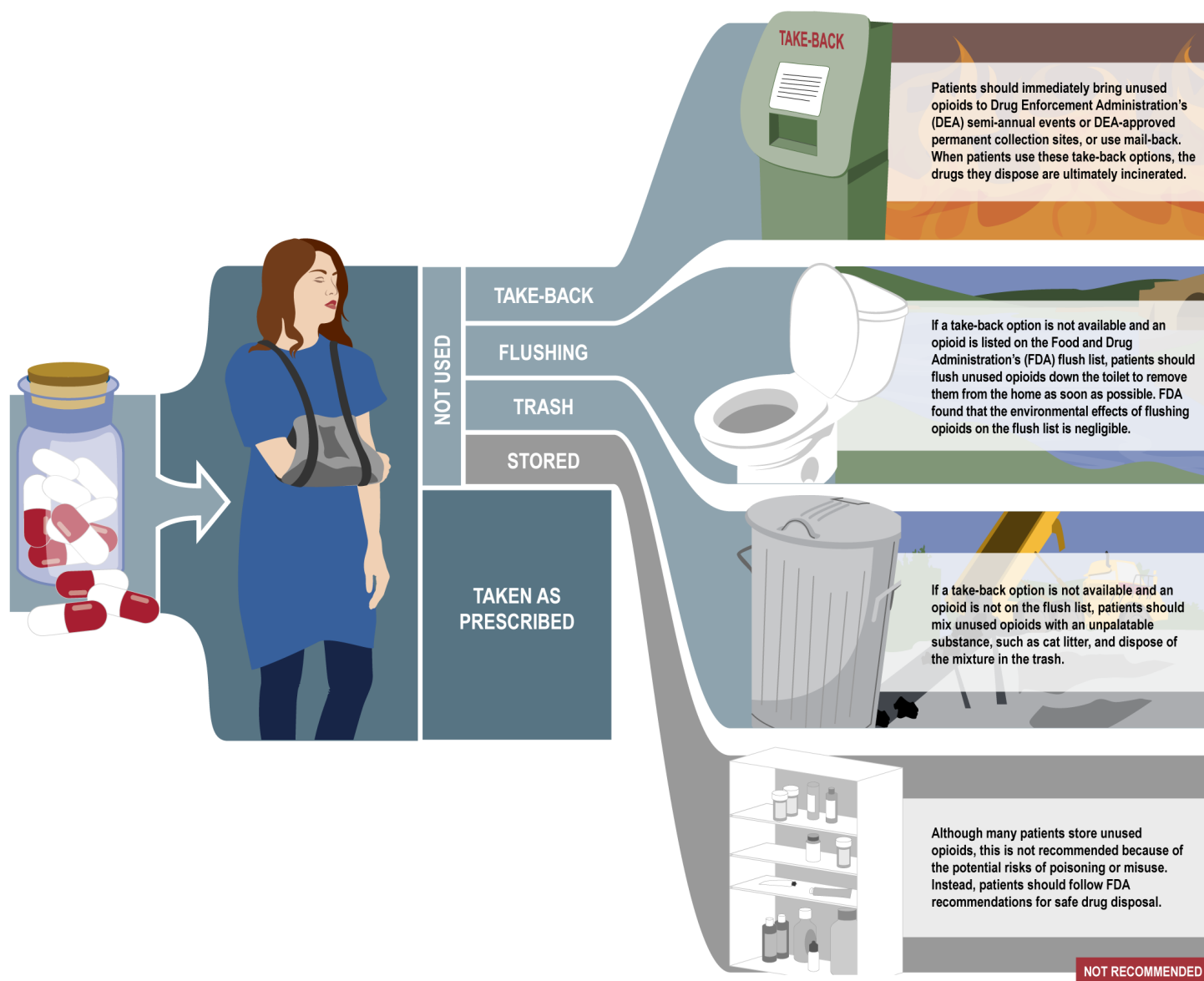
Federal Agencies Recommend Take-Back Options Whenever Feasible, Followed by Disposal Using the Toilet or Trash

According to DEA, FDA, and EPA, patients should use take-back options to dispose of unused opioids, whenever feasible. Only if take-back options are not feasible, FDA recommends flushing opioids on FDA's flush list down the toilet to remove them from the home as soon as possible.²⁵ For opioids not on the flush list, the agencies recommend placing the drugs in the household trash mixed with an unpalatable substance.²⁶ (See fig. 1). Officials from FDA said that the primary goal of these recommendations is to remove dangerous substances from the home as soon as possible to reduce accidental poisoning, which also may address issues related to intentional misuse. FDA officials explained that the agency has not measured the effects of its recommendations for disposing of opioids on opioid misuse, as of May 2019, because it is difficult to establish a causal link between the recommendations and any reductions in misuse.

²⁵See *Environmental Health: Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water*, [GAO-11-346](#) (Washington, D.C.: Aug. 8, 2011) for prior GAO work related to pharmaceuticals in drinking water.

²⁶FDA officials reported that these drug disposal recommendations were first developed by the Office of the National Drug Control Policy in 2007.

Figure 1: Patient Use and Food and Drug Administration's Recommendations for Disposal of Prescription Opioids



Source: GAO analysis of FDA documents. | GAO-19-650

Take-Back Options

DEA, FDA, and EPA recommend using a take-back option as the preferred method for patients to dispose of unused prescription opioids. Under this method, patients can bring unused opioids to DEA's semi-annual take-back events or to DEA-registered permanent collection sites,

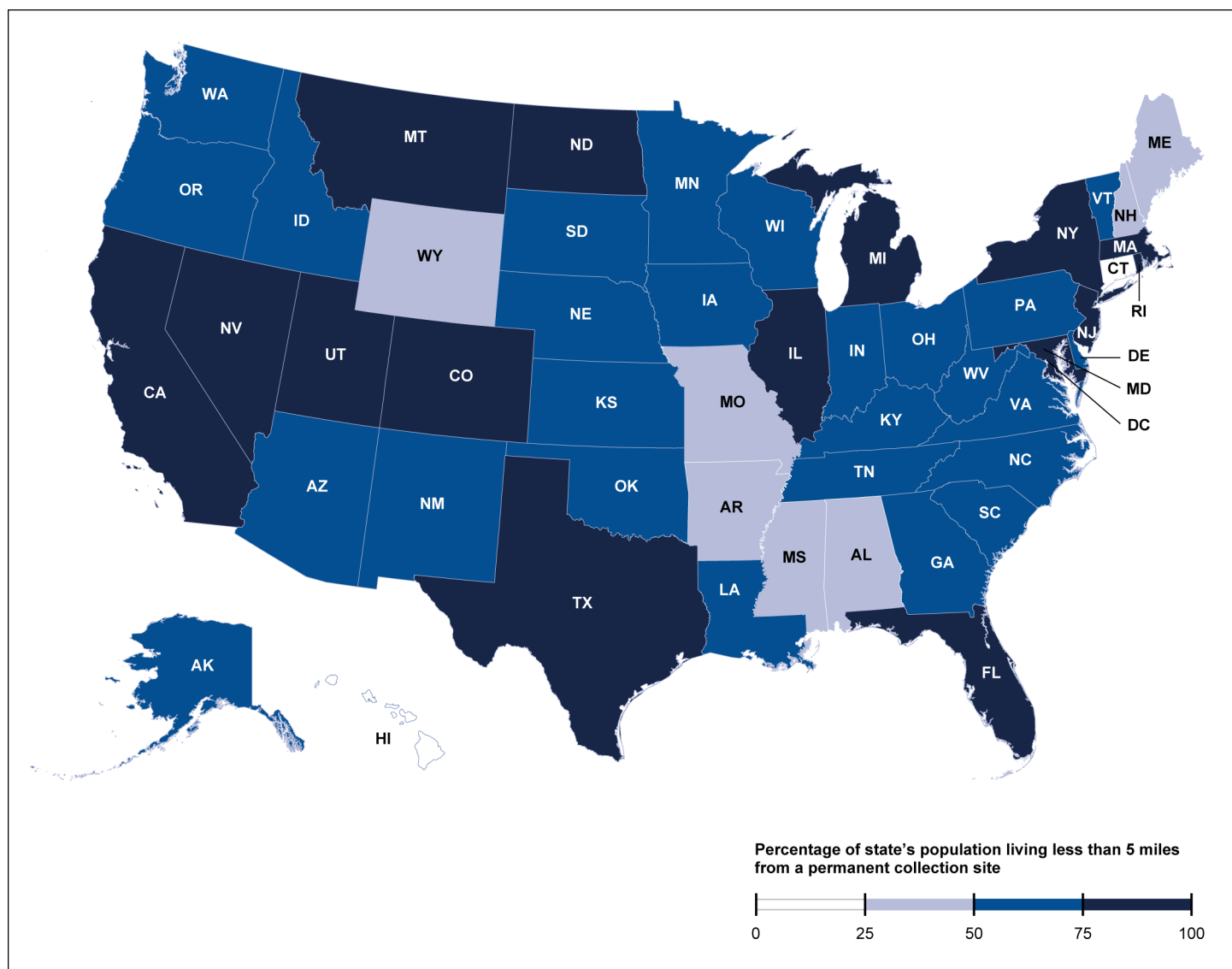
or use mail-back to deliver opioids to a DEA-registered collector for destruction. When patients use these take-back options, the drugs they dispose of are ultimately incinerated, which is the only method that DEA officials said is known to render the drugs non-retrievable, that is, permanently and irreversibly destroyed.

Our analysis of DEA and U.S. Census Bureau data shows that as of April 2019, 71 percent of the country's population lived less than 5 miles from a permanent collection site, and in 42 states, at least half of the population lived within 5 miles of a site. (See fig. 2). This number has increased since our April 2017 report, when we found that about half of the country's population lived less than 5 miles away from a site.²⁷ Our analysis also shows that 90 percent of the population lived within 15 miles of a site, though in rural areas only 57 percent lived within 15 miles. In addition, two studies found that patients were willing to bring unused opioids to a take-back location as long as it was located within 5 to 8 miles of their home address.²⁸

²⁷ See GAO, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs*, [GAO-18-25](#) (Washington, D.C.: Oct. 12, 2017). Our analysis was limited to permanent DEA-registered collection sites that use receptacles to collect unused prescription drugs from the public and does not include disposal options provided by law enforcement agencies, which do not need to register with DEA to collect controlled substances.

²⁸ K. I. Stoddard et al., "Investigating Research Gaps of Pharmaceutical Take-Back Events: An Analysis of Take-Back Program Participants' Socioeconomic, Demographic, and Geographic Characteristics and the Public Health Benefits of Take-Back Programs," *Environmental Management*, vol. 59 (2017): p. 871-884 and M. A. Kozak, "A Needs Assessment of Unused and Expired Medication Disposal Practices: A Study From The Medication Safety Research Network of Indiana," *Research in Social and Administrative Pharmacy*, vol. 12 (2016): p. 336-340.

Figure 2: Estimated Percentage of Population Living Less Than 5 Miles From a Drug Enforcement Administration (DEA)-Registered Drug Take-Back Permanent Collection Site, by State, April 2019



Source: GAO analysis of Drug Enforcement Administration and U.S. Census Bureau data; Map Resources (map). | GAO-19-650

Note: We analyzed April 2019 data from DEA about the locations of non-law enforcement entities that are authorized to install receptacles to collect controlled substances for disposal by the general public. We also used 2017 U.S. Census Bureau population estimates to estimate, by zip code, the portion of the population within certain distances of a permanent collection site.

Flushing

Food and Drug Administration's Flush List, as of May 2019

- Benzhydrocodone/Acetaminophen
- Buprenorphine
- Fentanyl
- Diazepam*
- Hydrocodone
- Hydromorphone
- Meperidine
- Methadone
- Methylphenidate*
- Morphine
- Oxycodone
- Oxymorphone
- Tapentadol
- Sodium Oxybate*

*These drugs are not opioids.

Source: Food and Drug Administration | GAO-19-650

If take-back options are not feasible, FDA recommends flushing the opioids on its flush list down the toilet, because a single dose can be fatal to a child or a pet. Flushing is a permanent way to remove opioids from the home.²⁹ FDA confirmed that as of June 2019, 11 of 14 drugs on the flush list are opioids, which represents about three-quarters of the approved opioid active ingredients intended for outpatient use (see sidebar). Some portion of drugs that are flushed down the toilet ultimately enter surface and wastewater streams. However, a 2017 FDA study on the environmental impact of drugs listed on the flush list concluded that flushing these opioids has negligible effects on the environment and human health, particularly relative to the amount of opioids that are excreted after taking them as prescribed, because not all of the drug is metabolized.³⁰ (See text box for a summary of the effects of disposal options on the environment.)

²⁹The flush list does not include antibiotics and hormones, which have known detrimental environmental effects. See <https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know> (accessed June 4, 2019). Opioids have been detected in wastewater samples in the US, Canada, Europe, South America, and Asia. See Campos-Manas et al, "Trends in Environmental Analytical Chemistry," (2018).

³⁰U. Khan et al., "Risks Associated With the Environmental Release of Pharmaceuticals on the U.S. Food and Drug Administration 'Flush List'," *Science of the Total Environment*, vol. 609 (2017). This study did not examine the human and environmental impacts of flushing drugs other than those on FDA's flush list.

Environmental Effects of Disposal Options

The environmental impact of opioid disposal depends on the method used—take-back options, flushing, or trash. According to Environmental Protection Agency (EPA) and Drug Enforcement Agency (DEA) officials, disposal of drugs through take-back options results in disposal by permitted incineration, which fully destroys the active form of the drugs. EPA officials told us that flushing or placing opioids in the trash can introduce active opioids into wastewater streams, groundwater, and surface waters.

Incineration of Drugs from Take-Back Options. Opioids disposed of using take-back options are destroyed by incineration, which, according to DEA officials, is the only method currently used to meet its non-retrievable standard for destruction. EPA officials told us that based on data from DEA, the amount of household pharmaceutical waste gathered and incinerated during DEA's semi-annual take-back events is small compared to the total amount of waste one incinerator burns on an average day. EPA officials recommended take-back options as the preferred method of opioid disposal.

Flushing. Opioids enter the water supply when excreted by patients who take opioids as prescribed and when patients intentionally flush unused opioids down the toilet. EPA officials told us that most wastewater treatment facilities are not designed to eliminate opioids from wastewater streams. Further, measureable concentrations of opioids have been reported in surface and ground water sources around the world.

Trash. Disposal of unused opioids in the trash often introduces opioids into landfills. Studies in scientific literature show that pharmaceutical ingredients have been observed in the water that passes through landfills, called leachate. Similar to opioids that are flushed, opioids in landfill leachate can end up in wastewater streams and other water sources, according to EPA officials.

Source: GAO analysis of information from EPA and DEA | GAO-19-650

Household Trash

If an opioid is not on the FDA flush list and a take-back option is not feasible, the agencies direct patients to take a series of steps to dispose of their opioids in household trash by:

- (1) mixing the drugs in an unpalatable substance such as dirt, cat litter, or used coffee grounds,
- (2) placing the mixture in a sealed container or plastic bag, and
- (3) throwing the container in the trash.

An EPA official said that mixing the drugs with an unpalatable substance is meant to deter misusers from searching through the trash to retrieve the drugs. Disposal of opioids in the trash—either with an unpalatable substance or in-home disposal product—removes them from the home, but this option may not be permanent and the drugs still may be available for misuse. Drugs that are disposed in the trash ultimately are introduced to landfills, where they can escape landfill containment and enter wastewater streams or ground water sources.

FDA Has Not Evaluated Commercial Disposal Methods

FDA's website notes the availability of commercial products for disposing of unused opioids and other drugs in the home.³¹ FDA officials stated that, as of May 2019, the agency had not evaluated the effectiveness of these products or made any recommendations related to their use, but they are aware that patients may opt to use these products.³² These products, known as in-home disposal products, are proprietary substances that patients can mix with their unused drugs, including opioids, before disposing of them in the trash. In-home disposal product vendors told us they sell or donate their products to pharmacies, local law enforcement, and community groups, which then distribute them to patients.³³ A representative from a group that distributes these products, the AmerisourceBergen Foundation, noted that in-home disposal products may be a convenient option for patients for whom take-back options are not feasible, and marketing materials from a product vendor instruct patients to use their product if a take-back option is not available. Vendors indicate that their products can prevent misuse of opioids by rendering drugs non-retrievable at home and by motivating patients to dispose of unused opioids. According to DEA officials, rendering opioids non-retrievable by using an in-home disposal product is challenging, because the drugs have a variety of chemical and physical properties and potencies. Furthermore, according to DEA officials, a lethal dose of fentanyl can be as low as 250 micrograms in adults—and lower in children—underscoring the importance of effective disposal.

Some vendors have presented evaluations of their commercial products. A recent comprehensive review of eight in-home disposal products raised concerns about the credibility of vendors' evaluations and concluded that additional independent laboratory analysis is needed to fully examine product performance and assess how well these products achieve stated

³¹See <https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know> (accessed June 4, 2019).

³²The SUPPORT Act allows FDA to require as part of a REMS that certain drugs be dispensed with safe disposal packaging or a safe disposal system for purposes of rendering the drug non-retrievable in accordance with DEA regulations. Pub. L. No. 115-271, § 3032(a), 132 Stat. 3894 (2018) (codified at 21 U.S.C. § 355-1(e)(4)).

³³All three product vendors we spoke with said that all or nearly all of their sales are to organizations that distribute products to patients rather than to patients themselves. For example, one vendor representative said that the in-home disposal product is available to patients for free at approximately 40 percent of all chain drugstores nationwide.

goals.³⁴ Our review of evaluations from three vendors found that the studies contained some inconsistencies and gaps in the evaluation methods used, raising questions about the studies' conclusions that the products are effective for disposing of opioids.

- In some cases, studies included detailed, but inconsistent, methods. For example, in four studies about one product, the researchers concluded that the product deactivated most of an opioid dissolved in water. However, one of the earlier studies reported that whole pills did not dissolve in water, which could impact the results, but later studies did not include similar data.
- In other cases, companies' evaluations were summaries of results that did not provide enough information to independently verify or assess whether the products deactivate opioids and prevent misuse. For example, one company's research documents presented images of a mixture as evidence that the drugs had degraded, rather than results of a test measuring if drugs were still detectable.
- In addition, the studies included little information about the products' effectiveness at treating mixtures of multiple drugs at the same time, a scenario that stakeholders have referred to as "real world" use testing.

³⁴Community Environmental Health Strategies LLC, *Medicine Disposal Products: An Overview of Products and Performance Questions*, (2019).

Few Patients Use Federally Recommended Opioid Disposal Methods; FDA and Others Have Taken Steps to Educate the Public

Few Patients Use Federally Recommended Methods to Dispose of Unused Opioids

Disposal methods—when patients use them promptly—remove unused opioids from the home and therefore can be effective at reducing opioid misuse. FDA officials said that the federally recommended methods for disposing unused opioids are intended to remove these substances from the home as soon as possible, and stated that as long as individuals dispose of opioids promptly rather than storing them, then FDA has achieved its goal.

However, the studies we reviewed suggest that most patients do not dispose of unused opioids using a federally recommended method. Specifically, three studies examined how patients disposed of unused opioids and found that between 12 percent and 41 percent of patients disposed of them using a federally recommended method.³⁵ For example, one of the studies found that of 570 survey respondents who had unused opioids, 12 percent of respondents reported using a take-back option, 14 percent reported that they flushed them down the toilet, and 6 percent reported that they threw them in the trash after mixing with an unpalatable substance.³⁶

³⁵M. V. Hill et al., “Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures,” 709-714 and A. Kennedy-Hendricks et al., “Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults,” 1027-1029 and M.J. Sabatino et. al., “Excess Opioid Medication and Variation in Prescribing Patterns Following Common Orthopaedic Procedures,” *Journal of Bone and Joint Surgery*, vol. 100-A, no. 3 (2018): p. 180-188.

³⁶Kennedy-Hendricks et al., “Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults,” 1027-1029.

Other studies we reviewed show that take-back options are often used to dispose of drugs other than opioids. Two studies found that less than 10 percent of the catalogued drugs brought to DEA take-back days were controlled substances, which included opioids, while another study weighed drugs brought to take-back events and permanent collection sites and reported less than 3 percent were controlled substances, including opioids.³⁷ The same study found that annually, controlled substances disposed of at take-back events and permanent collection sites accounted for about 0.3 percent of those dispensed in the area, and concluded that take-back events may have a minimal impact on reducing the availability of unused opioids for misuse.³⁸

Studies indicate that patients who receive an in-home disposal product may be more likely to dispose of unused opioids, but they may also be less likely to use federally recommended options like take-back or flushing. Two studies in our review found that patients who receive an in-home disposal product have reported that they are more likely to dispose of unused opioids than those who did not receive the product.³⁹ Use of in-home disposal products—which may not be effective at permanently destroying drugs—may deter patients from using federally recommended options, like take-back, that have been proven effective. For example, one of these studies found that only one of the 70 patients who received

³⁷DEA regulations prohibit authorized collectors from opening and cataloging the contents of permanent collection receptacles. 21 C.F.R. § 1317.75(c) (2018). Evaluations of the use and contents of collection receptacles are limited to receptacles maintained by law enforcement agencies, which are not subject to this prohibition. We identified three studies conducted in conjunction with law enforcement agencies that quantified the amount of opioids collected via collection receptacles: C. S. Ma et al., “Drug Take Back in Hawai’i: Partnership Between the University of Hawai’i Hilo College of Pharmacy and the Narcotics Enforcement Division,” *Journal of Medicine and Public Health*, vol. 73, no. 1 (2014): p. 26-30 and H. Stewart et al., “Inside Maine’s Medicine Cabinet: Findings From Drug Enforcement Administration’s Medication Take-back Events,” *American Journal of Public Health*, vol. 105, no. 1 (2015): p. e65-e71 and K. L. Egan et al., “From Dispensed to Disposed: Evaluating the Effectiveness of Disposal Programs Through a Comparison with Prescription Drug Monitoring Program Data,” *The American Journal of Drug and Alcohol Abuse*, vol. 43, no. 1 (2017): p. 69-77.

³⁸K. L. Egan et al., “From Dispensed to Disposed,” 69-77.

³⁹C. M. Brummett, R. Steiger, M. Engelsbe, et. al., “Effect of an Activated Charcoal Bag on Disposal of Unused Opioids After an Outpatient Surgical Procedure: A Randomized Clinical Trial,” *JAMA Surgery*, (2019) and A. E. Lawrence, A. J. Carsel, K. L. Leonhardt et al., “Effect of Drug Disposal Bag Provision on Proper Disposal of Unused Opioids by Families of Pediatric Surgical Patients: A Randomized Clinical Trial,” *JAMA Pediatrics*, (Published online June 24, 2019).

an in-home disposal product used a take-back option for disposal, despite the study taking place in a state where we estimated that 77 percent of the population lived less than 5 miles from a permanent collection site.

Studies indicate that patients are often unaware of federally recommended disposal options. Three of the 25 studies we reviewed suggest that many patients were not aware of federally recommended methods for disposing of opioids.⁴⁰ For example, a study of cancer patients who received opioid prescriptions reported that more than three-quarters of these patients were unaware of proper opioid disposal methods.⁴¹ Another 2016 study of 1,032 patients found that nearly half of the respondents did not recall receiving information on proper disposal from pharmacists, medication packaging, or media outlets.⁴²

Studies also indicate that patients choose not to dispose of unused opioids, and that they knowingly participate in the majority of opioid misuse. Five of the studies we reviewed found that between one-quarter and three-quarters of patients stored unused opioids for future use or had misplaced their unused opioids.⁴³ For example, one of these studies found that 49 percent of survey respondents kept or planned to keep unused opioids for future use, and 14 percent were likely to let a family member use their opioid medications in the future.⁴⁴ Federal data about

⁴⁰Kozak et al., "A Needs Assessment of Unused and Expired Medication Disposal Practices," 336-340 and Kennedy-Hendricks et al., "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults," 1027-1029 and J. Silvestre et al., "Frequency of Unsafe Storage, Use, and Disposal Practices of Opioids Among Cancer Patients Presenting to the Emergency Department," *Palliative and Supportive Care*, vol. 15 (2017): p. 638-643.

⁴¹J. Silvestre et al., "Frequency of Unsafe Storage, Use, and Disposal Practices of Opioids Among Cancer Patients Presenting to the Emergency Department," 638-643.

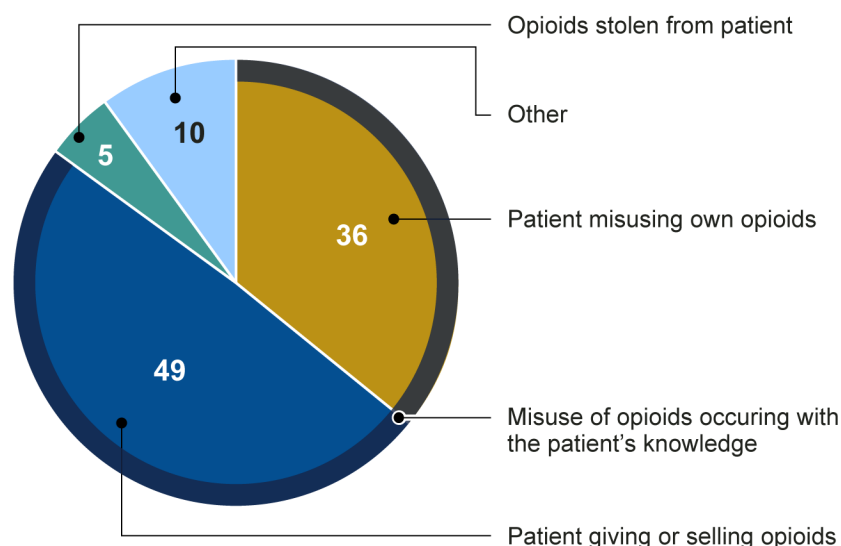
⁴²Kennedy-Hendricks et al., "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults," 1027-1029

⁴³Hill et al., "Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures," 709-714; Kennedy-Hendricks et al., "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults," 1027-1029; D. D. Maeng et. al., "Unused Medications and Disposal Patterns at Home: Findings From a Medicare Patient Survey and Claims Data," *Journal of the American Pharmacists Association*, vol. 56 (2016): p. 41-46; and M.J. Sabatino et. al., "Excess Opioid Medication and Variation in Prescribing Patterns Following Common Orthopaedic Procedures," 180-188.

⁴⁴Kennedy-Hendricks et al., "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults," 1027-1029.

the sources of misused opioids indicate that patients are complicit with most misuse. SAMHSA estimates that 5 percent of people nationwide who misused opioids in 2017 took these drugs from someone else without asking. In contrast, SAMHSA estimates that 85 percent of opioid misuse occurs with the patient's knowledge or active participation, either through the patient misusing his or her own prescription by taking the drug for pain other than for which it was prescribed or by giving or selling the prescribed opioids to another person. (See fig. 3).⁴⁵

Figure 3: Ways People Obtained Opioids for Misuse in 2017 (percent)



Source: GAO analysis of Substance Abuse and Mental Health Services Administration data. | GAO-19-650

Note: "Other" sources for misused opioids include approximately 6 percent of misusers who bought the opioids from a drug dealer or other stranger and about 5 percent who obtained them some other way. These data are from the 2017 National Survey on Drug Use and Health, a nationally representative survey that asks people about their drug use within the past year, among other things, and includes a question about the source of the last opioids that a respondent misused. Misuse occurs when a person uses a drug in a way not intended by the prescriber, such as a patient taking a prescribed medicine to relieve pain other than the pain for which the drug was prescribed or taking a prescription intended for another person.

⁴⁵SAMHSA, *Key Substance Use and Mental Health Indicators*.

FDA and Others Have Taken Steps to Educate Patients and Providers about Appropriate Opioid Disposal

To motivate patients to use federally recommended methods to dispose of unused opioids, FDA and some physician organizations have created educational materials on safe disposal methods. For example, FDA launched a public awareness campaign called “Remove the Risk” on April 25, 2019—complete with educational materials such as public service announcements, social media posts, fact sheets, and other web-based content.⁴⁶ AMA representatives reported that the AMA has provided physicians with educational material on drug disposal and prescribing. Specifically, AMA representatives told us that the association has compiled a two-page document for physicians containing information about drug disposal, links to DEA information on nearby permanent collection sites and take-back events, and FDA guidance on safe disposal of medications. This document included recommendations for physicians to talk to patients about safe use of prescription opioids, remind patients to store their medications in a safe place out of reach from children, and have a conversation with patients about the most appropriate ways to dispose of expired, unwanted, or unused opioids.

The AmerisourceBergen Foundation has also partnered with communities to promote safe opioid disposal by providing education about take-back options and commercial in-home disposal products to patients. A representative from the Foundation explained that its Safe Disposal Support Program provides non-profit organizations or municipalities with commercial in-home disposal products, which then can be distributed free of charge to other organizations, individuals, or households. It also recommends that patients use take-back options when available. The representative said that organizations are to demonstrate to patients how these products work either through a brief in-person demonstration at an event or through a video. According to the representative, these products and demonstrations help people reflect on what is in their home and needs to be disposed of, either using a product or a take-back option.

Despite such efforts, little is known about the extent to which stakeholders’ efforts to educate the public are effective in increasing use of federally recommended disposal methods. FDA officials said that they are not aware of the extent to which providers are familiar with all disposal methods or the extent to which providers discuss the importance

⁴⁶See <https://www.fda.gov/drugs/ensuring-safe-use-medicine/safe-opioid-disposal-remove-risk-outreach-toolkit> (accessed June 11, 2019).

of proper disposal with patients. As part of FDA's REMS requirements for outpatient opioids, manufacturers must make training available to health care providers involved in the treatment and monitoring of patients who receive opioids, which includes information about the need to communicate with patients about disposal of unused drugs. FDA officials said that opioid manufacturers must assess the effectiveness of their REMS, including an assessment of prescribers', other health care providers including pharmacists', and patients' understanding of the key risk messages conveyed through the educational materials. FDA expects to receive the next REMS assessment with the results of these analyses in 2020. The AMA has not been able to measure the effects of its recommendations, but provided anecdotal feedback from its members that many physicians do not consistently speak to their patients about disposal.

FDA officials and AMA representatives indicated that in addition to educating patients on opioid disposal methods, focusing efforts on reducing the amount of unused opioids would be an effective approach for reducing misuse and abuse. For example, FDA officials said that adding packaging configurations that contain smaller quantities of certain opioids could help prescribers to more carefully consider the amount of opioid pain medication they prescribe.⁴⁷ This in turn may reduce the number of unused opioids available in the home that could be inappropriately accessed by family members or visitors, and could potentially reduce the risk for misuse and abuse. Representatives from the AMA explained that it and other organizations are working to provide opioid prescribing resources and guidance to help physicians effectively manage patients' pain, which representatives said will reduce the number of unused opioids available for misuse.⁴⁸ FDA officials and a researcher also noted that dispensing opioids in packaging that makes it easy to count the number of unused pills may help patients identify intentional misuse.

⁴⁷On May 31, 2019, FDA issued a notice in the Federal Register soliciting comments about unit-dose packaging for opioids. 84 Fed. Reg. 25,283 (May 31, 2019).

⁴⁸For example, CDC developed and published the *CDC Guideline for Prescribing Opioids for Chronic Pain* to provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings. AMA representatives cautioned, however, that opioid restriction policies have had unintended negative consequences on substance use and pain care. Representatives from the AMA explained that it and other organizations also provide resources and guidance to help physicians effectively screen and refer patients for substance use disorders.

Agency Comments

The FDA and EPA provided technical comments on a draft of this report, which we incorporated as appropriate; the DEA did not have comments.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the Administrator of the DEA, the Administrator of the EPA, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix I.

A handwritten signature in black ink, appearing to read 'James Cosgrove', with a stylized flourish at the end.

James Cosgrove
Director, Health Care

Appendix I: GAO Contact and Staff Acknowledgments

GAO Contact

James Cosgrove, (202) 512-7114 or cosgrovej@gao.gov.

Staff Acknowledgments

In addition to the contact named above, individuals making key contributions to this report include Leslie V. Gordon (Assistant Director), A. Elizabeth Dobrenz (Analyst-in-Charge), Sam Amrhein, Jieun Chang, Diana Chung, Kaitlin Farquharson, and Dennis Mayo. Also contributing were Giselle Hicks, Cynthia Khan, and Ethiene Salgado-Rodriguez.

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EXPLORING OPTIONS FOR SAFE AND EFFECTIVE IN-HOME OPIOID DISPOSAL

INTRODUCTION

Prescription opioids remain a critical part of treatment regimens for patients with both acute and chronic pain conditions. However, misuse, abuse, and diversion of prescription opioids remains an ongoing crisis in the United States. In 2019 alone, [an estimated 9.7 million people](#) misused prescription pain relievers. During the Covid-19 pandemic, [opioid overdose deaths in the U.S. hit an all-time high](#).^{1,2}

Removing unused opioids from patients' homes can help prevent drug misuse and accidental overdose. To achieve this, it is important to have safe and effective opioid disposal options that patients can easily use and access. Providing consumers with multiple options to safely dispose of their opioids has become a priority component of local and state responses to the opioid crisis.

The range of disposal methods and programs available today form a patchwork of different approaches for patients which vary by location. In addition to providing opioid disposal programs to help keep patients and communities safe, it is important to understand why patients may be reluctant or unable to dispose of their medications, such as the inconvenience of disposal or an unwillingness to throw away medication for which they have paid. Understanding these two components

presents an opportunity for the FDA to use its authority to address the need for more comprehensive and patient-centered safe opioid disposal options on a federal level.

The passage of the [2018 SUPPORT for Patients and Communities Act](#) granted FDA the authority to require that drug manufacturers provide patients with a safe opioid disposal option when their prescription is dispensed. This specific new authority is part of FDA's broader authority to require drug manufacturers to implement [Risk Evaluation and Mitigation Strategies \(REMS\)](#) – drug safety programs for certain medications with serious safety concerns.

On June 28 and 29, 2021, the Duke-Margolis Center for Health Policy, under a cooperative agreement with the U.S. Food and Drug Administration (FDA), convened a private workshop with participants to explore different opioid disposal options available and consider the potential impact and benefits of FDA requiring manufacturers to provide a safe, in-home disposal option when opioids are dispensed. This document summarizes the workshop presentations and discussion to inform policymakers and public health professionals interested in safe and effective in-home opioid disposal.

The Current Landscape for In-Home Opioid Disposal?

Inappropriate prescribing of opioids has fueled the crisis in the U.S. Patients must have access to these drugs; however, health care systems and regulators must act to mitigate the substantial risks associated with these medications. While opioid prescribing has been declining, opioids are still inappropriately prescribed.^{3,4} Inappropriate opioid prescribing has led to many patients having unused tablets in their homes. Even when an opioid prescription is appropriate, patients are frequently

prescribed more tablets than needed, especially when the prescription is related to surgery or dentistry.⁴ When these unused tablets are not properly disposed of or securely stored, they may become available for misuse, abuse, and diversion. Proper opioid disposal is important in ensuring safe medication use. Safe, effective opioid disposal methods are an important component of a broader effort to address the opioid crisis in the United States.

Unused and improperly stored opioid analgesics can worsen the opioid crisis, leading to consequences such as overdose, death, and accidental ingestion by children (poisoning). [The CDC recommends](#) storing controlled substances, such as opioids, in their original packaging and in a locked cabinet or drawer. In an FDA literature review, most studies that analyzed unused opioid tablets reported that 50-70% of tablets went unused and 70-100% of patients stored opioids in unlocked locations.⁵ Even after widespread changes in prescribing practices, many patients still have unused tablets.

Partial solutions, such as “right-size” prescribing, safe storage, and child-resistant packaging, have not adequately addressed the large number of unused tablets already in patients’ homes. In Michigan, one researcher estimated that there are collectively 62 million unused tablets per year in patient homes from post-surgical prescriptions alone. Given this large number of unused pills, researchers have noted that even a small increase in disposal rates of leftover opioids could reduce the number of tablets that are available for inappropriate use, resulting in a large public health benefit. This meeting focused on access to opioid disposal options as one way to reduce abuse, misuse, and accidental ingestion of unused tablets.

Existing Opioid Disposal Efforts

Several opioid disposal options are already available to patients. These include kiosks available in retail and hospital pharmacies, health care centers, and police departments; drug take back events; flushing (for opioids on the FDA’s [“flush list”](#)); mixing with unpalatable substances and dumping in household waste; mail-back envelopes; and in-home disposal products that include commercially available disposal pouches, packets, and containers. Rather than an overarching national disposal program funded by drug manufacturers or the federal government, disposal solutions form a patchwork that vary by state and/or operating organization.

Chain Pharmacy Efforts in Safe Opioid Disposal

Some major chain pharmacies have started voluntarily offering disposal programs in response to the opioid crisis. Most chain pharmacies offer kiosks (monitored drop boxes in which patients can dispose of their unused medications) in some of their locations, and some also offer in-home disposal products. These in-home disposal products are typically either sealable pouches that contain chemicals

that neutralize medications or packets of chemical compounds that, when mixed with water and medications, sequester the medications. Kiosks may be especially useful for patients with large amounts of unused tablets. While not every chain pharmacy store has a kiosk, thousands are located across the country for patient use. Some chain pharmacies also partner with police departments for take back days.

There are variations in chain pharmacy disposal programs and how pharmacies dispense the in-home disposal products to patients. For some chain pharmacies, in-home products are dispensed with certain prescriptions, and in others, they are dispensed only upon request. Some chain pharmacies use algorithms to identify patients for in-home disposal product provision, such as opioid-naïve patients. In some pharmacies, when patients are dispensed an opioid prescription for the first time, they are offered a counseling session which includes education about the in-home disposal products. Aside from counseling sessions, chain pharmacies use different educational tools that are provided to patients for medication disposal, including instructions in a pamphlet or printed on the in-home disposal product itself. According to some chain pharmacy representatives at the meeting, patients seem to like in-home disposal products. Pharmacists are trained on safe drug disposal, and many see this interaction as an additional touchpoint in the clinician-patient relationship and opportunity for education.

State Legislation on Opioid Disposal

Several states have enacted laws that require manufacturers to fund drug disposal, including Washington, Oregon, Hawaii, California, New York, and Massachusetts. These laws typically include all drugs dispensed in the state, not just opioids. The drug disposal programs in these states typically focus on kiosks and are supplemented with mail-back envelopes, and they are often implemented by a consortium of manufacturers through a Pharmaceutical Product Stewardship Work Group (PPSWG).

In the meeting, participants took a closer look at Washington’s program – the first state-wide drug disposal program to be implemented. Washington’s drug take back law was passed in 2018 and was modeled on seven local county ordinances surrounding drug disposal. The program officially began in 2020. The law includes provisions for over-the-counter medicines, prescriptions, brands, generics, medications for household pets, medications in medical devices, and combination products.

Drug manufacturers fully fund the disposal programs, which are run by program operators. The Washington State Department of Health oversees program operators and approves proposals for new programs. Currently, the programs are using three different types of drug collection, including kiosks, take back days, and pre-paid, pre-addressed mail-back envelopes. In locations where program operators do not meet the kiosk convenience standard set by law, they must establish distribution centers where patients can access mail-back envelopes. Washington residents may also request a mail-back envelope and have it sent to their homes.

Washington's program is still new, and only preliminary data has been collected. Collected drugs are measured in pounds and are not separated by type, making it difficult to know how successful the programs are at collecting unused opioids specifically. In-home opioid disposal products are not currently covered under the state's law, though these products could supplement current disposal efforts.

In-Home Disposal Products

In-home disposal products typically take the form of pouches that contain chemical compounds that, when mixed with water, can neutralize or sequester medications and render them unusable. These products are available to patients in some clinical settings and pharmacies, but they are not yet widely used or supported by federal or statewide programs. In Texas, researchers at the University of Houston College of Pharmacy are trying to determine patient preferences and utilization rates of in-home opioid disposal products by assessing the use of single-use disposal systems for in-home drug disposal. Community prevention organizations (CPOs) in Texas are the main drivers of opioid disposal product distribution. This distribution is tracked via activity reporting sheets. However, it is not possible to track whether patients used the in-home disposal products and which medications they disposed of using the products because of United States Drug Enforcement Agency (DEA) regulations.

Some research does exist surrounding patient use of in-home disposal products. In one Michigan study comparing the effectiveness of providing an informational sheet about opioid disposal vs. an in-home disposal product, patients were more likely to dispose of their opioids with the in-home product. In addition, patients were less likely to participate in inappropriate disposal (such as through household trash) when provided with a disposal product.⁶

Other studies suggest that education combined with in-home product provision may further increase disposal rates.^{7,8}

Considerations for In-home Disposal Products

Based on a literature review, providing in-home disposal products to patients increased disposal rates, especially when clinicians provided enhanced patient education.⁵ However, in-home disposal products are relatively new, and there are limited studies that investigate how effective they are as an opioid disposal method. This leaves regulators and policymakers with many unanswered questions surrounding patient motivations and willingness to dispose of opioids, consumer preferences for safe disposal options, alignment of patient and provider preferences, and preferences of patients with chronic pain versus acute pain.

Addressing Patient Needs

Patients and caretakers have many different reasons for engaging in safe medication disposal, including disposing of unused pills post-surgery or after end-of-life care. One participant that works with patients offered their perspective on working with different patient needs, noting that it is important to provide patients and families with multiple options and to make disposal options as convenient as possible.

Meeting participants made a notable distinction between patients with chronic pain and acute pain (e.g., post-surgical patients), as these patient groups have different needs related to medication disposal.

In-home disposal options may serve as an accessible alternative to kiosks for patients with chronic pain, as many of these patients may have difficulty driving or leaving the house. However, chronic pain patients likely do not need a disposal option dispensed with each prescription as they are less likely to have unused pills. Acute pain patients, on the other hand, are more likely to have unused tablets and thus need a disposal option with each prescription. Addressing the difference in patient needs may help reduce waste from unused disposal products.

One speaker suggested that patients need to understand the “why” of opioid disposal, and pharmacists are in a prime position to educate patients about its importance.

Participants also offered solutions to encourage patient participation in opioid disposal, noting that text messages and emails could help remind patients to dispose of unused tablets. One speaker added that one state has a new system that flags patients with opioid prescriptions and calls them 10 days later, asking them how they have disposed of their medications and if they need additional resources. This model could help encourage disposal and meet patients' needs for an in-home disposal option.

Social and Behavioral Considerations

Social and behavioral considerations may play a role in forming strategies to encourage opioid disposal. Older individuals, according to public opinion polls, are less likely to dispose of their opioids. In many communities of color, the only disposal sites are in law enforcement buildings, which can be a barrier to access for individuals wishing to dispose via kiosks. Rural and underserved urban communities face a lack of access to disposal options, and patients in high-density urban centers may feel uncomfortable carrying medications to kiosks via public transit or in busy areas. Finally, patients may view opioids as a scarce resource that may be hard to access later. Declining prescribing rates may fuel this impulse to view unused tablets as a scarce resource and may lead to hoarding.

One participant is working to engage community health care workers in local health care facilities, which could increase in-home product distribution to those with low access to kiosks and take back days. Another participant noted that patient education in the home is often highly effective and that perhaps new solutions such as traveling vans that distribute these in-home products could be helpful in increasing patient convenience and disposal rates for older patients and patients with chronic pain.

Environmental Health and Safety

Some meeting participants expressed that in-home disposal products may pose safety concerns for patients. For example, one participant noted that most disposal products suspend medications in liquid solution without warnings about dermal exposures or guidance on how to clean up spills. In addition, waste material from in-home disposal products has not been proven to be non-hazardous or non-toxic because in-home disposal product manufacturers do not disclose product ingredients.

Meeting participants also expressed concerns about the environmental impact of in-home disposal products. While research suggests that some patients may feel reluctant to flush medications due to concerns about environmental pollution, there are additional environmental concerns associated with in-home disposal products being dumped in household waste and contributing to environmental pollution in landfills. Given that these products' chemical makeup is unclear, questions remain about the extent of in-home products' environmental risks. Waste management officials should be engaged to explore potential risks of large-scale in-home disposal product distribution.

Increasing Safe Disposal Using Any Method

Opioid disposal programs seek not only to provide patients with the means to dispose of their opioids, but also to encourage patients to do so. Little is known about which options patients prefer and which are most effective at encouraging patients to dispose of their medications. Participants discussed what is known about these preferences, as well as what factors make patients reluctant to use existing disposal options.

Incentivizing Behavior Changes

Several participants noted key motivators which may impact patients' willingness to dispose of their opioids. Stakeholders articulated that patients likely prefer convenience and asking individuals to undertake additional effort often reduces uptake of new interventions, despite apparent perceived benefits. In addition, patients might feel a sense of "thriftiness" leading them to be unwilling to throw away a product for which they have paid.

To achieve high disposal rates, a "one-size-fits-all" approach to disposal is insufficient. In addition to maintaining a variety of disposal solutions for patients, finding new approaches to encourage drug disposal could be beneficial in increasing disposal rates. One participant noted that patient motivations surrounding opioid disposal vary, so approaches for encouraging disposal should include emotional motivations, intellectual justifications, and financial incentives. Another participant added that working to instill a sense of "duty" in patients to return their opioids could create a shift in perspective that could lead to more disposal.

Applying Principles of Injury Prevention

The general principles of injury prevention can be applied to opioid disposal solutions. Education, engineering, and enforcement are key principles of injury prevention. Education helps patients understand the rationale for their behavior change, and this behavior change must be reinforced for sustained change over time. Engineering solutions are successfully implemented when the new technology is effective and reliable, as well as easily understood by key audiences. Enforcement strategies use policy or legislation to drive behavior change. These strategies must be widely known and understood, and there must be a cost to not participating in the desired behavior.

Additional injury prevention considerations may apply to opioid disposal. As one participant noted, one goal of injury prevention is making the safest behavior the easiest behavior. Interventions need to consider cultural issues, the needs of diverse communities, and they must be equitable.

Exploring Policy Options and Discussing Potential Implications of a REMS

Under SUPPORT Act Section 3032, FDA may require a drug to be dispensed to certain patients with safe disposal packaging or safe disposal system. Guiding principles for an FDA-required REMS for opioid disposal include considerations such as:

1. importance of an educational component of the REMS;
2. patient access to multiple disposal options depending on their needs;
3. the benefit of a REMS beyond current state and voluntary efforts; and
4. unintended consequences of a REMS mandate on patient access and existing opioid disposal programs.

In the meeting, experts weighed in on these points to inform FDA's decision-making process around the potential implementation of a REMS for opioid disposal.

Determining the Scope and Cost of a REMS

Meeting participants discussed the potential cost considerations and scope of a REMS for opioid disposal. Participants expressed concerns about who would be shouldering the cost of in-home products and their distribution, noting that this funding should be sustainable. Some participants noted that pharmacists are unable to bill payers for time spent educating and that overworked pharmacists should receive some sort of compensation for their additional responsibilities that would come with patient education about opioid disposal.

While costs are high for small quantities of in-home disposal products, at scale, the costs should decrease. However, participants added that cost-effectiveness studies should be conducted to assess in-home disposal product costs versus benefits at scale. Other disposal options also have high associated costs. One speaker highlighted that kiosk costs are high for voluntary disposal efforts and can be cost-prohibitive in some communities, as the transportation and security needs create financial obstacles.

Logistical Considerations

Participants contributed several perceived obstacles to the implementation of a REMS for opioid disposal. One participant noted that some pharmacies may have little storage space. Another noted that currently there are no publicly funded resources to help consumers locate kiosks and take back days, so a compiled website or another digital tool could be helpful to patients. Finally, patients are not always aware of the categories of drugs they are taking, so it could be important to find a drug disposal solution that will accommodate multiple types of drugs.

Distribution of the in-home disposal products is likely easier in large chain pharmacies than in community pharmacies, which have different sets of needs. However, it is important that community pharmacy needs to be taken into consideration so as not to leave out large groups of patients. For example, some states have very few or no chain pharmacies, such as North Dakota.

One speaker suggested that prepaid mail-back envelopes could present an eco-friendlier alternative to other commercially available in-home disposal products that are disposed of in household waste. One speaker mentioned that public opinion surveys show that individuals will use mail-back envelopes or packages and that the practice

is already regulated by the United States Postal Service and Drug Enforcement Administration. Multiple stakeholders mentioned in response that mail-back envelopes see low rates of return and that patients might prefer in-home disposal products. However, this could be due to a lack of patient education accompanying the mail-back envelopes.

Patient Education

Patient education would be a necessary component of a REMS program for opioid disposal. Educational approaches range from one-on-one patient education to mass media campaigns. For educational approaches to be successful, they must reach the target audience, the information must be appropriate, and the audience needs to understand and believe the information, as well as have the resources and skills to make the desired change. There is low general population awareness about opioid disposal programs or why it is important to dispose of unused opioids – for this reason, mass public education campaigns could be beneficial in increasing disposal rates.

In addition, it is important that patients receive the same message from all health care providers (prescribers, nurses, pharmacists, and other clinicians) at multiple touchpoints to reinforce education surrounding opioid disposal. One speaker noted that it is important that patient education be private to foster patient trust and confidentiality. Patients place a great degree of trust in their pharmacists and care providers, so leveraging these relationships in patient education could increase disposal rates. However, meeting participants stressed that opioid disposal education should be integrated into existing pharmacy workflows, and pharmacy practitioners should be compensated for their time spent on this education, documentation, and follow-up. Regulators should consider the time and resource burden on clinicians when considering a new REMS.

Evidentiary Needs

Meeting participants stressed that new policy enacted for drug disposal should be evidence-based rather than reactionary. One speaker noted that there is little data on current drug collection efforts, and the data that does exist is not standardized. Providing a framework for common metrics could help determine the efficacy of different opioid disposal options. Additionally, there is little known about what types of medications are included

in disposal efforts. DEA regulations prevent inventorying of medications collected in kiosks or mail-back envelopes and packages, therefore collecting data on the types of medication disposed or what percentage of collected drugs are opioids is difficult. Data that can be collected includes the total weight of the medication, but it is not separated by type of medication.

Currently, there seems to be no research comparing mail-back envelopes to in-home disposal products. Determining the rate of disposal with in-home disposal products is dependent on self-reporting, which could lead to bias; some participants suggested that introducing radio-frequency identification technology could help in tracking disposal rates via in-home products.

One participant suggested that there could be increased federal grant funding toward research in this area like the initiatives started after large tobacco settlements. Other participants noted that assessing the impact of a REMS through FDA-funded studies could be an important step in determining the public health value of in-home opioid disposal products. Assessment is an important component of a REMS, and participants added that surveys and quasi-experimental or experimental research are needed to determine the causal relationship between REMS and disposal rates.

Potential Unintended Consequences of a REMS

Meeting participants considered potential unintended consequences of a REMS for opioid disposal. Participants suggested that since individuals often hold onto pills for later use, it is possible that opioid prescribing could increase with increased disposal as patients would request new prescriptions with each episode of pain rather than taking unused pills from old prescriptions. In addition, in-home disposal products can be easily misplaced, thrown out, or left unused, generating waste amongst patients who do not utilize the products. Finally, a REMS for opioid disposal could create a sense of fear amongst patients who perceive the drugs as dangerous, potentially affecting their care if prescribed opioids for acute pain.

There may be system-level challenges associated with implementing a new REMS program for in-home opioid disposal that stem from coordinating the needs of regulators, manufacturers, vendors, and other stakeholders. The program would be a novel REMS using a new authority and would likely be a large

[shared system REMS](#). Furthermore, it could overlap with other approved shared system REMS for opioids, including the Opioid Analgesic REMS. Shared system

REMS come with their own set of challenges, such as determining governance structures and the time needed to coordinate such programs.

Conclusion

Disposal is an important component of safe medication use for the opioid drug class and could help prevent misuse or diversion of unused medication. Participants in this meeting discussed the different needs that patients have in disposing of unused medications, emphasizing that a **multi-faceted approach with a focus on patient education would likely be most successful in encouraging high rates of disposal**. A new REMS for opioid disposal, if implemented, should be done so in concert with state and local efforts in safe medication disposal and should consider the needs of different stakeholders in the health care system, including prescribers, pharmacists, and patients. While questions remain about the preference for in-home disposal products and the best way to incentivize their use, even a small increase in the disposal of opioid medications using this method, or the other methods described here, can have a large impact on public health.

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