Canadian Home Care Association
canadienne de soins et services à domicile

Building Operational Excellence
Home-Based Palliative Care

Managing Medication and Supplies in Home-Based Palliative Care

Evidence Synthesis

December 2019

ABOUT THE OPERATIONAL EXCELLENCE IN HOME-BASED PALLIATIVE CARE PROJECT

Operational Excellence in Home-Based Palliative Care is a 19-month project that builds on The Way Forward: An Integrated Palliative Approach to Care. The goal is to identify innovative operational practices that address specific service gaps and improve the quality, efficiency and accessibility of home and community palliative care. The project is a catalyst to improve operational infrastructure in home-based palliative care and enhance access to better home care as outlined in the Common Statement of Principles on Shared Health Priorities for federal, provincial and territorial governments. Visit https://cdnhomecare.ca/operational-excellence-in-home-based-palliative- care/ for more information.

This project was supported by a health funding contribution agreement from Health Canada. The views expressed herein do not necessarily represent the views of Health Canada.

ABOUT THE CANADIAN HOME CARE ASSOCIATION

Established in 1990, the Canadian Home Care Association (CHCA) is a national non-profit membership association dedicated to advancing excellence in home and community care. Through our diverse membership base, the CHCA represents public and private organizations that fund, manage and provide services and products in the home and community. In partnership with our members, the CHCA advances initiatives that address national priorities in home and community care. As a recognized authority, the CHCA facilitates knowledge sharing, creates connections, informs policy and practices, and advocates for integrated home and community care for all Canadians.

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ACKNOWLEDGMENTS

The author would like to acknowledge the Canadian Agency for Drugs and Technologies in Health (CADTH) for sharing their literature review.

EXECUTIVE SUMMARY

Purpose

The purpose of this evidence synthesis is to build upon previous work within the Canadian Home Care Association's Building Operational Excellence – Home-Based Palliative Care project by conducting a review of the research evidence and grey literature that addresses access, management and disposal of medications and supplies in home-based palliative care.

Research Question

What models, barriers and enablers exist for the access, management and disposal of medications and supplies in home-based palliative care?

Literature Review and Critical Appraisal

A search of both published and grey literature was conducted in 2019.

Following a relevance assessment and critical appraisal, the following sources were included in this synthesis: 1 high-quality guideline, 1 medium-quality systematic review, 6 medium-quality primary studies, 3 low-quality qualitative primary studies, and 3 low-quality primary studies

Key Findings

ACCESS TO MEDICATIONS

- Key findings included the enhancement of the education and role of medication prescribers, including prescriber education related to quantity and short versus long acting opioids. Another source recommended that the pharmacist should play a significant role in symptom management, medication safety and to support treatment decisions.
- Emergency medication kits were recommended by some sources. The kits provide easy and timely access to medications and should be available and safely stored in all community locations (including home care sites).

MANAGEMENT OF MEDICATIONS

- A high-quality guideline from the United Kingdom recommended that structured systems, policies and processes should be in place for all organizations (including home care) that have access to controlled drugs.
- Another source provided guidelines for nurses working in hospice and palliative care including educational, clinical practice, safe storage and disposal practices.
- In terms of medication management as the administration of medication, the evidence noted that many caregivers do not feel as though they have adequate support, making the administration of medications in the home care environment very stressful.
- Interventions to improve the administration of medications in home care included emergency medication kits, structured and tailored educational interventions, a medication therapy management program with a pharmacist, a caregiver medication diary, a syringe driver, and an advanced robotic device that dispensed medications to the patients at predetermined times.
- The included studies found many unsafe medication storage practices including storing unused

medications in the home instead of returning them for disposal, as well as unsafe storage practices like keeping the medications in unsecured and unlocked places around the home.
- Interventions to improve safe medication storage habits included having the healthcare provider review safe storage information with the patient/caregiver, educational campaigns to promote safe storage and promoting an easily accessible and lockable location to store the medications.

DISPOSAL OF MEDICATIONS

- Guidance from the Government of Canada recommended returning any unused medications to a pharmacy take-back program such as the one run by the Health Products Stewardship Association (HPSA) in British Columbia, Manitoba, Ontario and Prince Edward Island. If this is not an option, a method for disposal in the trash is outlined which involves separating the medication from its packaging, removing all labels from the packaging, placing the medication in a bag with an unappealing substance (e.g. cat litter) and disposing in the trash.
- Two studies examined current disposal practices and found that many patients/caregivers were unaware of disposal guidelines and the proper way to dispose of medications. A third study found that a large proportion of the medication dispensed was returned for disposal.
- Interventions to improve safe medication disposal included guidelines for disposal for when a patient dies in the home, the Canadian take-back program operated by the HPSA, the need for permanent take-back boxes in the United States, Ontario's patch-for-patch return policy, medication disposal pouches, and staff and patient educational programs.

DISPOSAL OF SUPPLIES

- Very little information was found about safe disposal of supplies. A medical sharps take-back program is operated in Ontario and Prince Edward Island by the HPSA. In addition, the high-quality NICE guideline contained information about disposal of bottles that contain small amounts of liquid medication.

QUALITY AND APPLICABILITY OF KEY FINDINGS

- This synthesis recommends focusing on the key findings of the highest quality and the highest applicability.
- The highest quality evidence comes from a high-quality guideline that recommends organizational policies and procedures to manage and monitor controlled drugs for organizations that have access to these drugs.
- The next highest-quality evidence comes from a medium-quality systematic review that recommended structured educational programs to assist patients with medication management.
- The most applicable evidence was found in Canadian grey literature documents. These documents are from reputable organizations and cover symptom management kits, safe storage of medications and safe disposal of medications.

CONTEXT

The Canadian Home Care Association (CHCA) is currently leading the Building Operational Excellence – Home-Based Palliative Care project. The purpose of this project is to identify 'innovative operational practices to address specific service gaps and improve the quality, efficiency and accessibility of home-based palliative care' Within this project are four areas of focus:

- Inclusion of advance care plans into the delivery of care in the home.
- Assessment and care planning.
- Effective communication strategies and tactics.
- Supplies, equipment and medication management (1).

The purpose of this evidence synthesis is to address the fourth area of focus: supplies, equipment and medication management. Some foundational work in this area has already been completed. In 2018, the CHCA conducted a modified E-Delphi process to gain consensus on priority areas for the Building Operational Excellence project. This included holding workshops with stakeholders and conducting telephone interviews and online surveys with patients and caregivers. Based on this feedback, the following five areas for improvement were identified:

- Processes to ensure that necessary medications are onsite in the home without duplication or delay.
- Processes to ensure that necessary equipment and supplies are onsite in the home without duplication or delay.
- Systems to organize supplies and medications in the home for quick and easy access and effective inventory management.
- Protocols for returning and or recycling supplies, equipment and medications that are cost-effective and user-friendly.
- Processes for safe disposal or diversion of narcotics such as opioids (2).

An experience map was then created that then built upon these results (Appendix A). The experience map is "a visual representation of opportunities and gaps shared by subject matters experts, patients and caregivers on operational processes to ensure safe access, storage, management and disposal of medications, equipment and supplies". The experience map lays out three areas of focus:

AREA OF FOCUS	OPPORTUNITIES	GAPS
ACCESS No duplication or delay	• Electronic order sets and dispensing guidelines • Standardized palliative symptom management kits	• Order delays, duplication and excess • Funding limitations and cost constraints • Inconsistent practices and protocols by pharmacies and across geographies
MANAGE Organize and maintain inventory	• Institute for Safe Medication Practices (ISMP) focus on preventing medication errors	• Inventories are not routinely kept in the home • No organizing protocols and systems • Not clear who is responsible for organizing inventory
DISPOSE Systems for easy return	• Health Product Stewardship Associations' 'Medications Returns Programs'	• Lack of processes for safe disposal and diversion of opioids • Not clear who is responsible for disposal • No guidelines on how to return or recycle equipment and supplies. (3)

The purpose of this evidence synthesis is to build upon this experience map by conducting a review of the research evidence and grey literature which addresses these topics.

RESEARCH QUESTION

Given the broad scope of the 'Management of Supplies, Equipment and Medication' experience map it was necessary to narrow the scope of the evidence synthesis. The decision was made to exclude equipment from the evidence synthesis, not only to focus the search, but also because there is not as much of a risk for social harm from the diversion of equipment from the home (e.g. hospital beds, wheelchairs) as there is from used supplies (e.g. medication sharps and used IV bags) and unwanted medications (esp. opioids and benzodiazepines). In addition, the issue of ownership is much different for equipment than it is for supplies and medications. Medical equipment is often rented to the patient by a private company that will pick up the equipment after a patient has died in the home. Supplies and medications, on the other hand, are owned by the patient, putting full responsibility for management and disposal on the caregiver once the patient passes away.

With the above parameters in mind, the following research question was created:

What models, barriers and enablers exist for the access, management and disposal of medications and supplies in home-based palliative care?

LITERATURE SEARCH AND CRITICAL APPRAISAL

A search of both published and grey literature was conducted in May 2019 by an Information Specialist at the Canadian Agency for Drugs and Technologies in Health (CADTH). The Information Specialist:

- Searched Pubmed;
- Conducted a focused internet search of the websites of selected Canadian and international health technology agencies;
- Limited the searches by date, from 2005 onwards;
- Included only English language publications.

In addition, focused searches of both Health Systems Evidence and Social Systems Evidence were conducted with the same parameters as the CADTH search to broaden the scope and target synthesized evidence. A total of 103 sources were found by the searches. These sources were then assessed for relevance based on the following criteria:

Inclusion criteria: focused on patient population over the age of 18 years, home-based care setting, interventions that focused on access, management and disposal of medications and supplies.
Exclusion criteria: pediatric patient population (under the age of 18), care in other settings (e.g. hospitals, long-term care homes).

Thirty sources remained following the primary relevance assessment. After full-text review 22 sources remained: 1 clinical guideline, 1 systematic review, 12 primary studies, 8 grey literature documents.

These sources were then critically appraised using the Infection Prevention and Control (IPAC) Guidelines Critical Appraisal Tool Kit (4), with the exception of the clinical guideline which was appraised using the AGREE II Instrument (5) because the IPAC tool kit did not have an appraisal tool for guidelines.

The results of critical appraisal are as follows:

- 1 high-quality guideline
- 1 medium-quality systematic review
- 6 medium-quality primary studies
- 3 low-quality qualitative primary studies
- 3 low-quality primary studies

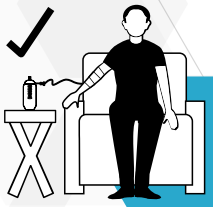
All of these sources were included in the key findings.

KEY FINDINGS

According to the research question there are six possible categories that the findings can fall into:

1. Access to medications
2. Management of medications
3. Disposal of medications
4. Access to supplies
5. Management of supplies
6. Disposal of supplies

Of these six categories, this review uncovered findings applicable to four: access to medications, management of medications, disposal of medications and disposal of supplies. The majority of the findings related to management and disposal of medications.



Access to Medications

This review identified two medium-quality primary studies, one low-quality qualitative study and one grey literature document that addressed the topic of access to medications. Subthemes in this category are prescriber education and role and emergency medication kits.

PRESCRIBER EDUCATION AND ROLE

Two medium-quality primary studies and one grey literature document pointed to the education and role of medication prescribers as an avenue to improve access to medications. One medium-quality study from the United States found that of the senior's population (aged 65 and older) covered by a Medicare regional health plan, more than half stored unused medications in their cabinets. The authors noted that this may point to medication overprescribing practices (6).

Another medium-quality study of a medication take-back event in the United States recommended changes to prescriber education that:

- emphasizes the importance of the quantity of medication prescribed and subsequently dispensed;
- encompasses both short- and long-acting opioid-containing products and their uses in acute and chronic pain (7).

The Ontario Palliative Care Network's (OPCN) recommendations for a model to improve palliative care in Ontario recommends that the patient have 24/7 access to pain and symptom management from the Core Team or the on-call providers (in-person or telemedicine). This includes having pharmacists play a significant role in symptom management, medication safety and to support treatment decisions throughout the patient's journey, including after-hours access to pharmacy services and expertise (8).

TABLE 1: Key Findings—PRESCRIBER EDUCATION AND ROLE

One medium-quality study from the United States found that more than half of patients stored unused medications in their cabinets. The authors noted that this may point to medication overprescribing practices (6). Another medium-quality study of a medication take-back event in the United States recommended changes to prescriber education that:

- emphasizes the importance of the quantity of medication prescribed and subsequently dispensed;
- encompasses both short- and long-acting opioid-containing products and their uses in acute and chronic pain (7).

A grey literature document from the Ontario Palliative Care Network (OPCN) recommends that the palliative home care patient have 24/7 access to pain and symptom management from the Core Team or the on-call providers (in-person or telemedicine). This includes having pharmacists play a significant role in symptom management, medication safety and supporting treatment decisions throughout the patient's journey, including after-hours access to pharmacy services and expertise (8).

EMERGENCY MEDICATION KITS

One low-quality primary study and the document from the Ontario Palliative Care Network (OPCN) examined the role of emergency medication kits in providing access to medications for home care.

The low-quality qualitative study from Australia examined the experiences of caregivers providing care to a dying person who was supplied with an Emergency Medication Kit (EMK). An EMK provides parenteral medications in the home setting to enable a timely response to an increase in symptoms and may help the patient to continue receiving care at home instead of being readmitted to inpatient care. Caregivers in the study reported that the kit provided easy access to the medications needed when symptoms exacerbated and provided a timely response as the caregiver could access the medications instantly and did not need to go through the regular community route. The study also found that while many caregivers saw the EMK as a resource that they could access, a substantial proportion saw it as for use only by the visiting palliative care nurses (9).

The OPCN recommends that standardized symptom management kits, supported by policies and protocols, should be available and safely stored in all community settings (e.g. patient's home) for the management of unexpected, emerging, or worsening symptoms. The OPCN also states that there be provincial standards for symptom management kits, including:

- standards pertaining to medications and doses;
- protocols for ordering and dispensing the kits and monitoring their utilization;
- safety standards; and,
- education for community nurses about the use of the kits (8).

TABLE 2: Key Findings—EMERGENCY MEDICATION KITS

One low-quality qualitative study from Australia examined the experiences of caregivers who provided care to a dying person when supplied with an Emergency Medication Kit (EMK). Caregivers in the study reported that:

- the kit provided easy access to the medications needed when symptoms exacerbated;
- the kit provided a timely response as the caregiver could access the medications instantly and did not need to go through the regular community route; and
- many caregivers saw the EMK as a resource that they could access, but a substantial proportion saw the EMK as for use by the visiting palliative care nurses only (9).

The grey literature document from the Ontario Palliative Care Network's (OPCN) recommends that standardized symptom management kits, supported by policies and protocols, should be available and safely stored in all community settings (e.g. patient's home) for the management of unexpected, emerging, or worsening symptoms. The OPCN also states that there should be provincial standards for symptom management kits (8).

Management of Medications

One high-quality guideline, one medium-quality systematic review, three medium-quality studies, three low-quality qualitative studies, two low-quality primary studies and two grey literature documents addressed the issue of medication management in home care.

The term 'management' itself was defined in three different ways across the evidence:

1. Management of organizational and clinical practice – broad policies and procedures that guide organizational and clinical practice on the issue of medication management.
2. Administration of medications / management of symptoms.
3. Storage of medications in the home.

Within these three broad areas, this review identified five subthemes to the findings:

- Organizational and clinical practices
- Administration of medications – patient and caregiver practices
- Administration of medications – interventions
- Storage of medications – patient and caregiver practices
- Storage of medications - interventions

ORGANIZATIONAL AND CLINICAL PRACTICES

One high-quality guideline and one grey literature document identified organizational and clinical practices as a means of managing medications in home care. The high-quality guideline from the United Kingdom recommends that all organizations that have access to controlled drugs, including home care organizations, have structured systems, processes and policies in place to maintain safe access, management and disposal of controlled drugs. These systems and processes include:

- Governance agreements with clear lines of responsibility and accountability for controlled drugs in their contact.
- A controlled drugs accountable officer responsible for quality assuring processes for managing controlled drugs in their organization.
- A controlled drugs policy and operating procedures for storing, transporting, destroying and disposing of controlled drugs (note: the guideline recommends that organizations consider using a risk assessment when establishing processes).
- Minimum standard operating procedures for processes relating to prescribing, supplying and administering controlled drugs, including clinical monitoring for people who have been prescribed controlled drugs.
- Safety guidance (from government and other regulatory bodies) about controlled drugs (e.g. patient safety alerts) that is incorporated into policy and acted on within a specified or locally agreed timeframe.
- Standard operating procedures for storing controlled drugs that are in-line with government regulations and take into account the security risk for the setting (high, medium, low), the storage environment (e.g. location, space, temperature), storage of unwanted and expired stock medications, and storage needs for drugs with similar or 'lookalike' packaging (10).

The Hospice and Palliative Nurses Association (HPNA) from the United States published a position statement on medication safety in hospice and palliative care that focuses on education, practice, policy, advocacy, safe storage and medication disposal for nurses working in hospice or palliative care. In terms of education, the HPNA states that all hospice and palliative care nurses:

- Must understand the concepts of medication safety including safe prescribing, safe medication storage in the home, and safe disposal.
- Must stay current on federal, state and local regulations.
- Should be aware of their local resources for federally approved take-back programs as they relate to environmental regulations in their communities (e.g. state, county, local) (11).

In terms of clinical practice, the HPNA position statement provides guidance for hospice and palliative care nurses, as well as registered nurses and advanced practice nurses:

HOSPICE AND PALLIATIVE CARE NURSES:

- Must ensure organizational policies for safe medication prescription, medication safety, and disposal of medications.
- Must engage in best practices for safe storage and medication disposal at the community level and globally.

REGISTERED NURSES:

- Have a legal responsibility to adhere to safe prescribing practices, which include the following actions:
  - Educate patients in the safe use of prescription medications such as opioids, benzodiazepines, and psychotherapeutic medications;
  - Review safe storage strategies for medications; and
  - Provide instructions on the proper disposal of expired, unused, or unwanted medications.

ADVANCED PRACTICE NURSES:

- As medication prescribers, have a legal responsibility to adhere to safe prescribing practices, which include the following actions:
  - Prescribe appropriate quantities;
  - Educate patients in the safe use of prescription medications like opioids, benzodiazepines, and psychotherapeutic medications;
  - Review safe storage strategies for medications; and
  - Provide instructions on the proper disposal of expired, unused, or unwanted medications (11).

The HPNA also outlines safe storage practices for hospice and palliative care nurses, which include:

- Keeping medications in the container they were prescribed in, not plastic bags or loose in drawers, purses, backpacks, briefcases, or luggage;
- Having a routine for medications, such as putting them away after administration;
- Using safety caps to keep medications out of harm's way for others (e.g., ensuring safety caps are replaced, using safety caps unless otherwise planning, and putting medications up and away out of reach of children); and,
- Securing potentially harmful medications such as opioids, benzodiazepines, by keeping these medications out of sight of children and visitors and using locked storage areas such as a lockable medicine cabinet, a lock box, or bank bag with a lock (11)

Finally, the HPNA recommends the following to ensure safe medication disposal:

- Policies and advocacy statements that encourage participation and promotion of takeback programs and take-back events.
- Educating the patient and caregiver about the United States Food and Drug Administration's (FDA's) medication disposal guidelines. (Note: home health agencies in the United States are not authorized to dispose of controlled substances) (11).

TABLE 3: Key Findings—ORGANIZATIONAL AND CLINICAL PRACTICES

The high-quality guideline from the United Kingdom recommends that all organizations that have access to controlled drugs, including home care organizations, have structured systems, processes and policies in place to maintain safe access, management and disposal of controlled drugs, including:

- Governance agreements.
- A controlled drugs accountable officer.
- A controlled drugs policy and operating procedures for storing, transporting, destroying and disposing of controlled drugs.
- Minimum standard operating procedures for processes relating to prescribing, supplying and administering controlled drugs.
- Safety guidance (from government and other regulatory bodies) about controlled drugs (e.g. patient safety alerts).
- Standard operating procedures for storing controlled drugs (10).

A grey literature document from the Hospice and Palliative Nurses Association (HPNA) (United States) outlines a position statement on medication safety in hospice and palliative care that focuses on education, practice, policy, advocacy, safe storage and medication disposal for those in hospice or palliative care. Guidance includes:

- Educational guidelines
- Clinical practice guidelines
- Storage guidelines
- Medication disposal guidelines (11).

ADMINISTRATION OF MEDICATIONS – CAREGIVER PRACTICES

Three low-quality qualitative studies examined the current medication administration practices of caregivers. One low-quality qualitative study from Australia examined the experiences of caregivers who provided care to a dying person who was supplied with an Emergency Medication Kit (EMK). The study examined caregiver's experiences before the provision of the EMK and found that they had employed a number of strategies to manage medications including keeping a written record of all medications and care activities. They also found that many of these strategies were insufficient to maintain acceptable levels of symptom control (9).

Another low-quality qualitative study from the United Kingdom examined bereaved family members recollections of managing end-of-life medications when delivering care to a patient dying at home. The study found that caregivers used a number of strategies to facilitate medication management including recording keeping on a chart. Some caregivers found the responsibility for managing medications to be daunting given the consequences of making a medication error. For instance, caregivers noted concerns about dosage errors, especially the fear of overdosing the patient, or not being able to administer the drugs when the patient becomes too ill to administer medications orally. The same study found that caregivers were particularly concerned about end-of-life drugs, morphine in particular, and about how the implementation of a syringe driver could signal the patients' transition into the dying phase. Overall, the family caregivers in this study did not see themselves as having adequate support to deliver end-of-life medications in the home (12).

A third low-quality qualitative study from the Republic of Ireland found that the management and administration of medications was particularly stressful for caregivers who were managing medications for palliative care patients at the end of life, especially when multiple medications were involved. This led to issues of timing and coordination. Caregivers asked for more information on what each medication was for so they could prioritize the most important medications. While some caregivers did not report issues with providing as-needed medications – in fact, many found it empowering - others saw as-needed medications as another source of stress. Other issues noted by the caregivers included the cost burden of the medications if they were not covered by insurance and the excess of medications left over once the patient had passed away. Caregivers saw this as a waste of resources, both in terms of wasted medications and wasted finances/tax dollars (13).

TABLE 4: Key Findings—ADMINISTRATION OF MEDICATIONS—CAREGIVER PRACTICES

One low-quality qualitative study from Australia examined the experiences of caregivers who provided care to a dying person when supplied with an Emergency Medication Kit (EMK). The study examined caregiver's experiences before the provision of the EMK and found that they had employed a number of strategies to manage medications, including keeping a written record of all medications and care activities. They also found that many of these strategies were insufficient to maintain acceptable levels of symptom control (9).

Another low-quality qualitative study from the United Kingdom examined bereaved family members recollections of managing end-of-life medications when delivering care to a patient dying at home. The study found that:

- Caregivers used a number of strategies to facilitate medication management including recording keeping on a chart;
- Some caregivers found the responsibility for managing medications to be daunting given the consequences of making a medication error;
- Caregivers were particularly concerned about end-of-life drugs and about how the implementation of a syringe driver could be a signal of transition into the dying phase;
- Overall, the family caregivers in this study did not see themselves as having adequate support to deliver end-of-life medications in the home (12).

A third low-quality qualitative study from the Republic of Ireland found that the management and administration of medications was particularly stressful for caregivers who were managing medications for palliative care patients at the end of life, especially when multiple medications were involved. The study also found that:

- Caregivers asked for more information on what each medication was for so that they could prioritize the most important medications;
- Some caregivers did not report issues with providing as-needed medications, but others saw as-needed medications as another source of stress;
- Caregivers were concerned about the cost burden of the medications if they were not covered by insurance and the excess of medications left over once the patient had passed away (13).

ADMINISTRATION OF MEDICATIONS – INTERVENTIONS

One medium-quality systematic review, two medium-quality qualitative primary studies, three low-quality qualitative studies and one low-quality primary study examined interventions aimed at improving the administration of medications in the home care setting. The medium-quality systematic review focused on studies that had evaluated interventions for family caregivers managing pain medications for patients with advanced cancer. The included studies were from the United States (n=5), United Kingdom (n=1), Norway (n=1), and Taiwan (n=1). All of the interventions included in the review had the following components:

- Face-to-face education or training sessions;
- Support through written or other resources;
- Opportunities for questions and discussion; and
- Follow-up contacts for coaching and/or reinforcement (14).

The interventions were delivered by a specially trained clinician (nurse, psychologist) or researcher in the patient's home or in hospital outpatient clinics. All of the interventions focused on the following topics:

- Managing pain and pain medication;
- Addressing barriers to pain management;
- Knowledge about how analgesics work;
- Beliefs about addiction and tolerance;
- Fears about side effects and overdose;
- Excessive stoicism; and,
- Poor communication between patients, family carers and health professionals (14).

Overall, the systematic review found that educational interventions have the potential to improve a caregiver's knowledge and self-efficacy for pain medication management and change misconceptions about cancer pain and medications if the interventions:

- Contain structured and tailored elements;
- Are delivered in one or more face-to-face sessions;
- Are supported by written and/or other resources; and
- Include further contact with a trained clinician (nurse or psychologist) for reinforcement or review (14).

One medium-quality study from the United States found that high proportions of caregivers in their study had not received additional support to perform medication responsibilities. Less than 40% had additional formal or informal support with managing the patient's medications. The study also found that among caregivers with additional support, many had disagreements with their support about their treatment plans. Many characteristics previously identified as barriers to caregiving tasks and medication management (e.g. racial/ethnic minority status, low socioeconomic status) were found to be more likely associated with less support with medication management. The study recommends targeting these individuals with additional interventions, as well as targeting those with low self-efficacy and those managing complex medication regimens (15).

Another medium-quality study from the United States of the senior's population (aged 65 and older) covered by a Medicare regional health plan, recommended the implementation of medication therapy management programs in which pharmacists have direct one-to-one interactions with patients about their medication regime (6). This finding is echoed by a low-quality qualitative study from the United Kingdom that examined bereaved family member's recollections of managing end of life medications when delivering care to a patient dying at home. The authors recommend increasing the role of community pharmacists by having them provide advice and training in the safe management, storage and disposal of medications (12).

Apart from patient education, the remainder of the findings examined the provision of medication kits with a medication diary or specific technologies to assist caregivers with medication administration and management. One low-quality qualitative study from Australia examined the experiences of caregivers who provided care to a dying person when supplied with an Emergency Medication Kit (EMK). The study found that the medication diary that was supplied along with the EMK was useful to some caregivers and could act as a communication tool between caregivers and health care professionals (9).

Another low-quality qualitative study from the Republic of Ireland examined the use of a syringe driver to administer medications for palliative care patients at the end of life. A syringe driver is a small pump that delivers medication at a constant rate though subcutaneous infusion. The study noted that participants had overall positive experiences when using a syringe driver to manage medications. This said, some caregivers worried about device malfunction and asked for specific guidelines about what to do if the driver failed (13).

A third low-quality study from Finland examined the use of an advanced robotic device to promote medication adherence for elderly home-care patients. The device is activated at predetermined dosing times. When a medication dose is to be taken, the device provides a spoken reminder message, a sound signal, a light signal in the dose button, and written instructions. When the patient presses the device's dispenser button, the device delivers a sachet containing the medication(s). If the patient misses a dose, the telecare component of the dispenser contacts a primary care nurse for follow-up (16).

The study found that all patients and all-but-one nurse found the device easy to use. Most nurses regarded the machine as safe with two exceptions: one patient did not take the medications because the device's instructions stopped, and another patient was afraid of the sounds the device was making. Overall, the authors stated that the device was promising for two reasons:

- Medications are delivered according to the patients need as opposed to the caregiver's schedule;
- The device could reduce the need for nurses to visit home care patient's homes, thus reducing resource use and cost. (16)

TABLE 5: Key Findings—Administration of Medications—INTERVENTIONS

One medium-quality systematic review focused on studies that had evaluated interventions for family carers managing pain medication for patients with advanced cancer. The review found that educational interventions have the potential to improve caregiver's knowledge and self-efficacy for pain medication management and change misconceptions about cancer pain and medications if the interventions:

- Contain structured and tailored elements;
- Are delivered in one or more face-to-face sessions;
- Are supported by written and/or other resources; and
- Include further contact with a trained clinician (nurse or psychologist) for reinforcement or review (14).
- One medium-quality study from the United States found that high proportions of caregivers in the study had not received additional support to perform medication responsibilities. The study also found that:
- Among caregivers with additional support, many may have disagreements with their support about their treatment plans;
- Many characteristics previously identified as barriers to caregiving tasks and medication management (e.g. racial/ethnic minority statues, low socioeconomic status), were found to be more likely associated with less support with medication management. The study recommends targeting these individual with additional interventions; and
- Targeting those with low self-efficacy and those managing complex medication regimens is recommended (15).

Another medium-quality study from the United States of the senior's population (aged 65 and older) covered by a Medicare regional health plan, recommended the implementation of medication therapy management programs where pharmacists have direct one-to-one interactions with patients about their medication regime (6).

One low-quality qualitative study from the United Kingdom examined bereaved family members recollections of managing end of life medications when delivering care to a patient dying at home. The authors recommend increasing the role of community pharmacists by having them provide advice and training in the safe management, storage and disposal of medications (12).

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Another low-quality study from Finland examined the use of an advanced robotic device to promote medication adherence for elderly home-care patients. The study found that all patients and all-but-one nurse found the device easy for patients to use. Overall, the authors stated that the device was promising for two reasons:

- Medications are delivered according to the patients need as opposed to the caregiver's schedule; and,
- The device could reduce the need for nurses to visit home care patient's homes, thus reducing resource use and cost (16).

STORAGE OF MEDICATIONS – PATIENT AND CAREGIVER PRACTICES

Two medium-quality primary studies examined the medication storage practices of patients and caregivers. The first medium-quality study found that of the senior's population (aged 65 and older) covered by a Medicare regional health plan in the United States, more than one-half stored unused medications in their cabinets. Of these unused medications, approximately 8% were controlled substances such as narcotic pain medications (e.g., hydrocodone, oxycodone, fentanyl) and benzodiazepines for psychiatric disorder treatments (e.g., alprazolam, lorazepam) (6).

The other medium-quality study was of cancer outpatients in the United States. The study found that:

- Less than 10% of patients store their opioids under lock and key;
- Over 45% have unused opioids at home;
- More than 40% saved opioids for future use;
- Nearly 10% reported sharing their opioids and over 15% reported losing their opioids; and,
- Nearly 40% were unaware that opioids could be fatal when taken by others (17).

TABLE 6: Key Findings—STORAGE OF MEDICATIONS - PATIENT AND CAREGIVER PRACTICES

One medium-quality study found that more than one-half stored of the seniors involved in the study stored unused medications in their cabinets. Of these unused medications, approximately 8% were controlled substances such as narcotic pain medications and benzodiazepines for psychiatric disorder treatments (6).

The other medium-quality study was of cancer outpatients in the United States. The study found that:

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- More than 40% saved opioids for future use;
- Nearly 10% reported sharing their opioids and over 15% reported losing their opioids; and,
- Nearly 40% were unaware that opioids could be fatal when taken by others (17)

STORAGE OF MEDICATIONS – INTERVENTIONS

One high-quality guideline, one medium-quality study, one low-quality study and one grey literature document examined interventions to promote safe storage of medications in the home. The high-quality guideline from the United Kingdom recommends that all organizations that have access to controlled drugs should provide the patient/caregiver with the following information about how to store drugs safely, including:

- The person's preference for a lockable or non-lockable storage box;
- Whether the controlled drugs will be accessible to people who should and should not have access to them; and,
- Whether the storage method could increase the risk of controlled drug-related incidents, including patient safety incidents (10).

The safety bulletin on safe storage and disposal of medications from the Institute of Safe Medication Practices (ISMP) Canada states that the ideal medication storage location should provide easy accessibility for the intended user while preventing or discouraging inappropriate access and accidental ingestion by anyone else, especially children. A locking device is strongly suggested, either for the medication container or for the cabinet in which medications are stored (19).

One medium-quality study of cancer outpatients in the United States examined the use of public education campaigns to promote the safe storage of medications. The study recommends educational campaigns to foster safe storage (e.g. Lock Your Meds by the Florida Family Partnership) and notes that there is an overall need for universal education of all patients receiving opioids regarding safe storage, use, and disposal to minimize the risks of diversion or accidental poisoning. The same study recommends medication lock bottles with combination locks to help address the problem of unsafe storage (17).

A low-quality study from the United States also examined the impact of a patient education program on patterns of use, storage and disposal of opioids among cancer outpatients and found improvements in the knowledge and practices of patients related to use, storage and disposal. After implementation of the education program:

- Fewer patients had unused opioids at home;
- More patients kept their opioids in a safe place;
- More patients never shared their opioids with someone else;
- Fewer patients reported unsafe use of opioids;
- More patients believed that improper use of opioids is a common problem in the society;
- More patients were aware of the danger of their opioids for others;

- Patients were less likely to share their opioids with someone else;
- Patients were less likely to practice unsafe use of opioids;
- Patients were less likely to have unused medication at home; and
- Patients were more likely to keep their medications in a safe place (hidden or locked) (18).

The same study noted that:

- Patients had to be motivated for the educational materials to work;
- Contact with staff when the materials are given is an opportunity to emphasize the value of that knowledge;
- Take home information allows patients to access the information at their own convenience and share the information with their support system (e.g. caregivers, family); and,
- Educational materials must use simple, plain and concise language (18)

TABLE 7: Key Findings—STORAGE OF MEDICATIONS - INTERVENTIONS

One high-quality guideline from the United Kingdom recommends that all organizations that have access to controlled drugs should provide the patient/caregiver with the following information about how to store drugs safely, including:

- The person's preference for a lockable or non-lockable storage box;
- Whether the controlled drugs will be accessible to people who should and should not have access to them; and
- Whether the storage method could increase the risk of controlled drug-related incidents, including patient safety incidents (10).

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One medium-quality study from the United States of cancer outpatients recommends educational campaigns to foster safe storage. The authors' note that there is an overall need for universal education of all patients receiving opioids regarding safe storage, use, and disposal to minimize the risks of diversion or accidental poisoning. The same study recommends medication lock bottles with combination locks to help address the problem of unsafe storage (17).

One low-quality study from the United States examined the impact of a patient education program on patterns of use, storage and disposal of opioids among cancer outpatients. After implementation of the education program, the study found improvements in safe practices (e.g. safe storage, not sharing medications) as well as knowledge about the dangers of opioid diversion into society. The study also noted that:

- Patients had to be motivated for the educational materials to work;
- Contact with staff when the materials are given is an opportunity to emphasize the value of that knowledge;
- Take home information allows patients to access the information at their own convenience and share the information with their support system (e.g. caregivers, family); and,
- Educational materials must use simple, plain and concise language (18).

Disposal of Medications

One high-quality guideline, five medium-quality studies, one low-quality primary study and seven grey literature documents addressed the issue of medication disposal in the home. Three subthemes were identified within this category:

- Medication disposal processes – government guidance
- Medication disposal – patient and caregiver practices
- Medication disposal – interventions

MEDICATION DISPOSAL PROCESSES – GOVERNMENT GUIDANCE

This review found five grey literature documents that describe medication disposal processes that are recommended by the government agencies. The Government of Canada's website on the safe disposal of prescription drugs recommends checking the medicine cabinet and removing all expired and unused prescription drugs, over-the-counter medications and natural health products. These can then be taken to a local pharmacist for disposal through the Health Products Stewardship Association program. The website also states that unused or unwanted medications should never be flushed down a toilet or sink as this can lead to traces of pharmaceuticals in the water and environment. Disposal in the trash is recommended as a last resort. Medications should be removed from their original containers, all identifying information on the prescription label should be scratched out, then the medication should be hidden in something unappealing (e.g. kitty litter or coffee grounds), then placed in a closed bag, empty can or other sealed container to prevent the drug from leaking or breaking out of a garbage bag (20).

The Institute for Safe Medication Practices Canada's (ISMP) safety bulletin on the safe storage and disposal of medications makes the following recommendations for safe disposal:

- Taking unused medications to a community pharmacy for proper disposal is an ideal method as it is easy to perform, minimizes the risk for diversion, does not impose a financial burden on the patient or caregiver, and is environmentally sound.
- Disposing of medications in the trash is not acceptable as home garbage containers are often vulnerable to access by children and pets, as well as to drug diversion.
- There are compelling arguments against widespread use of flushing medications down the toilet, given that the potential environmental and health impact of most products is unknown (19).

The recommended methods of disposal in the United States are more difficult for a patient or caregiver to follow given that there is no consensus between the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) on disposal. The FDA states that some medications should be flushed down the toilet while the EPA promotes altering medications before disposal because flushing medications into the sink or toilet affects the water supply (11). Apart from this issue, the FDA provides clear guidance to Americans about the disposing of medications. The FDA's website on the disposal of unused medications states that the best way to dispose of most old, unused, unwanted, or expired medication is to drop it off at a drug take-back site, location, or program immediately. These take-back sites can be permanent (e.g. pharmacies, hospitals or law enforcement agencies) or temporary (e.g. events such as Drug Take Back Days) (21).

The FDA also recommends flushing certain medications that are on their flush list (e.g. Oxycodone, Fentanyl) if medication take back options are not available. The rationale for flushing is to prevent accidental poisoning. According to the FDA, environmental exposure through flushing of dangerous medications on the flush list has less potential for harm than ingestion/exposure. Disposal in the trash is another option if take back locations are not available, and the medication does not have any specific disposal instructions (e.g. FDA flush list). The following process is recommended:

1. Mix medicines (liquid or pills - do not crush tablets or capsules) with an unappealing substance such as dirt, cat litter, or used coffee grounds;
2. Place the mixture in a container such as a sealed plastic bag;
3. Throw away the container in your trash at home; and
4. Delete all personal information on the prescription label of empty medicine bottles or medicine packaging, then trash or recycle the empty bottle or packaging (21).

These recommendations are similar to the New Hampshire Department of Environmental Services' guidelines for disposing of pharmaceuticals in the home. Unwanted medications can be:

- Taken to a drop box at a local police station.
- Brought to a national take-back day.
- Brought to a medication disposal kiosk at a pharmacy where available.
- Disposed of in the trash according to the FDA method (22).

TABLE 8: Key Findings—MEDICATION DISPOSAL –GOVERNMENT GUIDANCE

The Government of Canada's website on the safe disposal of prescription drugs recommends checking the medicine cabinet and removing all expired and unused prescription drugs, over-the-counter medications and natural health products. These can them be taken to a local pharmacist for disposal through the Health Products Stewardship Association program (20).

The Institute for Safe Medication Practices (ISMP) Canada's safety bulletin on the safe storage and disposal of medications makes the following recommendations for safe disposal:

- Taking unused medications to a community pharmacy for proper disposal is an ideal method as it is easy to perform, minimizes the risk for diversion, does not impose a financial burden on the patient or caregiver, and is environmentally sound.
- Disposing of medications in the trash is not acceptable as home garbage containers are often vulnerable to access by children and pets, as well as to drug diversion.
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MEDICATION DISPOSAL – PATIENT AND CAREGIVER PRACTICES

Two medium-quality studies and one low-quality study examined the medication disposal practices of patients and caregivers. A medium-quality study of cancer outpatients from the United States found that more-than-half do not routinely dispose of opioids and only one-quarter were aware of proper disposal methods. The authors noted that the lack of uniform guidelines and easily accessible take-back programs in the United States, as opposed to Canada, Australia and some Latin American countries, could be leading to an increasing availability of unused or expired opioids for abuse and diversion (17). Another medium-quality study found that opioid prescriptions returned for disposal at a medication take-back event in the United States had greater than 60% of the amount dispensed returned for disposal (7).

One low-quality study from the United States that describes an initiative to improve patient/caregiver knowledge of safe medication disposal found that:

- Over half of respondents (n = 15) stated that they had unused medications in their household;
- 14 of 15 said that a nurse or doctor had never talked to them about how to safely dispose of medications;
- 60% of respondents disposed of their medications in the trash, sink, or toilet; and,
- Only 13% of individuals demonstrated proficiency in safe disposal of medications (23).

TABLE 9: Key Findings—MEDICATION DISPOSAL –PATIENT AND CAREGIVER PRACTICES

A medium-quality study of cancer outpatients from the United States found that more than half do not routinely dispose of opioids and only one-quarter were aware of proper disposal methods. The authors noted that the lack of uniform guidelines and easily accessible take-back programs in the United States, as opposed to Canada, Australia and some Latin American countries, could be leading to an increasing availability of unused or expired opioids for abuse and diversion (17).

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- 60% of respondents disposed of their medications in the trash, sink, or toilet; and,
- Only 13% of individuals demonstrated proficiency in safe disposal of medications (23).

MEDICATION DISPOSAL – INTERVENTIONS

One high-quality guideline, three medium-quality studies, two low-quality studies and three grey literature documents examined interventions that could increase safe disposal practices among patients and caregivers. The high-quality guideline provided specific direction about what to do when controlled drugs need to be removed after a person has died in their home. The provider should consider:

- Discussing the removal of controlled drugs with a family member or carer.
- Recording the action taken and details of the controlled drugs listed in the person's medical record or notes.
- Having a witness to the removal.

- Any requirements of the coroner to keep medicines in the person's home for a period of time.
- Taking the drugs to a health professional, such as a community pharmacist who is legally allowed to possess controlled drugs, for safe disposal at the earliest opportunity (10).

The Institute for Safe Medication Practices (ISMP) Canada's safety bulletin on the safe storage and disposal of medications also discusses how medications should be disposed of after the death of person receiving palliative care in the home. The bulletin cites an Ontario study that recommended having a pharmacist conduct an in-home medication review and remove unused medications. Having the home care service provider pick-up symptom relief kits after death of the patient is another option recommended by the ISMP Canada bulletin (19).

Take-back events and permanent drop boxes were both provided as options to improve safe disposal. The website for the Health Products Stewardship Association (HPSA) outlines their programs for disposal of medications and medications sharps in Canada. The HPSA represents producers of consumer health products and was formed to ensure the safe and effective collection and disposal of their products. It "operates collection and disposal programs that focus on prescription drugs, natural health products, over-the-counter medications, and medical sharps waste generated by the public in their homes" (24). These disposal programs mostly consist of take-back programs held in pharmacies. Unused prescription drugs, over-the-counter medications and natural health products are accepted for disposal at pharmacies in British Columbia, Manitoba, Ontario and Prince Edward Island. The website lists the impact of this program as:

- Nearly 3 million kilograms of medications collected since the inception of the program.
- Nearly 5700 participating pharmacies.
- 160 member producers (24).

Provinces not included in the HPSA initiative often have a pharmacy disposal program specific to that province. For example, the Alberta Pharmacists Association runs a medication take-back program through pharmacies called ENVIRx (25).

Two medium-quality studies examined the impact of medication take-back programs in the United States. One medium quality study of a medication take-back event, Operation Medicine Drop, found that community take-back events could be a successful intervention as 69.6 million doses of unwanted drugs were collected during these events over a 5-year period. However, the study identified the following barriers to take-back events:

- The legal requirement to have law enforcement at events to prevent diversion of medications.
- Pharmacists or pharmacy technicians are needed to identify and verify controlled substances and other drugs of concern.
- Financial considerations as it costs $1.25 US/pound to incinerate unwanted drugs (26).

The study recommends expanding the take-back programs to include permanent drop boxes, which could be housed in law enforcement offices in every county in the state. This said, the study acknowledged that this placement could be a barrier as many individuals may be apprehensive to enter a law enforcement office to use the drop box (26). This recommendation is similar to that of a medium-quality study from the United States. The study recommended expanding take-back programs to include collection sites at physician offices, hospitals, and local community pharmacies. These expanded take-back programs would also need to be supported with community-wide public awareness campaigns (6).

Related to pharmacy take-back programs is the Patch-for-Patch Fentanyl Return Policy in Ontario. This is a legislative initiative that aims to reduce the risk of harm through a policy that requires patients to return their used fentanyl patches to the pharmacy before being able to access their next refill (19).

Medication disposal pouches are another medication disposal option identified by this report. One low-quality study points to these pouches as a potential way for patients to dispose of medications at home. The pouches contain active carbon that breaks down the medications when added along with water to the pouch. The pouch can then be placed in the garbage. The pouches can assist with medication disposal as they do not require the patient/caregiver to leave the home to dispose of the medications as they would with take-back programs (23).

The remaining interventions all concern patient and public education. ISMP Canada recommends two of their resources:

- Prevent Medication Accidents - an information card developed to provide key information for patients and families about proper storage and disposal of unnecessary medications in the home.
- A handout to address the proper use, secure storage, and disposal of opioids prescribed to treat pain after surgery (19).

One medium-quality study from the United States that examined the effectiveness of a promotional program for a medication take-back event found that exposure to this campaign was successful in disposing of expired, unwanted, or unused medicine in a collection site. Those exposed to the campaign had more than twice the odds of the unexposed of disposing expired, unwanted, or unused medicine stored in their homes at a collection site set up as part of the National Collection Day (27).

One low-quality study from the United States examined the impact of a patient education program on patterns of use, storage and disposal of opioids among cancer outpatients. The study found an improvement in the knowledge and practices of patients related to use, storage and disposal. After implementation of the education program:

- More patients were aware of the proper methods of opioid disposal; and,
- More were aware of proper opioid disposal methods (18)

The World Health Organization's 'Safe management of wastes from health-care activities' recommends a broad training and public awareness program that:

- Creates awareness and fosters responsibility for good hygiene among all workers, patients and visitors at health-care facilities;
- Explains how good health-care waste management protects public health; and
- Informs the public in general about the risks from poor hygiene and health-care practices, with particular regard to people living or families of patients treated at home (28).

Approaches to public education recommended in the WHO document include:

- Poster exhibitions;
- Medical staff explaining to new patients and visitors their personal responsibilities to help maintain good hygiene and safe waste management; and,
- Information signs and pictograms that are explicit, use diagrams, illustrations and consistent colour coding to convey the message to a broad audience, including illiterate people and those with a lower educational capacity (28).

TABLE 10: Key Findings—MEDICATION DISPOSAL –INTERVENTIONS

One high-quality guideline provided specific direction about what to do when controlled drugs need to be removed after a person has died in their home. The provider should consider:

- Discussing the removal of controlled drugs with a family member or carer.
- Recording the action taken and details of the controlled drugs listed in the person's medical record or notes.
- Having a witness to the removal.
- Any requirements of the coroner to keep medicines in the person's home for a period of time.
- Taking the drugs to a health professional, such as a community pharmacist who is legally allowed to possess controlled drugs, for safe disposal at the earliest opportunity (10).

The Institute for Safe Medication Practices (ISMP) Canada's safety bulletin on the safe storage and disposal of medications also discusses how medications should be disposed of after the death of person receiving palliative care in the home. The bulletin cites an Ontario study that recommended having a pharmacist conduct an in-home medication review and remove unused medications. Having the home care service provider pick-up symptom relief kits after death of the patient is another recommended option (19).

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- The legal requirement to have law enforcement at events to prevent diversion of medications.
- Pharmacists or pharmacy technicians are needed to identify and verify controlled substances and other drugs of concern.
- Financial considerations as it costs $1.25 US/pound to incinerate unwanted drugs (26).

The same study recommends expanding the take-back program to include permanent drop boxes, which could be housed in law enforcement offices, in every county in the state. This said, the study acknowledged that this placement could be a barrier as may individuals may be apprehensive to enter a law enforcement office to use the drop box (26).

A medium-quality study from the United States of the senior's population (aged 65 and older) recommended expanding take-back programs to include collection sites at physician offices, hospitals, and local community pharmacies. These expanded take-back programs would also need to be supported with community-wide public awareness campaigns (6).

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- Explains how good health-care waste management protects public health; and
- Informs the public in general about the risks from poor hygiene and health-care practices, with particular regard to people living or families of patients treated at home (28).

WHO also recommends poster exhibitions, information signs and staff interaction as the delivery methods for the education program (28).

Disposal of Supplies

This review only identified three grey literature documents that were relevant to the topic of access, management and disposal of supplies. All three documents related to the disposal of supplies.
In addition to their pharmacy medication take-back programs, the Health Products Stewardship Association (HPSA) has programs for disposal of medical sharps in Ontario and P.E.I. The website lists the impact of this program as:

- Over 1.5 million kilograms of medical sharps collected since the inception of the program in 1999.
- Nearly 5700 participating pharmacies.
- 160 member producers (24).

Provinces not included in the HPSA initiative often have a pharmacy take-back program specific to that province. For example, the Alberta Pharmacists Associations' take-back program ENVIRx also accepts medical sharps (25).

The United States Food and Drug Administration website provides the following recommendations for the disposal of used needles and syringes:

- Place the needles and other sharps in a sharps disposal container; and,
- Dispose of the used sharps containers according to your community guidelines (examples include: drop boxes or supervised collection sites, household hazardous waste collection sites, mail-back programs, residential special waste pick-up services) (21).

The high-quality guideline from NICE states that when disposing of bottles containing irretrievable amount of liquid controlled drugs, one should:

- Consider rinsing the bottle and disposing of the liquid into a pharmaceutical waste bin;
- Remove or obliterate labels and other identifiers from the container; and
- Dispose of the clean, empty container into the recycling waste (10).

TABLE 11: Key Findings—DISPOSAL OF SUPPLIES

The Health Products Stewardship Association (HPSA) has programs for disposal of medications sharps in Ontario and P.E.I. Provinces not included in the HPSA initiative often have a pharmacy take-back program specific to that province. For example, the Alberta Pharmacists Associations' take-back program ENVIRx also accepts medical sharps (25).

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DISCUSSION – QUALITY AND APPLICABILITY OF KEY FINDINGS

In order to focus the key findings and prioritize future actions the findings can be sorted according to the highest quality of evidence and the most applicable evidence. Two documents stand out in terms of quality: the high-quality NICE guideline 'Controlled drugs: safe use and management' (10) and the medium-quality systematic review by Latter et all 'How can we help family carers manage pain medicines for patients with advanced cancer? A systematic review of intervention studies' (14).

Table 12 summarizes the key findings from the NICE guideline. Two issues with applicability of these results need to be noted. First, the NICE guideline is from the United Kingdom which limits applicability as the Canadian healthcare system differs from the U.K. in terms of governing legislation. However, there are enough similarities that these findings can be applied to the Canadian context with minor adaptations. Second, although according to the guideline the results are applicable to all organizations that have access to controlled drugs, organizations delivering home care face unique challenges that are not faced by broad institutions. For example, inventories of medications are much easier to maintain when the medications are kept in a dedicated storage room in a hospital as opposed to being dispersed across the various home care patients' residences.

TABLE 12: SUMMARY OF Key Findings—NICE GUIDELINES

MANAGEMENT OF MEDICATIONS – ORGANIZATIONAL PRACTICES

The NICE guideline from the United Kingdom recommends that all organizations that have access to controlled drugs, including home care organizations, have structured systems, processes and policies in place to maintain safe access, management and disposal of controlled drugs. These systems and processes include:

- Governance agreements with clear lines of responsibility and accountability for controlled drugs in their contact.
- A controlled drugs accountable officer responsible for quality assuring processes for managing controlled drugs in their organization.
- A controlled drugs policy and operating procedures for storing, transporting, destroying and disposing of controlled drugs. (note: it is recommended that the organization consider using a risk assessment when establishing processes).
- Minimum standard operating procedures for processes relating to prescribing, supplying and administering controlled drugs, including clinical monitoring for people who have been prescribed controlled drugs.
- Safety guidance (from government and other regulatory bodies) about controlled drugs (e.g. patient safety alerts) that is incorporated into policy and acted on within a specified or locally agreed timeframe.
- Standard operating procedures for storing controlled drugs that are in-line with government regulations and take into account the security risk for the setting (high, medium, low), the storage environment (e.g. location, space, temperature), storage of unwanted and expired stock medications, and storage needs for drugs with similar or 'lookalike' packaging.

MANAGEMENT OF MEDICATIONS – STORAGE

- All organizations that have access to controlled drugs should provide the patient/caregiver with the following information about how to store drugs safely, including:
- The person's preference for a lockable or non-lockable storage box;
- Whether the controlled drugs will be accessible to people who should and should not have access to them; and,
- Whether the storage method could increase the risk of controlled drug-related incidents, including patient safety incidents.

DISPOSAL OF MEDICATIONS

- When controlled drugs need to be removed after a person has died in their home the provider should consider:
- Discussing the removal of controlled drugs with a family member or carer.
- Recording the action taken and details of the controlled drugs listed in the person's medical record or notes.
- Having a witness to the removal.
- Any requirements of the coroner to keep medicines in the person's home for a period of time.
- Taking the drugs to a health professional, such as a community pharmacist who is legally allowed to possess controlled drugs, for safe disposal at the earliest opportunity.

DISPOSAL OF SUPPLIES

- When disposing of bottles containing irretrievable amount of liquid controlled drugs, one should:
- Consider rinsing the bottle and disposing of the liquid into a pharmaceutical waste bin;
- Remove or obliterate labels and other identifiers from the container; and
- Dispose of the clean, empty container into the recycling waste (10).

Table 13 summarizes the findings from the Latter et all systematic review. Although the findings represent medium-quality synthesized evidence, there are a few issues in terms of applicability. First, the review includes studies five from the United States and one study each from the United Kingdom, Norway and Taiwan. Although there are similarities in the healthcare systems between these countries, there are also differences that must be considered before acting on these findings. For example, the face-to-face training sessions recommended by the review may not be viable for home care staff to conduct with every patient or caregiver. Second, the review focused on patients with advanced cancer only. It is unclear whether the interventions described in the review could apply to home care patients with other diagnoses or to patients in the palliative phase of care.

TABLE 13: Key Findings— LATTER ET AL SYSTEMATIC REVIEW

MANAGEMENT OF MEDICATIONS

All of the educational interventions included in the systematic review had the following components:

- Face-to-face education or training sessions;
- Support through written or other resources;
- Opportunities for questions and discussion; and
- Follow-up contacts for coaching and/or reinforcement.

The interventions were delivered by a specially trained clinician (nurse, psychologist) or researcher in the patient's home or in hospital outpatient clinics. All of the interventions focused on the following topics:

- Managing pain and pain medication;
- Addressing barriers to pain management;
- Knowledge about how analgesics work;
- Beliefs about addiction and tolerance;
- Fears about side effects and overdose;
- Excessive stoicism; and,
- Poor communication between patients, family carers and health professionals.

Overall, the systematic review found that educational interventions have the potential to improve carer's knowledge and self-efficacy for pain medication management and change misconceptions about cancer pain and medications if the interventions:

- Contain structured and tailored elements;
- Are delivered in one or more face-to-face sessions;
- Are supported by written and/or other resources; and
- Include further contact with a trained clinician (nurse or psychologist) for reinforcement or review (14).

Table 14 provides an overview of all of the Canadian findings included in this review. Canadian key findings are the most applicable as these will have been developed within the context of Canada's healthcare system, including the legislation that governs issues such as access to controlled drugs. Although these findings are highly applicable, it must be noted that all are grey literature documents and will score very low on critical appraisal assessments. This said, all of the Canadian sources are from reputable organizations and it can be assumed that efforts were made to ensure the recommendations were of a high quality.

TABLE 14: Key Findings— CANADIAN FINDING

ONTARIO PALLIATIVE CARE NETWORK – ACCESS TO MEDICATIONS

The Ontario Palliative Care Network's (OPCN) recommendations for a model to improve palliative care in Ontario recommends that the patient have 24/7 access to pain and symptom management from the Core Team or the on-call providers (in-person or telemedicine). The OPCN also recommends that pharmacists play a significant role in symptom management, medication safety and supporting treatment decisions throughout the patient's journey, including after-hours access to pharmacy services and expertise.

The OPCN recommends that standardized symptom management kits and related policies and protocols should be available and safely stored in all community settings (e.g. patient's home) for the management of unexpected, emerging, or worsening symptoms. The OPCN also states that there be should provincial standards for symptom management kits, including:

- Standards pertaining to medications and doses;
- Protocols for ordering and dispensing the kits and monitoring their utilization;
- Safety standards; and,
- Education for community nurses about the use of the kits (8)

INSTITUTE FOR SAFE MEDICATION PRACTICES (ISMP) CANADA –STORAGE AND DISPOSAL OF MEDICATIONS

The Institute for Safe Medication Practices (ISMP) Canada's safety bulletin on the safe storage and disposal of medications also discusses how medications should be disposed of after the death of person receiving palliative care in the home. The bulletin cites an Ontario study that recommended having a pharmacist conduct an in-home medication review and remove unused medications. Having the home care service provider pick-up symptom relief kits after death of the patient is another option recommended by the ISMP Canada bulletin.

The Patch-for-Patch Fentanyl Return Policy in Ontario is a legislative initiative that aims to reduce the risk of harm through a policy that requires patients to return their used fentanyl patches to the pharmacy before being able to access their next refill.

ISMP Canada also recommends two of their resources:

- Prevent Medication Accidents - an information card developed to provide key information for patients and families about proper storage and disposal of unnecessary medications in the home.
- A handout to address the proper use, secure storage, and disposal of opioids prescribed to treat pain after surgery. (19)

GOVERNMENT OF CANADA – DISPOSAL OF MEDICATIONS

The Government of Canada's website on the safe disposal of prescription drugs recommends checking the medicine cabinet and removing all expired and unused prescription drugs, over-the-counter medications and natural health products. These can them be taken to a local pharmacist for disposal through the Health Products Stewardship Association program. Unused or unwanted medications should never be flushed down a toilet or sink as this can lead to traces of pharmaceuticals in the water and environment. Disposal in the trash is recommended as a last resort option. To dispose of medications in the trash:

- Medications should be removed from their original containers;
- All identifying information on the prescription label should be scratched out;
- The medication should be hidden in something unappealing (e.g., kitty litter or coffee grounds);
- Place the medication in a closed bag, empty can or other sealed container to prevent the drug from leaking or breaking out of a garbage bag (20).

HEALTH PRODUCTS STEWARDSHIP ASSOCIATION – DISPOSAL OF MEDICATIONS AND SUPPLIES

The website for the Health Products Stewardship Association (HPSA) outlines their programs for disposal of medications and medicals sharps in Canada. The HPSA "operates collection and disposal programs that focus on prescription drugs, natural health products, over-the-counter medications, and medical sharps waste generated by the public in their homes" (24). These disposal programs mostly consist of take-back programs held in pharmacies. Unused prescription drugs, over-the-counter medications and natural health products are accepted for disposal at pharmacies in British Columbia, Manitoba, Ontario and Prince Edward Island. The website lists the impact of this program as:

- Nearly 3 million kilograms of medications collected since the inception of the program.
- Nearly 5700 participating pharmacies.
- 160 member producers (24).

Provinces not included in the HPSA initiative often have a pharmacy disposal program specific to that province. For example, the Alberta Pharmacists Association runs a medication take-back program through pharmacies called ENVIRx (25).

In addition to their pharmacy medication take-back programs, the Health Products Stewardship Association (HPSA) has programs for disposal of medications sharps in Ontario and P.E.I. The website lists the impact of this program as:

- Over 1.5 million kilograms of medical sharps collected since the inception of the program
- Nearly 5700 participating pharmacies.
- 160 member producers (24).

Provinces not included in the HPSA initiative often have a pharmacy take-back program specific to that province. For example, the Alberta Pharmacists Associations' take-back program ENVIRx also accepts medical sharps (25).

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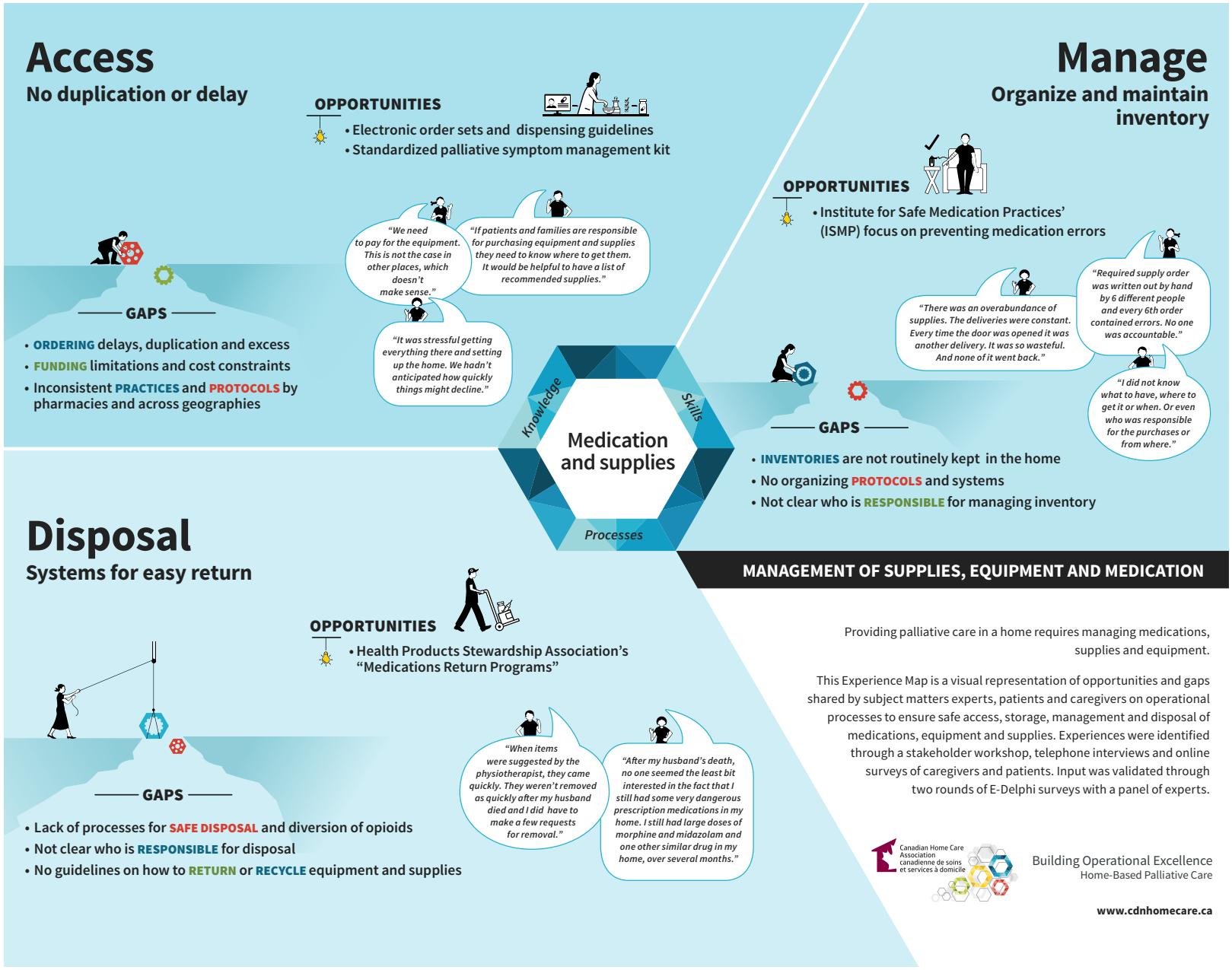
APPENDIX A – Experience Map: Management of Supplies, Equipment and Medication



APPENDIX B – Data Extraction Forms

CITATION
de la Cruz M, Reddy A, Balankari V, et al. The Impact of an Educational Program on Patient Practices for Safe Use, Storage, and Disposal of Opioids at a Comprehensive Cancer Center. Oncologist. 2017 Jan;22(1):115-121.
YEAR
2017
JURISDICTION
United States
FOCUS OF STUDY
"…to determine whether an improvement had occurred in the patterns of use, storage, and disposal of opioids among cancer outpatients with implementation of a patient educational program." (116)
METHODS USED
prospective cross-sectional survey (116)
STUDY SAMPLE
"…outpatients in the PC (note: palliative care) clinic at The University of Texas MD Anderson Cancer Center (UT MDACC)." (116) "Consecutive patients who had attended the PC clinic for a follow-up visit from December 2014 to December 2015 were initially screened and then approached if they were at least 18 years old; had received opioids for at least 1 month; were able to read, write, and converse in English; and had no cognitive impairment. Only those patients who were returning for a follow-up visit to the PC clinic and were taking opioids for at least 1 month as documented in a previous clinic note were invited to participate in the study." (116) "Patients who were in acute symptom distress as determined by the attending clinic physician were excluded." (116) "300 adult cancer outpatients receiving opioids in our PC clinic after initiation of the educational program and compared them with 300 control patients who had completed an opioid use, disposal, and storage safety survey before the initiation of the educational program. The 300 patients in the control group belonged to a previous cohort." (116) The proportion of races and sexes sampled was similar to the patient population seen in other PC studies our group has conducted at MD Anderson Cancer Center. "116) Average age: 55 years Gender: 57.7% female

KEY FEATURES OF THE INTERVENTION

"The educational program consists of the EM (note: educational materials) and the personalized education and counseling given by our PC (note: palliative care) staff."

"For each patient who received an opioid prescription in the PC clinic, the information contained in the EM was reviewed with that patient and their accompanying family member or caregiver. They were also given personalized education regarding safe opioid use, storage, and disposal. An overview of the general points of the EM was reviewed with the patient and caregiver. Elaboration of certain points and questions from the patient and caregiver were answered during the clinic visit." (116)

KEY FINDINGS

"After the receipt of the educational materials, fewer patients had unused opioids at home (38.1% vs. 46.6%; p = .0497), more patients kept their opioids in a safe place (locked, 14% vs. 9.5%; hidden, 75.4% vs. 69.9%; p = .0025), and more patients were aware of the proper methods of opioid disposal (76.5% vs. 28%; p< .0001)." (118)

"After implementation of the educational materials, more patients never shared their opioids with someone else (96.9% vs. 91.6%; p = .0311), fewer patients reported unsafe use of opioids (17.7% vs. 25.3%; p = .0344), more patients believed that improper use of opioids is a common problem in the society (p < .0001), and more patients were aware of the danger of their opioids for others (p = .0099)." (118)

"The patients who received the EM were more aware of proper opioid disposal methods (76% vs. 28%; .0001), less likely to share their opioids with someone else (3% vs. 8%; p = .0311), and less likely to practice unsafe use of opioids (18% vs. 25%; p = .0344; Table 2). Patients who received the EM were less likely to have unused medication at home (38% vs. 47%; p = .0497) and more likely to keep their medications in a safe place (hidden, 75% vs. 70%; locked, 14% vs. 10%; p = .0025)." (119)

"The patients who recalled having received the EM were more likely to be female (148 of 232 [63.8%] vs. 33 of 68 [48.5%]; p = .0237). The comparison of the use, storage, and disposal of opioids between groups 1 and 2 is shown in Table 3. Those who did not recall receiving the EM were more likely to have unused medications at home (37 of 68 [55.2%] vs. 88 of 232 [38.1%]; p = .0124) and are less aware of proper opioid disposal (37 of 68 [55.2%] vs. 176 of 232 [76.5%]; p = .0007). (119)

"Of the 213 patients, surveyed, 90 (42%) reported receiving their information regarding opioid storage, use, and disposal from the PC clinic and staff. Other sources of information reported by the surveyed patients included other health care providers (60 of 213 [28%]), family or friends (7 of 213 [3%]), and the media (58 of 213 [27%]). " (119)

"Following the implementation of an educational program in the PC clinic, an improvement in the knowledge and practices relating to opioid use, storage, and disposal was observed. Improvements were observed for the patients who recalled receiving the EM and those who did not. Overall improvement was seen across all three domains covered in the EM. Most patients reported that knowledge was gained from the education provided in the PC clinic." (119)

"It has been previously shown that EM in the form of pamphlets or brochures is only useful if the patient is motivated to learn and know more. The contact with the PC staff when the EM is given is a

powerful act of persuasion that can encourage patients to read the EM that they would otherwise have disregarded. This would be especially true for patients who have been to the PC clinic multiple times and have built rapport and trust with the medical staff. Patients must feel invested in acquiring the additional knowledge for the EM to work. That added contact with PC staff is an opportunity to emphasize the value of that knowledge." (120)

"The EM that patients take home with them each time they receive an opioid prescription allows them to reference information at their own convenience. It is a tangible reminder of the information discussed during their clinic visit. They are also able to readily share this information with caregivers, family, and others, further reinforcing the information and knowledge." (120)

"the need to use simple, plain, and concise language in the EM to ensure understanding and compliance. This is especially relevant, because the EM can also serve as a starting point for discussions of patients' concerns or could be a prompt sheet that patients can use to gather more information from medical care providers." (120)

"Despite the EM presented and the awareness of proper disposal, more than one third of our patients still had unused opioids at home for several reasons, including possible future use, which might have been a reflection of anxiety in achieving good pain control. A significantly higher proportion of patients had their opioids hidden after receiving the EM, an indication of the success of the program in improving opioid storage among patients prescribed with narcotics." (120)

"The 300 patients in the control group belonged to a previous cohort, which presents a possible limitation, because this previous control group might have acquired education on opioid use, storage, and disposal from the media or other sources that could have influenced their behavior." (120)

CRITICAL APPRAISAL

Analytic Study – Moderate study design of low quality

CITATION
Fleming E, Proescholdbell S, Sachdeva N, et al. North Carolina's Operation Medicine Drop: Results from one of the nation's largest medication disposal programs. N C Med J 2016; 77: 59–62.
YEAR
2016
JURISDICTION
United States
FOCUS OF STUDY
"From September 2010 to October 2014, the US Drug Enforcement Administration (DEA) funded take-back events to allow for the safe disposal of unwanted, expired, and/or unneeded medications. The purpose of this article is to describe the results of Operation Medicine Drop, a statewide drug take-back effort in North Carolina." (2)
METHODS USED
Descriptive analysis of take back event files (event registration system and program documents). Measures used: number of events, counties where events were held, number of unit doses (pills) collected. (3)
STUDY SAMPLE
Individuals who disposed of medications using Operation Medicine Drop program.
KEY FEATURES OF THE INTERVENTION
"Safe Kids North Carolina (Safe Kids NC) launched Operation Medicine Drop in March 2010, coinciding with Poison Prevention Week. Safe Kids NC is an organization of 41 local coalitions covering 71 of the state's 100 counties; its mission is to prevent injuries among children under the age of 19 years [8]. Working with local health departments, hospital systems, fire departments, police departments, medical practices, and individuals committed to injury prevention." (2) "With its community-based events, Operation Medicine Drop allows people to discard unused medications with no questions asked, and these medications are then safely and legally disposed of using an EPA-approved incinerator. Local coalitions register their events with Safe Kids NC and work with local law enforcement agencies, who take possession of the medications and report the number or pounds of medications to Operation Medicine Drop and the SBI." (3)
KEY FINDINGS
"From March 2010 to June 2014, Operation Medicine Drop held 1,395 events with 245 different participating law enforcement agencies in 91 of the state's 100 counties, and these events collected 69.6 million unit doses." (3) "Over the course of 5 years, Operation Medicine Drop collected 69.6 million doses of unwanted drugs. These numbers exceed reports in the media from fall take-back events in other states, which reported collecting between 500 and 1,000 lbs." (3)

Barriers
"The Controlled Substances Act requires the participation of law enforcement in drug take-back events to prevent possible diversion." (3)
"In addition, pharmacists or pharmacy technicians are needed to identify and verify controlled substances and other drugs of concern." (3)
"Cost is another major barrier that potentially limits whether community-based groups can maintain these efforts. It costs $1.25 per pound to incinerate unwanted drugs. For events held on September 27, 2014, for example, North Carolina collected 10,800 lbs of drugs, and the cost for incineration alone was estimated at $13,500." (4)

"The expansion of Operation Medicine Drop to include permanent drop-off boxes could dramatically change individuals' ability to discard unused medications. Operation Medicine Drop is working with various programs…to place permanent drop boxes in every county. Housed in law enforcement offices, these drop boxes would be more accessible to people than the Operation Medicine Drop events, which operate on a limited schedule. However, anecdotal evidence suggests that some community members might not be as willing to take unused medications and drugs to law enforcement agencies." (4)

Study Limitations
"Our efforts to measure the impact of Operation Medicine Drop are limited by the electronic system that is currently in place. In this system, groups organizing take-back events are only asked to record the quantity of pills collected. Thus there is no way to divide the total collection by drug class." (4)

"Second, we are limited in our ability to explore the causal relationship between Operation Medicine Drop's take-back events and the number of drug poisoning deaths in the counties where Operation Medicine Drop has held events. Currently, we are only able to describe what Operation Medicine Drop has done in bringing partners together to collect and safely destroy unwanted prescription drugs. With more robust data collection and evaluation measures, perhaps, we could describe the overall impact on public health." (4-5)

"our analysis is limited by the data reported to DEA. Individual weights for the drugs collected at each police department or sheriff's office are not reported. Instead, DEA only receives a total weight, which limited our ability to account for all drugs that had been dropped off in each county in the fall 2014 take-back events." (5)

CRITICAL APPRAISAL

Descriptive Study – Weak study design of medium quality.

CITATION
Haughey CW, Lawson D, Roberts K, Santos M, Spinosa S. Safe Medication Disposal. Home healthcare now. 2019 Mar/Apr;37(2):106-110.
YEAR
2019
JURISDICTION
United States
FOCUS OF STUDY
"The purpose of this article is to describe a project to improve patient/caregiver knowledge of safe medication disposal conducted by University of Pennsylvania nursing students during a community nursing clinical rotation." (107)
METHODS USED
5-question survey administered by nursing students
STUDY SAMPLE
15 home care patients
KEY FEATURES OF THE INTERVENTION
The survey consisted of the following questions: 1. Do you have medications that you do not use regularly? 2. Are there reasons you keep unused medications? 3. Do you know that medications have expiration dates? 4. How do you throw away unused medications? 5. Has a doctor or nurse ever talked to you about how to safely dispose of your medications? "The nursing students distributed medication disposal pouches for drug deactivation and disposal, an information sheet with disposal tips from the FDA, and a list of disposal receptacles/sites in the five counties the home care and hospice agency serves." (109)
KEY FINDINGS
"Eight of 15 (53%) respondents stated they had unused medications in their household" (109) "14 out of 15 (93%) respondents stated that a nurse or doctor had never talked to them about how to safely dispose of medications." (109) "the survey determined 60% of respondents disposed of their medications in the trash, sink, or toilet and only 13% of individuals demonstrated proficiency in safe disposal of medications." (109) Follow-up "Because many patients had limited mobility and/or were homebound, it was unrealistic for them or their caregivers to drive to the disposal receptacles/sites. For this reason, the students also included

the FDA-approved instructions for at-home disposal that consisted of a detailed step-by-step guide for proper disposal in coffee grounds, kitty litter, or dirt" (109)

"The medication disposal pouches contain active carbon that breaks down the medications when added along with water to the pouch. The pouch can then be placed in the garbage. The medication disposal pouches are easily accessible, environmentally friendly, and require minimal additional actions when disposing of medications." (109)

"Providing patients with medication disposal pouches gives them the resource needed to properly dispose of medications at home. Other strategies, such as drug take-back days and DEA approved receptacles in the community require the individual to leave their homes to properly discard the medications. The described two-pronged intervention at the home care agency requires minimal effort on the part of the patient or caregiver and could drastically reduce excess medications in homes." (110)

CRITICAL APPRAISAL

Descriptive Study – Weak study design of low quality.

CITATION
Joyce BT, Berman R, Lau DT. Formal and informal support of family caregivers managing medications for patients who receive end-of-life care at home: a cross-sectional survey of caregivers. Palliat Med. 2014 Oct;28(9):1146-1155.
YEAR
2014
JURISDICTION
United States
FOCUS OF STUDY
"The objective of this study is to characterize caregivers having or lacking additional formal/informal support with managing medications for elderly hospice patients, using key characteristics previously identified as barriers to caregiving and managing medications." (1147)
METHODS USED
Computer-assisted telephone survey
STUDY SAMPLE
"referrals of their patients receiving end-of-life care at home and the corresponding primary informal caregiver on record" (1148) "Eligible caregivers had to (1) be unpaid, aged 18+ years, English-proficient, and self identified as primary caregiver; (2) have medication responsibilities for a home hospice patient aged 60+ years; and (3) have no cognitive/sensory deficits precluding a telephone interview. Recruitment ended when we reached our sample size goal of 120 caregivers." (1148)
KEY FEATURES OF THE INTERVENTION
"The survey assessed caregiver and patient socio-demographics, additional support, caregiver–patient relation, caregiving experience, caregiver's psycho-emotional health, and medication management." (1148)
KEY FINDINGS
Formal/informal support and disagreements "About 39% had no additional formal or informal support with managing the patient's medications" "Almost equal proportions had any formal support (30%) and only informal support (31%) with medication management, and nine respondents (7.5%) had both formal and informal support." (1149) Discussion "Not only did a large proportion of participating caregivers (~40%) report no additional support with medication management, but many characteristics (such as racial/ethnic minorities and low socioeconomic status) previously identified as barriers to caregiving tasks and managing medications were inversely associated with having support with medication management." (1150)

"Others have reported lower percentages of caregivers (ranging from 15% to 20%) lacking additional support with unspecified caregiving tasks, our larger finding therefore suggests that fewer caregivers may rely on support for medication-related duties." (1150)

"Subpopulations characterized by both medication management difficulty and lack of access to additional support (e.g. racial/ethnic minorities) should be targeted for additional intervention by hospice support teams. Targeting caregivers with low self-efficacy and those managing complex medication regimens may also be necessary to ensure adequate support with medication-related tasks." (1152)

"Our study suggests that high proportions of caregivers may not receive additional support to perform medication responsibilities and, among caregivers with additional support, sizable proportions may encounter disagreements concerning treatment plans with their support." (1153)

"As the current population ages across a number of countries, caregivers are projected to have even less access to informal support than previous generations, underscoring the need to ensure adequate access to formal support that is of high quality, acceptable, and substitutable for informal support." (1153)

CRITICAL APPRAISAL

Descriptive Study – Weak design of medium quality.

CITATION
Latter S, Hopkinson JB, Richardson A, Hughes JA, Lowson E, Edwards D. How can we help family carers manage pain medicines for patients with advanced cancer? A systematic review of intervention studies. BMJ Supportive & Palliative Care. 2016;6(3):263-275
YEAR
2016
JURISDICTION OF INCLUDED STUDIES
United States (5) United Kingdom (1) Norway (1) Taiwan (1)
FOCUS OF REVIEW
Systematic review of published studies evaluating interventions for family carers managing pain medication for patients with advanced cancer. The specific questions addressed were: (1) What are the pain medication management interventions for family carers of patients with advanced cancer that have been evaluated? (2) What were their effects, positive or otherwise, on family carers and on patients' pain? (3) Were any particular intervention characteristics or components (eg, intensity, tailoring, timing, underpinning theoretical framework) associated with improved outcomes?
KEY FINDINGS
"All eight interventions included between one and three face-to-face education or training sessions, typically supported by written and/or other resources, opportunities for questions and discussion, and follow-up contacts for reinforcement or further coaching" (267) "The interventions were delivered to patients and family carers together by a specially trained clinician (nurse, psychologist) or a researcher studies in the patient's home or in hospital outpatient clinics" (267) "None of the studies used health professionals who were providing routine patient care to deliver interventions, although Vallerand et al's study included home care nurses, some of whom received pain management education (Power over Pain) independently of the patient-carer dyads they recruited to the trial." (267) The duration and intensity of interventions, and the period of time over which they were delivered varied greatly between studies." "All the interventions focused on managing pain and pain medication, addressing widely recognised 'barriers' to pain management; knowledge about how analgesics work; beliefs about addiction and tolerance; fears about side effects and overdose; excessive stoicism; and poor communication between patients, family carers and health professionals" (267) "They included cognitive and behavioural components, providing a mixture of information and teaching or coaching to develop practical and coping skills, solve problems and/or improve

communication. Some interventions had additional components, such as providing information or training in non-drug pain management, for example, relaxation, massage and imagery; creating plans to maintain coping; change behaviour or anticipate problems, which could be reviewed and revised during follow-up." (267)

"The results indicate that educational interventions with structured and tailored elements delivered in one or more face-to-face sessions, supported by written and/or other resources, and/or including further contact for reinforcement and review, have the potential to improve carers' knowledge and self-efficacy for pain medicines management, and change misconceptions about cancer pain and medications." (271)

"Our findings suggest that educational interventions have the potential to help family carers manage cancer pain and associated medications, but the mechanisms that bring about positive effects remain unclear." (272)

"we were unable to discern any clear pattern of association between particular intervention characteristics and measured effects on family carer outcomes. There was no indication that outcomes were improved by providing multiple face-to-face education sessions, or by spending more time with family carers." (272)

"We suggest that these positive effects may be due, in part, to delivering an appropriate intervention to a well-defined group for whom pain management is a pressing concern." (273)

"We suggest that for pain and medication management interventions it is more meaningful to ask not about timing, per se, but how to provide timely help for family carers, conceptualising 'timeliness' as a subjective and context-dependent aspect of an intervention." (273)

"Current evidence suggests that there is potential for health professionals to improve family carers' knowledge and self-efficacy in managing cancer pain medicines by including them with patients during face-to-face education, supported by written or other materials, and appropriate follow-up, an approach that has not been linked with any obvious or serious harms." (273)

"Evidence from the eight studies reviewed suggests that educational interventions delivered face-to-face, supported by written and/or other resources and appropriate follow-up, have the potential to improve family carers' knowledge and self-efficacy for pain management, and reduce attitudinal barriers. No adverse effects of interventions were reported." (274)

"There were no discernible patterns of association between particular intervention characteristics, for example, time spent in interaction or providing individualised information, and effects on family carer outcomes." (274)

CRITICAL APPRAISAL

Review – Medium quality systematic review (strength of study design is not applicable to systematic and narrative reviews.

CITATION
Maeng DD, Snyder RC, Medico CJ, et al. Unused medications and disposal patterns at home: Findings from a Medicare patient survey and claims data. J Am Pharm Assoc (2003) 2016; 56: 41–46.
YEAR
2016
JURISDICTION
United States
FOCUS OF STUDY
This study sought to provide answers to the following questions: 1. What specific medications may represent the most frequently left unused once purchased by sampled patients? 2. What fraction of these medications are left unused? 3. What methods are used to dispose of these medications? 4. Why were these medications left unused by patients? (42)
METHODS USED
"combining detailed drug level information obtained from health insurance claims data with patient telephone survey data." (42) "Based on the information obtained from each patient's pharmacy claims data, each patient was queried about specific medications for which they were known to have prescriptions. Therefore, the phone survey focused on patient's experiences with using each drug rather than on drug identification." (42)
STUDY SAMPLE
This study focused on the senior population (aged 65 years and older) covered by Medicare, The data for this study were obtained from the Medicare Advantage members of a regional health plan, Geisinger Health Plan (GHP) Study sample selection was restricted to inclusion of GHP (Geisinger Health Plan) Medicare Advantage members aged 65 years or older with Part D coverage through GHP as of December 31, 2013. Of these members, a random sample of 2,000 was drawn. (n=49,000)
KEY FEATURES OF THE INTERVENTION
"The telephone survey was designed so that each member could recall and provide information specific to each medication name that appeared in his or her claims data. For instance, the interviewer would ask if the member had ever taken a specific medication that appeared in the claims data. If the member confirmed taking the medication, the interviewer would go on to ask if there were any unused portions. If unused portions remained, the interviewer would ask how much remained and why the medication was left unused." (42-43)

KEY FINDINGS

"More than one-half (55%) of the unused medications were reportedly kept in the respondents' cabinets. Moreover, approximately 15% (n 36) of unused medications in the sample were controlled substances, such as narcotic pain medications (e.g., hydrocodone, oxycodone, fentanyl) and benzodiazepines for psychiatric disorder treatments (e.g., alprazolam, lorazepam)." (44)

"Slightly less than one-half of the unused controlled substances (16 of 36) were reportedly kept in cabinets, whereas approximately 16% (6 of 36) were reportedly taken to local drug take-back programs." (44)

"The presence of unused medications poses two broad challenges. Proliferation of unused medications may indicate a lack of patient adherence if not due to a dosage or medication change or the need for further education on appropriate use." (44)

"The data also indicate that controlled substances for pain and psychiatric disorders were some of the most frequently unused medications. Unused portions of these medications may be a result of prescribing behaviors that lead to excess tablets and refills, or a lack of patient understanding of appropriate use. Such a finding related to controlled substances suggests that providers should remain aware of these prescribing patterns and use the minimum quantity of tablets and refills that are anticipated. Limiting quantity and refills for prescriptions may decrease the presence of unused medications in the community; it can also promote more patient/provider interaction for refills to assess patient response and adherence treatment" (45)

"Implementation of medication therapy management (MTM) programs, such as the ones available for Medicare Part D beneficiaries, may be a viable strategy. MTM programs typically involve direct, one to-one interaction between a pharmacist and a patient. The MTM pharmacist can, for example, help to determine if a patient has stopped taking certain medications because of adverse reactions and to prevent refill of such medications in the future." (45)

"Because patients who receive medications through mail-order pharmacies may be more likely to have unused medications an in-person medication list review of mail-ordered drugs with an MTM pharmacist also may be a strategy." (45)

"Medications pose environmental and public health challenges with improper disposal. A majority of unused medications, including controlled substances, is kept in patients' homes indefinitely or is possibly given to other individuals. This suggests potentially serious community health and legal concerns and provides potential for drug diversion in the community." (45)

"This study reveals that the quantity of unused medications disposed by such unproven methods is not likely to be minimal. Table 4 implies that some patients are simply keeping unused medications at home. Further challenges exist as safe and proper disposal options of unused medications for patients may be limited. Table 4 suggests that the use of drug take-back programs is low. Although drug take-back programs provide the most secure and safe disposal methods, these programs are often unavailable, poorly advertised, or inaccessible for many patients. (45)

"Community-wide campaigns to increase public awareness of expanded take-back programs that includes physician offices, hospitals, and local community pharmacies as collection sites also may be adopted." (45)
CRITICAL APPRAISAL
Descriptive Study – Weak study of medium quality.

CITATION
Payne S, Turner M, Seamark D, et al. Managing end of life medications at home--accounts of bereaved family carers: a qualitative interview study. BMJ supportive & palliative care. 2015 Jun;5(2):181-188.
YEAR
2015
JURISDICTION
United Kingdom
FOCUS OF STUDY
To explore how bereaved family members recall managing end of life medications when delivering care to a patient dying at home in England.
METHODS USED
Cross-sectional qualitative research – face-to-face interviews in participants' homes (182)
STUDY SAMPLE
"We purposively sampled bereaved family carers to select those with direct experience of providing care for an older person dying at home. The inclusion criteria included: family carers of older deceased people (aged 50 years +) from any cause of anticipated death; death occurring in the home of the carer or patient; a minimum of 2 weeks care in the private home prior to death; adult carer (≥18 years); and recruited at least 6 months but not more than 24 months following the death." (182) 59 total participants
KEY FEATURES OF THE INTERVENTION
"The main interview was designed to elicit chronological narratives of care provision during the end of life using open-ended questions and follow-up prompts." (182) "In this paper, we report on these questions only: To what extent were you involved in administering medications? How did you feel about this? Did you get any support from a pharmacist or district nurse? Were any controlled drugs prescribed and, if so, did they raise any particular issues?" (182)
KEY FINDINGS
Managing complex medications "All 59 participants were involved in managing end of life medications, especially once the patient became dependent and was in the final phase of dying. The degree to which they regarded this as burdensome was on a continuum from not at all to greatly." (184)

"A number of strategies to facilitate medication management were described: 'I made a copy of all the tablets and the different times he was to have them and which ones […] I made a chart on the computer and just printed it out each time, and that was very helpful.' [A11 SW Female 60]" (184)

"Some participants reported the responsibility as demanding because they feared the consequences of making a mistake or because they did not fully understand the medication regimes, especially when distressed, which made decision-making difficult." (184)

Carers' anxiety about medications
"While there was recognition that these medications were necessary to provide symptom relief, some cited concerns about dosage errors, especially overdosing patients, or failing to administer the drugs when the patient becomes too ill to use the oral route. 'I was really anxious just to follow the instructions and I wrote everything down carefully that I had given her. I didn't attempt to give her an overdose, ' [B14 NW Male 72]" (185)

"The family carers sampled indicated that they had a major role in providing care and ensuring symptom management by careful medication delivery. It is not surprising that it was perceived to be a demanding responsibility and at times for some, anxiety provoking, given that they reported little information or education to facilitate their role." (185-86)

"Our data indicate particular concerns about how end of life drugs, especially morphine, were perceived by family carers and that a syringe driver was seen as marking a transition into the final dying phase." (186)

"the findings from this study indicate that the family carers sampled did not believe themselves to have adequate support to safely deliver end of life medications to patients dying at home." (186)

"Without adequate preparation, sufficient information/education and support in dealing with end of life medication, the implementation of current home-based end of life care policies seems destined to result in additional distress and burdensomeness for family carers." (186)

"There may be opportunities to increase the role of community pharmacists to provide advice and training in the safe management, storage and disposal of medications. Our study indicates that more effective communication is required from the primary care team about end of life medications." (186)

"Communication between GPs, community nurses and family carers about their roles and responsibilities regarding end of life medications may help to prevent the anxieties reported." (186)

CRITICAL APPRAISAL

Descriptive Study – Weak study of low quality (note: qualitative study)

CITATION
Rantanen P, Parkkari T, Leikola S, Airaksinen M, Lyles A. An In-home Advanced Robotic System to Manage Elderly Home-care Patients' Medications: A Pilot Safety and Usability Study. Clin Ther. 2017 May;39(5):1054-1061.
YEAR
2017
JURISDICTION
Finland
FOCUS OF STUDY
To examine “the safety profile and usability of an integrated advanced robotic device and telecare system to promote medication adherence for elderly home-care patients.” (1054 - abstract)
METHODS USED
“Two phase project: Phase I aimed to verify under controlled conditions in a single nursing home (n 17 patients) that no robotic malfunctions would hinder the device’s safe use. Phase II Records from dispensing machine Interviews with patients and nurses.
STUDY SAMPLE
Phase I – 17 patients from a single nursing home (1057) Phase II 27 home-care patients – “participants were home-dwelling patients of three HC units. They were (1) on long-term daily tablet or capsule medicines, (2) native Finnish speakers, (3) at least 18 years of age, and (4) assessed by a nurse to be committed to treatment and to taking their medicines.” (1057)
KEY FEATURES OF THE INTERVENTION
“The usual HC (note: home care) model begins with the physician’s orders to the pharmacy, then the medicines are sent to the care unit and from the care unit to the patient (Figure2). Beyond baseline, the intervention in this study added an in-home advanced robotic system (Figure1) into the usual HC model for managing all enrolled patient’s on-time medication use (Figure2).” (1056) “a spoken reminder message, a sound signal, a light signal in the dose button, and written instructions on the device’s display are activated at individually predetermined dosing times. These remind the patient to access their medicines by pressing a dose button on the device’s front panel. Reminders are also generated for medicines not in the robotic unit(e.g., insulin and inhalers).” (1056) “When the patient presses the device’s dispenser button, the device delivers a sachet containing the medicine(s).” (1056)

"If a patient misses a sachet, the telecare system passes that information to the HC unit for action. According to the patient's needs and medicines, a nurse can contact the patient or come to the home and give the dose(s). The device sequesters unused dose(s) in a locked canister if the sachet is not retrieved within a predetermined time." (1056)

"The telecare system records data on sachets dispensed or sequestered and tracks alarms. If a problem is encountered in obtaining a sachet, the device sends that information to the telecare system where there is a chain of emergency contacts. The telecare system ensures responsibility for addressing the alarm and is coordinated through successive levels of oversight. The alarm remains activated until the event causing it has been resolved." (1056)

"The device is secure, monitored to detect tampering, and always connected to a central telecare system through a wireless connection." (1056)

"All patients received baseline medication reviews before initiating ADD (note: automated dose dispensing), so the sachets sent to the pharmacy and then to the robotic unit started with a clinically validated baseline." (1057)

"Before the intervention, all Phase I and II patients were interviewed using a structured questionnaire to determine their experiences with the ease and regularity of taking their prescribed medicines as scheduled." (1057)

Phase II "assessed (1) the device's performance in giving participants their medicine sachets according to their individual treatment plan and (2) patients' and nurses' perceptions on whether the device helped patients take their medicines regularly, on the device's usability, and their willingness to recommend the device." (1057)

KEY FINDINGS

Phase I

"The 17 nursing home patients had 457 total days using the device in Phase I (mean,26.9 per patient) (Table). They responded to the device's reminder and successfully pressed the dispenser button 98.0% of the time (1344 presses/1371 alerts), but on 5 occasions they did not remove the medicine sachet." (1058)

"The nurses unanimously reported that the remote care system, and its functions, did not cause an actually dangerous or near dangerous situation for any patient. These failures to deliver a medicine sachet were not dangerous because in every case of a technical malfunction (i.e., the device did not deliver the sachet) the patient still received their medicines (because the telecare system immediately sent information about the malfunction and the sachet was removed manually). Thus, no medication doses were missed, just the time to take them was delayed maximally by 1 to 2 hours." (1059)

Phase II

"The device was used for 727 days by 27 patients (mean, 26.9 days per patient).The device's dispenser button was pressed successfully 99.3% of the time (2075 presses/2090 alerts),and 98.7% of the alerts resulted in on-time medicine sachet retrievals by the patients." (1059)

"All but one of the Phase II patients reported that the device functioned reliably. That one respondent stated that the device functioned "reliably, except for the sound function." (1059)

"HC nurses regarded the machine as safe, except in two cases: (1) the medication was not taken by the patient because the machine's audio instructions stopped, and (2) one psychiatric patient was afraid of the machine's sound." (1059)

"All patients and 96% of the nurses found the device to be easy for the patients to use. The one nurse who stated the devices use not to be easy, responded that the patient had said "I need a human being, not a machine." (1059)

"In Phase II, 89% of patients and 88% of nurses would recommend or probably recommend this device for further use" (1059)

"Sequestering medicines in a tamper-proof robotic device and delivering them on predetermined individually optimal dosing schedules focuses on the patient's clinical need rather than on a caregiver's schedule." (1059)

"This kind of device could further reduce the need for nurses to visit HC patients' homes if the purpose is solely to give medicines. Instead, their home visits could be planned and focused on educating patients about their conditions and medicine use, including a review of their medications. On a population level, the increase in efficiency of use of professional personnel is substantial. This could also improve quality of care as one of the current major problems in geriatric care is inappropriate medication use." (1060)

"This pilot clinical safety and usability study has limitations: (1) small sample size, (2)short duration, (3) no direct observation of medicine consumption (patients were selected by nurses based on their assessment that the potential participant was motivated to take their medicines), and (4) data were missing on the frequency of home visits by nurses at baseline in Phase II." (1060)

CRITICAL APPRAISAL

Descriptive Study – Weak study of low quality

CITATION
Reddy A, de la Cruz M, Rodriguez EM, et al. Patterns of storage, use, and disposal of opioids among cancer outpatients. Oncologist. 2014 Jul;19(7):780-785.
YEAR
2014
JURISDICTION
United States
FOCUS OF STUDY
"to determine the patterns of storing, using, and disposing of opioids among cancer outpatients in a tertiary cancer hospital." (781)
METHODS USED
Self-administered questionnaire
STUDY SAMPLE
"Consecutive patients who attended the SCC for a follow-up visit between November 1, 2012, and April 1, 2013, were initially screened and then approached if they were at least 18 years old; received opioids for at least 1 month; were able to read, write, and converse in English; and had no cognitive impairment. Only those patients who were returning for a follow-up visit to the SCC and were on a regimen of opioids for at least 1 month as documented in a previous clinic note were invited to participate in the study." (781) "300 patients (86% participation rate) participated in the survey." (781) "The mean age was 56 years, 47% were male, 72% were white, and 63% were married. Lung (22%) was the most common cancer type, and 89% had advanced cancer. Of the 300 patients, 58 (19%) were CAGE positive, 26 (9%) had history of illicit drug use, and 120 (40%) had a MEDD greater than 100mg." (781)
KEY FEATURES OF THE INTERVENTION
"The questionnaire comprised 23 questions related to the patient's home/living situation and storage, use, and disposal of opioids. The questions were formulated by the study investigators based primarily on the recommendations by the FDA and DEA and a literature review regarding safe use, storage, and disposal of prescription pain medications." (781) "After completing the questionnaire, the patients were provided with a handout regarding proper medication disposal and storage, including the current FDA guidelines. (781) Patients' demographic and clinical information, including opioid prescription history, scores on the CAGE (cut down, annoyed, guilty, eye-opener) [29] alcoholism screening questionnaire, history of tobacco and/or illicit drug use, and the morphine equivalent daily dose (MEDD), was collected through chart review. (781)

KEY FINDINGS

"only 28 (9%) stored their opioids under lock and key, and 138 (46%) have unused opioids at home. More than half (159 of 300) did not routinely dispose of opioids; of those, 70 (44%) saved opioids for future use, and almost three-fourths (223 of 300) were unaware of proper opioid disposal methods." (781)

"A total of 78 patients (26%) reported unsafe use by sharing (9%) or losing (17%) their opioids, and 117 (39%) were unaware that their opioid could be fatal when taken by others." (781)

"Patients with positive CAGE scores or a history of illicit drug use were more likely to use opioids unsafely. Patients who were never married or single also had higher odds of unsafe use." (782)

"The unsafe practices around opioid use in cancer patients represent an avenue for increased drug abuse and accidental overdose because of the excessive amounts of opioids that are accessible to others." (782)

"Patients who had a history of positive CAGE scores or illicit drug use were more likely to store their opioids securely but also were more likely to share or lose their opioids." (782)

"Only 25% of the patients in our study were aware of proper opioid disposal methods. The current absence of uniform guidelines for safe and effective opioid disposal represents an increasing availability of unused or expired opioids for abuse and diversion. Unlike some Latin American countries, Canada, and Australia, the U.S. does not have regulated and easily accessible drug take-back programs for consumers." (784)

"Apart from safe disposal of opioids, providing access and education with regard to safe storage of opioids is equally important. The Florida Family Partnership started the "Lock Your Meds" campaign to foster safe storage practices in an attempt to minimize prescription drug abuse [40]. A wide variety of currently available medication lock bottles with combination locks may also aid in safely storing opioid medications. A pharmaceutical company with a new opioid product is now voluntarily providing free access to such locking pill bottle caps and discounted safe-storage units to reinforce safe storage practices" (784)

"Our findings reveal the need for universal education of all patients receiving opioids regarding safe storage, use, and disposal to minimize the risks of diversion or accidental poisoning." (784)

"therefore, our findings may not generalizable to other cancer patients, to noncancer patient populations, and to non-English-speaking patients." (784)

CRITICAL APPRAISAL

Descriptive Study - Weak study design of medium quality.

CITATION
Rosenberg JP, Bullen T, Maher K. Supporting Family Caregivers With Palliative Symptom Management: A Qualitative Analysis of the Provision of an Emergency Medication Kit in the Home Setting. Am J Hosp Palliat Care. 2015 Aug;32(5):484-489.
YEAR
2015
JURISDICTION
Australia
FOCUS OF STUDY
"to examine the lived experience of caregivers who have supported a dying person at home. In particular, it explores caregivers' perceptions of providing this care when supplied with an EMK." (485)
METHODS USED
Semi-structured telephone interviews
STUDY SAMPLE
"a sample of 99 patient–caregiver dyads in a specialist community palliative care service in Canberra, Australia, who were provided with an EMK on admission. A subsample of 18 caregivers self-selected to participate in a telephone interview; 12 were female, 6 were male; ages ranged between 29 and 89, with a mean age of 55 years. All identified as either Australian or New Zealander." (485)
KEY FEATURES OF THE INTERVENTION
"An EMK (note: emergency medication kit) provides parenteral medications in the home setting to enable a timely, appropriate response to exacerbations of symptoms that may lead to otherwise preventable admissions to inpatient care." (484)
KEY FINDINGS
Theme 1: Pre-EMK Experiences Sub-theme: Self-management "Respondents identified a number of strategies (note: for managing medications), including maintaining a written record of all medications and care activities: 'We were just recording, writing down. I set up a table, made up a table on the computer so everyone knew where we were at. So we'd all write on it, whoever was there, so we knew what mum was having and we sort of got her to describe her pain so that we'd know if she needed more or less.'" (485) Sub-theme: Need for support "for most respondents, the strategies employed were not sufficient to maintain acceptable levels of symptom control, and the need for support was identified." (485)

Theme 2: EMK Usage

Use by caregivers, use by nurses, and the medication diary.

Sub-theme: Use by caregivers

"A number of respondents saw it as a resource for them to access: '(It was) for us to use if he took a sudden turn and sort of suddenly got into difficulty or pain, or sort of extreme agitation and so we would be able to administer something to him so we wouldn't have to wait and try and handle the situation until one of the nurses could come back.' The issue of timely administration of medication, possible because of its availability to caregivers for use, was noted as a key justification for its presence in the home." (486)

Sub-theme: Use by nurses

"substantial proportion of the interviewed sample understood it as a resource for use only by the visiting specialist palliative care nurses: 'My understanding of what it was for was that it was medication that could alleviate or ease some of her more painful symptoms and it was to be administered by a professional carer, not by myself, but it was available on-site so that if she experienced severe symptoms that I could call a carer [ie: nurse] and say it's after-hours, we've already got the medication here, I just need you to come and administer it.' (486)

Sub-theme: Medication diary

"The medication diary was utilized by some, but by no means all, of the caregivers interviewed. For those who did, it was considered to be very useful for recording information at a difficult time: 'But we weren't left out on a limb at all and it was good to actually write down what we had done because otherwise you'd—with all the stress of it all and everything you could—I suppose you could easily get a bit confused with what you had given him.'" (486)

"It also acted as a communication tool between the caregivers and the health care professionals involved: 'I just wrote it all down, everything that I was giving to her, getting her pain scale and working on it from that and so when the palliative care team came I could say, ''This is what I've given her, nothing's helped. Her pain was at this and it's gone down to that but she's still in pain.''" (486)

Theme 3: Positive Factors and Benefits

Sub-theme: Accessibility

Caregivers found it reassuring that the EMK improved accessibility should symptoms become difficult to control; the EMK was viewed as a solution to a problem: 'Well, it's good to know that the kit's there. It's always helpful that it's, you know, that you know that if she needed something . . .stronger than an over the counter, there was stuff in the kit that would . . . that's sort of like a peace of mind sort of thing. To have the kit there obviously means that . . . it was easier to solve the problem.'" (486-487)

Sub-theme: Timeliness

Perhaps the most significant benefit identified by caregivers was that the EMK enabled a timely response to the exacerbation of symptoms. A number of experiences were recounted demonstrating the difficulties in accessing medication in the community:. . . in the old scheme, you know, you had to go and get a prescription and you had to find a doctor and then you had to find a chemist and you were away from them for untold hours, you know, and of course it meant that they . . . were still in pain and everything like that before you actually got the medication and then you had to get someone to come and put it in and . . . it was a big performance.'" (487)

Sub-theme: Effective symptom control
"In turn, this timeliness was seen to directly and positively impact upon symptom control: 'I just rang up and the lady came round in twenty minutes . . . and they just administered it and it was all under control again like within an hour or two, and it made a huge difference.'" (487)

Sub-theme: Caregiver confidence
"It was very clear that caregivers gained confidence through the education provided to them by the palliative care specialist nurses when the EMK was introduced. This respondent was fulsome in their feedback and illustrates the overriding context of the EMK being understood as one part of the over all caregiving experience: 'They explained it so well and the nurse who came—well everyone who came was excellent but the one who came and gave me the most instruction explained—she spent a long time there and she explained it all so well, and not only how to use that but how to help him, and move him, and all of that sort of thing. No, because of the time they put in they didn't just sort of leave it there and blurt out a few obscure instructions . . . I was able to really have much more of an understanding of what to do.'" (487)

Theme 4: Negative Factors and Challenges
Sub-theme: Low caregiver confidence
"This respondent clearly articulated how overwhelming and intimidating the expectations of being a caregiver can be: 'The nurse was saying we would have to administer these intravenous drugs and although they put a catheter in her leg I felt yucky about doing that, and also the nurse was very worried about me being here on my own with her and having to turn her on my own. I kept thinking I'm not trained for any of this, I know nothing about caring for someone else.'" (487)

Sub-theme: Fear of hastening death
Some caregivers were reluctant to administer medication to the person in their care, reporting concerns that this may in fact hasten death. This caregiver recounted her bereaved mother's concern that the medication administered to her late husband may have hastened his death:' . . .mum has been grieving a great deal but she sort of said ''What did they give him or what we gave him there at the end that might have made him . . . (pause)'' She is starting to comprehend it was pretty awful but she was not wanting us to hasten his passing. Well that was a concern for her and I have had to try and explain to her and she's sort of getting it now that it was just to help him feel comfortable.'" (487)

Sub-theme: Storage safety
Quite a few participants noted the need for safe storage, particularly where small children were regular visitors to the house or where they considered there may be a risk from others: 'We kept it up high because a lot of little grandchildren and people came like that, we kept it up high. The only thing I would say is that—I mean you would be very discerning I'm sure of who you left it with.'" (488)

CRITICAL APPRAISAL

Descriptive Study – Weak study of low quality (note: qualitative study)

CITATION
Sheehy-Skeffington B, McLean S, Bramwell M, O'Leary N, O'Gorman A. Caregivers experiences of managing medications for palliative care patients at the end of life: a qualitative study. Am J Hosp Palliat Care. 2014 Mar;31(2):148-154.
YEAR
2014
JURISDICTION
Republic of Ireland
FOCUS OF STUDY
to explore: • the impact of polypharmacy at the end of life, as perceived by caregivers; • the use of syringe drivers at home for palliative care patients; • the use of as-needed medications by informal caregivers; • other issues, perceived by caregivers, with managing medications for palliative care patients at home. (149)
METHODS USED
Qualitative focus group
STUDY SAMPLE
"Participants were sought using purposive sampling. The database of the service was searched to identify patients who had died at home, while under the care of the community palliative care team (CPCT), during a 2-month period, 6 to 7 months prior to the study taking place." (149) "Of a total of 34 people contacted, 13 agreed to participate and 3 of these requested the participation of another family member who had been involved in the care of the patient at home. Thus, in total, 16 people participated in 3 focus groups that took place in 2011." (149)
KEY FEATURES OF THE INTERVENTION
No intervention – examination of experiences as a caregiver for a palliative care patient
KEY FINDINGS
Impact of Polypharmacy at the End of Life/Issues With Administration of Medications "Administration of medications was a stressful experience for most participants, particularly when their loved one was taking multiple medications. The size, formulation, and taste of medications, all came up as issues. 'We used to call them elephant tablets, they were so big.' 'I can't understand myself, in this day and age, how they can't make something acceptable to taste, you know.'" (150-151)

"Timing of medications was also a challenge for caregivers. 'But the only thing I found a bit of a nuisance was—you know the way you have to give tablets before—half an hour before a meal. So that was getting a bit confusing because you know, you'd be up in the morning say—I was trying to rush two tablets into my father before I was getting the breakfast ready and stuff and then I'd say—you have to wait now for twenty minutes and then I'll give you the breakfast.'" (151)

"The most difficult challenge, however, was the number of medications, even to the extent that this appeared to have a significant psychological impact on patients and their caregivers. 'Even if they were all small . . . you've a handful of tablets . . . do you know what I mean? Like, there could be up on 11 tablets in there for all different things, you know.'" (151)

"Most caregivers (11 of 16) felt they would have liked more information on what each medication was for, in order to help them prioritize the most important medications. Those who cared for patients on medications for comorbidities would have liked these medications to have been rationalized earlier. There appeared to be some variation in the amount of guidance and information that families were given regarding the medications prescribed. All agreed that clear written information on what each medication was for and when it should be taken would be useful. 'But, thinking back now . . . things are clearer now, I suppose . . .and, while she was on medication for blood pressure and a lot of other bits and pieces, you wonder why maybe they could not have been eliminated when we knew that she wasn't going to get better and I'd love to know now could we have stopped or weaned her off those medications earlier and just stick with the ones that may have helped her pain. And that I'd love to know and I don't know it and I don't know who to ask.'" (151)

The Use of Syringe Drivers

"In general, patients were commenced on syringe drivers because they could no longer manage oral medications. Many participants felt that this was a significant milestone in the patient's illness, namely that it signaled a short prognosis. However, in some cases the families had experience of a syringe driver at an earlier point in the disease trajectory and therefore did not associate it with impending death. 'We knew it was a big stepping stone, d'you know what I mean, and this is it; once this happens there's no going back.'" (151)

"In terms of the actual effects of the syringe driver in their experience, most participants described a positive effect in terms of relief of symptoms and an easing of the burden of oral medications. In fact, many caregivers wished the syringe driver had been started earlier. 'It was a joyous day when the pump went on mammy, and we were just so sorry that . . . when we seen how easy it was and we were just . . . everybody just calmed right down and it was very calming and we were just saying: why did we not have this a couple of weeks ago, when we'd seen . . . she really had gone through a lot.'" (151)

"…the syringe driver was also a source of stress for some, partly because of their perception of its importance in symptom control—they were fearful that the driver would stop or run out of medication before someone came to change it and that this could result in suffering for their loved one. 'We used to watch it going down - 'cos we were sitting all the time with Dad and you'd sort of think—oh my gosh, I wonder how much left . . . we were so scared of it running out because it was the first time that we felt he had any reasonable pain control . . .You're sitting there watching somebody and you're thinking—this is getting smaller and smaller, they're down to two bars, or it's down to one bar or . . . '" (152)

The Use of Medications As Needed for Symptom Control
"Most caregivers were happy to take on the role of administering as-needed medications. They found it empowering, and it alleviated their feelings of helplessness watching their loved one suffer. I used to feel good giving it to her because you felt, you know, that you were helping; you were physically able to do something instead of just watching them in pain and not being able to do anything, you know . . . '" (152)

"It could also be a source of stress, however, particularly if there was a choice of more than one medication to give. Tiredness also affected caregivers' ability to make decisions about as-needed medications. 'You're giving so many drugs, so often that you'd be totally confused. And you're so tired and you're all brain brillo-padded . . . '" (152)

Other Issues With Managing Medications
"Access to medications was difficult for some participants for a variety of reasons. Some medications were not covered by the Medical Card—a government scheme that pays for medications for those of lower income or eligible patients with certain conditions. Others were not covered by the drug repayment scheme that subsidies medications for those not eligible for medical cards, so that there is a ceiling amount above which they are not charged further. This could lead to a cost burden on patients and families trying to obtain important medications for symptom control." (152)

"Many families were upset by having an excess of medications dispensed, which were unused and had to be disposed of after the patient died. I felt that was a disgrace actually 'cos my doctor came into the house when my dad died, you know to sign the death cert and stuff, and he took a black bag of tablets out of my house and he said they'd all be going into the fire thing or whatever. I thought that was an awful waste of taxpayers' money, to be quite honest, you know." (152)

"In all 3 aspects of medication management that this study sought to explore polypharmacy / administration of medications, the use of syringe drivers, and the use of as needed medications—clear information and guidelines emerged as an important way that health care professionals can ease anxiety for caregivers of patients at the end of life. It was also clear from the discussions that this information needs to be in a written form, as caregivers are often exhausted and under a lot of strain, so that verbal instructions are unlikely to be remembered clearly, or relayed to other caregivers, when needed." (153)

CRITICAL APPRAISAL

Descriptive Study – Weak study of low quality (qualitative study)

CITATION
Welham GC, Mount JK and Gilson AM. Type and frequency of opioid pain medications returned for disposal. Drugs Real World Outcomes 2015; 2: 129–135.
YEAR
2015
JURISDICTION
United States
FOCUS OF STUDY
This study aims to (1) quantify the prescription opioids returned for disposal to a local take-back program, and (2) explore selected drug characteristics that may predict the quantity of unused opioids. (130)
METHODS USED
"Items of information recorded from labels were: drug name and strength; date dispensed; brand name or generic product; directions for use; quantity dispensed; and quantity remaining (determined by counting the number of dosage units in the returned prescription bottle)." (130) "Days' supply remaining was the outcome variable of interest. It was calculated using the number of dosage units remaining, that is, the amount of unused medication returned in the take-back event." (131) "Statistical analysis was conducted using SPSS (v. 19, IBM Corporation, Somers, NY, USA). Descriptive statistics were calculated for the number of dosage units remaining and dispensed, the days' supply remaining and dispensed, and the percent remaining." (131) "Linear regression was used to identify predictors of days' supply remaining." (131)
STUDY SAMPLE
761 households participating in a medication take back event in Wisconson, United States (130)
KEY FEATURES OF THE INTERVENTION
"a 4-h medication take-back event known as MedDrop in Dane County, WI, USA. At the time, MedDrop was a series of biannual collection events, held as a drive-through service where volunteers collected unwanted medications for disposal from drivers, who represented households." (130)
KEY FINDINGS
"…C-II controlled substances. They accounted for 37.9 % of all returned prescriptions and 47.6 % of all returned dosage units. C-IIs included short- and long-acting/extended-release formulations, as well as single-entity and combination products. Notably, all C-II combination products were oxycodone containing products, and accounted for 20 % of all returned prescriptions." (132) "C-IIs were dispensed and returned with a greater number of dosage units (56.6 ± 60.5 vs. 31.7 ± 22.4, $p < 0.001$, 29.5 ± 37.8 vs. 20.5 ± 17.9, $p < 0.001$, respectively) and were dispensed and returned with a

larger days' supply (14.5 ± 18.3 vs. 4.3 ± 4.8, p < 0.001; 7.3 ± 8.8 vs. 2.7 ± 3.7, p <0.001, respectively). (132)

"All models showed that days' supply of medication dispensed was a strong predictor of days' supply remaining. An increase of one-day supply dispensed resulted in an additional quarter- (Model 1; B = 0.229) to half- (Model 4; B = 0.494) day supply returned for disposal." (132)

"Three findings of this study are particularly relevant to prevention of nonmedical use of prescription opioids. First, opioid prescriptions returned for disposal had greater than 60 % of the amount dispensed remaining unused. Second, drug utilization differed by drug characteristics. Notably, short acting C-II and C-III combination opioids accounted for greater than 80 % of the prescriptions returned for disposal. And finally, the day supply dispensed was the strongest predictor of day supply remaining, regardless of other drug characteristics." (133-34)

"the findings of this study are most relevant to education and disposal. Prescriber education, through continuing education, school curricula and resources such as REMS, should emphasize the importance of the quantity of medication prescribed and subsequently dispensed. Quantities prescribed should reflect the clinical need of the patient" (134)

"prescriber education should acknowledge differences in use based on drug characteristics. For example, patients used a 2-week supply of long-acting/extended-release medications versus a 2.5 days' supply of short-acting medications. Notably, short-acting medications, particularly hydrocodone- and oxycodone-containing products, constituted a large proportion of the prescriptions returned for disposal. As such, prescriber education should encompass both short- and long-acting opioid-containing products and their uses in acute and chronic pain." (134)

CRITICAL APPRAISAL

Descriptive Study – Weak study of medium quality.

CITATION
Yanovitzky I. The American Medicine Chest Challenge: evaluation of a medication takeback and disposal campaign. J Stud Alcohol Drugs 2016; 77: 549–555.
YEAR
2016
JURISDICTION
United States
FOCUS OF STUDY
“the primary goal of this study was to profile a national drug take-back program and to assess public exposure and response to a public communication campaign promoting this program in a single state (New Jersey), where this program was first implemented.” (550)
METHODS USED
“a telephone survey with a representative sample of adults in New Jersey (N = 906) 2 weeks following the conclusion of the statewide collection day event in November 2010.” (550) “The response rate was 20.1% for the landline sample and 10.7% for the cell phone sample, which is typical of public opinion polls” “The combined landline and cell phone sample was weighted to represent known parameters in the state population, using sex, age, race, and Hispanic ethnicity matching to U.S. Census Bureau data. Post-stratification weights were calculated to adjust for response bias.” (550-551)
STUDY SAMPLE
a representative sample of adults in New Jersey (N = 906)
KEY FEATURES OF THE INTERVENTION
“The American Medicine Chest Challenge (AMCC) is an ongoing community-based public health initiative, with law enforcement partnership, designed to raise awareness about the dangers of prescription drug misuse and organize a drug take-back collection event that is held annually in November in communities across the country.” (550) “The AMCC public health campaign invites individuals and families to participate in AMCC’s Five-Step Challenge, which includes (a) taking inventory of their prescription and over-the-counter (OTC) medicine; (b) locking their medicine cabinet; (c) disposing of expired, unwanted, or unused medicine in their home or at an AMCC disposal site; (d) taking their medicine(s) exactly as prescribed; and (e) talking to their children about the dangers of prescription drug misuse.” (550) “AMCC’s strategy seeks to combine a localized social marketing campaign with an annual community event that provides residents with a safe and convenient way to dispose of expired, unwanted, or unused medicine they store in their homes.” (550)

"Assuming sufficient exposure and attention to the campaign, AMCC expects the target audience they reach to (a) exhibit awareness and concern about the problem of prescription drug misuse in their community, (b) recall information about simple actions everyone can take to safeguard and/or dispose of prescription medicine at home, and (c) report taking the specific actions recommended by the campaign." (550)

KEY FINDINGS

Exposure to the AMCC Campaign
"About 97% of respondents (N = 906; weighted sample characteristics of study participants are shown in Table 1) recalled seeing or hearing news stories or ads that told about teenagers abusing prescription drugs. More than a third of all respondents reported seeing or hearing such information at least daily (14%) or a few times a week (24%)." (551)

Public awareness and preferred solutions to the prescription drug misuse problem
"…when asked about what they think is the single best thing people can do to prevent teenagers from getting and misusing prescription drugs, the most common answer respondents gave was greater parental involvement (37%), and their responses were about equally divided among three specific types of actions parents can take: (1) talk to their kids about the risks of prescription drug misuse, (2) closely monitor their kids' behavior and actions in and outside the home, and (3) serve as a positive role model by decreasing their own intake of prescription and OTC medicine at home. Other common solutions proposed by respondents included more drug education (22%), disposal of medicine people store in their homes (12%), greater oversight from the state regarding the prescription of drugs (7%), keeping youth occupied with normative activities (4%), and increasing law enforcement efforts (3%)." (552)

"The results shown suggest that although exposure to the AMCC campaign had no independent effect on respondents' likelihood of perceiving drug abuse as a major problem facing youth in the state, it did increase their likelihood of identifying prescription drug misuse as the most important problem. Specifically, respondents who could recall any exposure to the AMCC campaign had 1.8 times the odds of the unexposed to identify prescription drug misuse as a major problem when the effects of confounders were controlled for." (552)

Prescription drug preventive behaviors
"Only 5% of the 906 respondents reported searching in the past 30 days for information on the Internet about safely disposing of prescription drugs, compared with 21% who reported having one or more conversations with others about prevention of prescription drug misuse." (553)

"for the specific prescription drug preventive behaviors promoted by the AMCC campaign, 33% of respondents reported taking an inventory of the prescription and OTC medicines stored in their home in the past 30 days; 11.5% locked their medicine cabinet; 24% disposed of expired, unwanted, or unused medicine in household trash; 13% flushed medicine down a drain; and 9% used the collection sites that were set up during the AMCC 2010 collection day event." (553)

"42% of respondents took none of the specific prescription drug preventive behaviors recommended by the campaign, 33% completed one of these, 18% managed two, and 7% reported taking three or more of the recommended actions." (553)

"respondents who had any exposure to the AMCC campaign had 2.4 times the odds of the unexposed to have had one or more conversations with others about prescription drug misuse prevention." (553) "As for the specific prescription drug preventive behaviors promoted by the AMCC campaign, the confounder-adjusted effect of campaign exposure was statistically significant only for disposing of expired, unwanted, or unused medicine in a collection site and talking to kids about the dangers of prescription drug misuse. Specifically, those exposed to the campaign had more than twice the odds of the unexposed of disposing of expired, unwanted, or unused medicine stored in their homes at a collection site set up as part of the national collection day and 1.65 times the odds of talking to kids about the risks of prescription drug misuse." (553)
CRITICAL APPRAISAL
Descriptive Study – Weak study of medium quality.

CITATION
FDA. Disposal of unused medicines: what you should know. U.S. Food and Drug Administration. 2019, Apr. 29.
YEAR
2019
JURISDICTION
United States
FOCUS OF SOURCE
Web resource To provide guidance on how American citizens should properly dispose of unused, unwanted or expired medication
KEY FINDINGS
The best way to dispose of **most types*** of old, unused, unwanted, or expired medicines (both prescription and over the counter) is to drop off the medicine at a drug take back site, location, or program **immediately**. **Drug Take Back Options** Medicine take back options are the best way to safely dispose of **most** types of unneeded or expired prescription and over the counter medicines. Note that there are a few, select medicines with specific instructions to **immediately flush** down the toilet **only** if a drug take back option is not readily available. (Examples include: Oyxcodone, and Diazapam) There are generally two kinds of take back options: • Permanent collection locations and sites • Periodic events Before disposing of prescription medicines using a drug take back option, be sure to remove all personal information on the label of pill bottles or medicine packaging. **Permanent Collection Locations and Sites** Some facilities and business are registered with the U.S. Drug Enforcement Administration (DEA) to collect old, unused, unneeded, or expired medicines. These authorized drug collection locations safely and securely gather and dispose of pharmaceuticals containing controlled substances, as well as other medicines. In your community, such authorized collection locations may be in retail pharmacies, hospital or clinic pharmacies, and law enforcement agencies/ facilities. Some authorized collectors may also offer mail

back programs or collection receptacles (drop off boxes) to assist you in safely disposing of your unused medicines.

Periodic Events
The U.S. Drug Enforcement Administration (DEA) periodically hosts National Prescription Drug Take Back events. During these Drug Take Back Days, temporary drug collection sites are set up in communities nationwide for safe disposal of prescription drugs.
Local law enforcement agencies may also sponsor medicine take back events in your community. You can also contact your local waste management authorities to learn about events in your area.

Flushing
You should **immediately flush** the medicine down the toilet **only if:**

- your medicine is on the flush list **and**
- a drug take back location is not readily available

Medicines on this flush list may be especially harmful and, in some cases, fatal with just one dose if they are used by someone other than the person for whom they were prescribed. An example of such a drug is the fentanyl patch, which is an opioid.

Immediately flushing these types of medicines down the toilet helps keep children, pets, and other individuals safe by making sure these powerful and potentially dangerous drugs are not accidentally ingested, touched, or misused

Disposal in Trash
If no drug take back sites, locations, or programs are available in your area, **and** there are no specific disposal instructions (such as flushing) in the medication guide or package insert, you can follow these simple steps to dispose of most medicines in your trash at home*****:

1. Mix medicines (liquid or pills; do not crush tablets or capsules) with an unappealing substance such as dirt, cat litter, or used coffee grounds;
2. Place the mixture in a container such as a sealed plastic bag;
3. Throw away the container in your trash at home; and
4. Delete all personal information on the prescription label of empty medicine bottles or medicine packaging, then trash or recycle the empty bottle or packaging.

Drug Disposal Q&A
Q1. What are FDA's recommendations for removing unused or expired medicines (including prescription, over the counter (OTC), and dietary supplements) from the home?

Almost all medicines can be safely disposed of through drug take back programs or using U.S. Drug Enforcement Administration (DEA) authorized collectors.

When these options are **not** immediately available, consumers may also dispose of most unwanted medicine in their trash at home.

If the prescription medicine is on the flush list **and** a DEA authorized collector or drug take back program is **not** immediately available for drop off, FDA recommends that these medicines be disposed of by flushing.

The prescription medicines on the flush list contain controlled substances and are especially harmful if taken accidentally by someone other than the patient. These medicines should **not** be thrown in the trash because this method may still provide an opportunity for a child or pet to accidentally take the medicine.

Q2. How do I get rid of needles and syringes?
The FDA recommends a two-step process for properly disposing of used needles and other sharps.

Step 1: Place all needles and other sharps in a sharps disposal container immediately after they have been used.
This will reduce the risk of needle sticks, cuts, and punctures from loose sharps. Sharps disposal containers should be kept out of reach of children and pets.
Note: Overfilling a sharps disposal container increases the risk of accidental needle-stick injury. When your sharps disposal container is about three-quarters (3/4) full, follow your community guidelines for getting rid of the container (Step 2, below).

DO NOT reuse sharps disposal containers.
Be prepared when leaving home. Always carry a small, travel-size sharps disposal container in case other options are not available.

Step 2: Dispose of used sharps disposal containers according to your community guidelines.
Sharps disposal guidelines and programs vary depending on where you live. Check with your local trash removal services or health department (listed in the city or county government (blue) pages in your phone book) to see which of the following disposal methods are available in your area:

Drop Box or Supervised Collection Sites
You may be able to drop off your sharps disposal containers at appropriate chosen collection sites, such as doctors' offices, hospitals, pharmacies, health departments, medical waste facilities, and police or fire stations. Services may be free or have a nominal fee.

Household Hazardous Waste Collection Sites
You may be able to drop off your sharps disposal containers at local public household hazardous waste collection sites. These are sites that also commonly accept hazardous materials such as household cleaners, paints and motor oil.

Mail-Back Programs
You may be able to mail certain FDA-cleared sharps disposal containers to a collection site for proper disposal, usually for a fee. Fees vary, depending on the size of the container. Follow the container manufacturer's instructions because mail-back programs may have specific requirements on how to label sharps disposal containers.

Residential Special Waste Pick-Up Services
Your community may provide special waste pick-up services that send trained special waste handlers to collect sharps disposal containers from your home. These services are typically fee-based and many

have special requirements for the types of containers they will collect. Some programs require customers to call and request pick-ups, while other offer regular pick-up schedules.

For more information specific to your state, call Safe Needle Disposal at 1-800-643-1643 or e-mail info@safeneedledisposal.org. Information they can provide for your state includes:

- types of sharps containers that can be used,
- disposal programs in your area,
- how to label your sharps disposal containers,
- how to secure the lid of your sharps disposal container, and
- whether sharps disposal containers can be thrown away in the common trash.

Q3. 'I live in an assisted living community and take my own medications' or 'My family member was in hospice and has since passed away.' How can I safely dispose of medicines that are no longer needed?

First, check with the health care management team in your community or hospice to find out the best way to dispose of unused or unwanted medicines.

If you learn that you are responsible for disposal of these medicines, follow the directions below:

1. The preferred method of medicine disposal is a drug take back option.
2. If these options are **not** readily available, check to see if your medicine is on the flush list. If it is, you should dispose of it by flushing it down the toilet. These flush list medications are potentially dangerous and should **not** be disposed of in the trash.
3. If your medicine is not on the flush list, you can follow these instructions to dispose of in the trash at home.

Some opioid products with uncommon dosage forms (e.g., sprays, lozenges) have product-specific disposal instructions. Review the instructions that came with your prescription or contact your health care professional (e.g., pharmacist, doctor) to find out how to properly dispose of these medicines.

Q4. Why are some medicines on the flush list while other medicines are not? What is the rationale for this policy?

The few, select medicines recommended for disposal by flushing are safe and effective when used as prescribed but they could be especially harmful to children, pets, or others if taken accidentally. Some of the possible harmful effects include breathing difficulties or heart problems, which could lead to death.

For these reasons, FDA recommends that when it is not possible to immediately drop off these medicines at a drug take back program or a DEA authorized collector, consumers should flush them down the toilet to immediately and permanently remove this risk from their home.

We believe that the risk of harm from accidental exposure to this small, select list of medicines far outweighs any potential risk to the environment that may come from disposal by flushing. FDA continues to work with and encourage manufacturers of these medicines to develop alternative, safe disposal systems as reducing this risk is of our utmost concern.

CITATION
Health Canada. Safe disposal of prescription drugs. Health Canada. 2014.
YEAR
2014
JURISDICTION
Canada
FOCUS OF SOURCE
To provide guidance to Canadians on how to safely dispose of prescription drugs.
KEY FINDINGS

Safe disposal
Help ensure that prescription drugs and other pharmaceuticals do not pose a risk to you and to others.

- Check your medicine cabinet and remove all expired and unused prescription drugs, over-the-counter medications and natural health products. If you do not know if a drug is still safe, check with your pharmacist.
- Bring unused and expired prescription drugs, over-the-counter medications and natural health products to your local pharmacist for proper disposal.

Do not flush medicines down the toilet or sink.

Take-back programs
You can return your unused and expired medications to any pharmacy in Canada any day of the year. In addition, some municipalities and local police forces offer take-back programs. These programs provide safe and easy ways to dispose of unused and expired drugs and health products we have in our homes.

Drugs collected in take-back programs include:

- prescription drugs
- over-the-counter medications
- natural health products

Unfortunately, these programs collect only a fraction of unused and expired pharmaceuticals. The rest end up in the environment, especially in the soil and in the water.
If the area you live in does not have a take-back program, contact your pharmacy or municipality for assistance.

Garbage disposal
If you must throw your medications in the garbage, take these steps:

1. Remove medications from their original containers. Scratch out all identifying information on the prescription label. This will help protect your identity and the privacy of your personal health information.
2. Hide the medications in something unappealing, such as used coffee grounds or kitty litter. This makes the drug less attractive to children and pets, and unrecognizable to people who go through the trash seeking drugs.
3. Place this mixture in a closed bag, empty can or other sealed container to prevent the drug from leaking or breaking out of a garbage bag.

Pharmaceuticals and the environment
Over the past few decades, there has been a dramatic increase in new human and veterinary drugs introduced to the Canadian marketplace.

Due to improper disposal of these drugs, there are traces of pharmaceuticals in the environment--in the soil and in the water. Concentration levels of these products may be very low. But they may be enough to have adverse effects on the environment and on human health. Effects can also build up over time.

Provides links to Health Products Stewardship Association: http://healthsteward.ca/
Partners with pharmacists to provide drop off locations for returning medications and medical sharps. Sharps programs provide user with free safe collection container.

CITATION
1. Health Products Stewardship Association. Safely return unwanted medications and medical sharps. 2019. http://healthsteward.ca/
YEAR
2019
JURISDICTION
Canada
FOCUS OF SOURCE
To provide information about how Canadians can return unwanted medications or medical sharps to a local pharmacy that participates in the Health Products Stewardship Associations program.
KEY FINDINGS
The Health Products Stewardship Association (HPSA) operates returns programs that are an easy and safe way to dispose of medications and other health products that we all have in our homes. We encourage the public to safely return their medications and medical sharps instead of throwing them away or being misused by others. And it's free for consumers and pharmacists! HPSA represents producers of consumer health products in Canada. The association was formed by producers to ensure the safe and effective collection and disposal of their products. We fulfill their stewardship obligations in provinces that have Extended Producer Responsibility (EPR) regulations regarding consumer health products (CHP). We also serve as a national industry liaison and members' representative to help raise awareness on proper disposal issues. Governed by a board of directors representing companies that produce consumer health products, HPSA is a federally registered not-for-profit organization. It operates collection and disposal programs that focus on prescription drugs, natural health products, over-the-counter medications, and medical sharps waste generated by the public in their homes. Provides a list of pharmacies participating in the program across Canada. Accepted for medication take-back Any of the following items that are unused or expired: • Prescription drugs (BC, MB, ON, PE) • Over-the-counter medications (BC, MB, ON, PE) • Natural health products (BC, MB, ON, PE) Instructions for medication take-back: Remove or black out any personal identification from all medications to be returned. Collect all dry medications such as pills and tablets into a bag or container. Keep liquids, creams and inhalers in their original packaging. Bring your products to one of our participating pharmacies in your area.

Accepted for medical sharps take back: Any medical sharps used on humans or companion animals to inject medications (in ON and PE only).

Instructions for medical sharps take-back:
Visit your local participating pharmacy to receive an approved sharp container free of charge. Once you have your container follow these steps:

1. Recap needles and drop or place into an approved sharp container. DO NOT OVERFILL.
2. When ready to return, permanently close the container by inserting the tab into the opening to secure the lid down.
3. Take back the secured container to a participating pharmacy.

Impact

- Nearly 3 million kilograms of medications collection since the inception of the program
- Over 1.5 million of medical sharps collection since the inception of the program
- Nearly 5700 participating pharmacies
- 160 member producers

CITATION
Hospice and Palliative Nurses Association. Medication Safety in Hospice and Palliative Care. HPNA Position Statement. J Hosp Palliat Nurs. 2019 Apr;21(2):E1-e4.
YEAR
2019
JURISDICTION
United States
FOCUS OF SOURCE
To provide the position of the Hospice and Palliative Nurses Association on medication safely including safe storage and disposal.
KEY FINDINGS

Position Statement
"It is the position of the Hospice and Palliative Nurses Association (HPNA) that medication safety is an essential aspect of hospice and palliative nursing. Hospice and palliative nurses are instrumental in public education about medication safety for patient with serious illnesses, their family, and the community." (E1)
 	
Education
• Hospice and palliative nurses must understand the concepts of medication safety including safe prescribing, safe medication storage in the home, and safe disposal.
• Hospice and palliative nurses must stay current on federal, state, and local regulations.
• Hospice and palliative nurses should be aware of their local resources for federally approved take-back programs as they relate to environmental regulations in their communities (eg, state, county, local).
 	
Clinical Practice
• Hospice and palliative nurses must ensure organizational policies for safe medication prescription, medication safety, and disposal of medications.
• Hospice and palliative nurses must engage in best practices for safe storage and medication disposal at the community level and globally.
• Registered nurses have a legal responsibility to adhere to safe prescribing practices, which include the following actions:
  o Educate patients in safe use of prescription medications such as opioids, benzodiazepines, and psychotherapeutic medications;
  o Review safe storage strategies for medications; and
  o Provide instructions on the proper disposal of expired, unused, or unwanted medications.
• Advanced practice registered nurses, as medication prescribers, have a legal responsibility to adhere to safe prescribing practices, which include the following actions:
  o Prescribe appropriate quantities;
  o Educate patients in the safe use of prescription medications like opioids, benzodiazepines, and psychotherapeutic medications;
  o Review safe storage strategies for medications; and
  o Provide instructions on the proper disposal of expired, unused, or unwanted medications.

Policy / Advocacy

- Hospice and palliative nurses and their organizations have a responsibility to participate and promote takeback programs and take-back events.

Safe Storage

- "The first step includes keeping the medications in the container they were prescribed in, not plastic bags or loose in drawers, purses, backpacks, briefcases, or luggage"
- "The second step is having a routine for medications, such as putting them away after administration"
- The third step includes using safety caps and keeping medications out of harm's way for others. Such strategies include ensuring safety caps are replaced, using safety caps unless otherwise planning, and putting medications up and away out of reach of children.
- For opioids, benzodiazepines, and other potentially harmful medications, it means securing medications. This includes keeping medications out of sight of children and visitors. Strategies include locking medications in a medicine cabinet, a lock box, or bank bag with a lock.

Medication Disposal

"Within the Centers for Medicare & Medicaid Services conditions, home health agencies are not authorized to dispose of controlled substances, but both hospice and home health agencies are encouraged to partner with authorized collectors in take-back programs. Here, the nurse's role is to provide education on disposal."

"There are guidelines published for disposal by the Food and Drug Administration (FDA), and most publications for consumers are based on the content in these guidelines. The FDA developed these guidelines to encourage the proper disposal of medicines and help reduce harm from accidental exposure or intentional misuse when no longer needed. Medication disposal falls into several areas: take-back programs for unused medications, trash disposal with appropriate alteration of the medication to make it unusable, and flushing programs."

Take-Back Programs

"Take-back programs allow the public to take unused drugs to a central location for proper disposal, including authorized collectors like pharmacies or clinic programs where individuals can mail back prescriptions. These must be overseen by law enforcement agencies for specified days of take-back programs."

"The US Department of Justice, in collaboration with the Drug Enforcement Administration, organizes a national take-back day every year. Local law enforcement agencies often sponsor medicine take-back programs in the community. Authorized sites may be retail, law enforcement locations, or hospital or clinic pharmacies. Some offer mail-back programs or collection receptacles (ie, drop boxes)."

"Trash disposal should focus on altering substances and making them unappealing and undesirable. This method of disposal consists of 3 steps: remove labels from original bottles or containers to hide the fact it is a medication; mix crushed pills or liquids with coffee grounds, tea leaves, kitty litter, or dirt to render them unrecognizable; or place the mixture in a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag."

It should be noted that there is no consensus between the FDA and the Environmental Protection Agency on disposal. The FDA states that medications should be flushed down the toilet, while the Environmental Protection Agency promotes altering medications before disposal, as flushing medications into the sink or toilet affects the water supply."

CITATION
ISMP Canada. Safe storage and disposal of medications. ISMP Canada Safety Bulletin. 8(5), July 27, 2018.
YEAR
2018
JURISDICTION
Canada
FOCUS OF SOURCE
key messages to guide both clinicians and patients on the safe storage and disposal of medications in the community (1)
KEY FINDINGS
Safe Storage ideal medication storage location provides easy accessibility for the intended user while preventing or discouraging inappropriate access and accidental ingestion by anyone else, especially children. (1) A locking device is strongly suggested, either for the medication container or for the cabinet in which medications are stored (1) **Safe Disposal** The ideal method of medication disposal should be easy to perform, should minimize risk for diversion, should not impose a financial burden, and should be environmentally sound. (1) Taking unused medications to a community pharmacy for proper disposal meets all of these criteria and is therefore recommended. (1) Disposing of medications in the trash is not acceptable, because home garbage containers are often vulnerable to access by children and pets, as well as to drug diversion. (1-2) Although flushing medications down the toilet has often been used as a disposal alternative, there are compelling arguments against widespread use of this practice, given that the potential environmental and health impact of most products is unknown (2) Topical patches containing opioids, such as fentanyl and buprenorphine, pose unique disposal risks. The Patch-for-Patch Fentanyl Return Policy is an Ontario legislative initiative that aims to reduce the risk of harm; evaluation of this program will be of interest. (2) NOTE: Safeguarding our Communities Act (Patch for Patch Return Policy), 2015, S.O. 2015, c. 33 (https://www.ontario.ca/laws/statute/15s33) – requires patients who receive a prescription for fentanyl to return their patches to the pharmacy before receiving new ones (https://www.ocpinfo.com/regulations-standards/practice-policies-guidelines/Patch_For_Patch_Fentanyl_Return_Fact_Sheet/)

The website of the Health Products Stewardship Association (HPSA) provides information about locations and processes for safe medication disposal in every Canadian province. The HPSA also administers medication return programs for participating pharmacies in British Columbia, Manitoba, Ontario, and Prince Edward Island; through these programs, patients can take unneeded medications to participating pharmacies. (2)

In addition, HPSA, its partners, and participating pharmacies conduct an annual campaign encouraging families to declutter their medicine cabinets and to return unneeded and expired medicines to the pharmacy. (2)

Special Circumstances
Upon the death of a person who has been receiving palliative or end-of-life care in the home, the family is often left to dispose of the patient's unused medications. A "situation assessment" was conducted at an Ontario hospital by a multidisciplinary team to evaluate methods for disposal of unused medications in these circumstances. The study objectives were to identify preferred practices and to provide educational materials for families and healthcare providers with the ultimate goal of improving medication storage and disposal in these cases. (2)

A suitable action identified by the team was to have a pharmacist conduct an in-home medication review and remove unused medications. (2)

Another good practice is to have the home care service provider pick-up symptom relief kits* when they are no longer needed. (2)

(Citation: Hyland B, Fan M, Hamilton M, Reding R, Trbovich P. Informing patients and families about storage and disposal of opioids [poster]. Canadian Society of Hospital Pharmacists Professional Practice Conference; 2018 Feb 4-6; Toronto (ON). Can J Hosp Pharm. 2018 Jan-Feb;71(1):61.)
Cite as secondary source

Resources for Patients and Families
"Prevent Medication Accidents" (Figure 1) is an information card developed to provide key information for patients and families about proper storage and disposal of unnecessary medications in the home. (2) https://www.ismp-canada.org/download/OpioidStewardship/storage-disposal-information.pdf

Another resource handout was developed to address the proper use, secure storage, and disposal of opioids prescribed to treat pain after surgery. (2) https://www.ismp-canada.org/download/OpioidStewardship/OpioidsAfterSurgery-EN.pdf

CITATION
New Hampshire Department of Environmental Services. Emptying the Medicine Cabinet: Disposal Guidelines for Pharmaceuticals in the Home. Environmental Fact Sheet. 2019.
YEAR
2019
JURISDICTION
United States
FOCUS OF SOURCE
Providing disposal guidelines for disposing of medicine (note: also includes intravenous bags and sharps)
KEY FINDINGS
Disposal of medications Take your unneeded or expired medication from your household to a drop box at a local police station. (1) the US Drug Enforcement Administration coordinates a National Drug Take Back Day almost 100 locations throughout New Hampshire every April and October (1) some pharmacies have established medication disposal kiosks (1) In addition to the options above, medicine from households can be disposed of in household trash using the following method: 1) Pour medicine into a sealable plastic bag. 2) If the medicine is a solid, add a small amount of water to dissolve it. 3) Add coffee grounds, kitty litter or something similar to the liquid medicine in the plastic bag. 4) Seal the bag and immediately dispose of it in the trash. 5) Use a marker to black out any personal contact information on the empty medicine container prior to disposing of it in the trash. (1) Flushing medicine down the toilet or drain is never advised unless accompanying product information instructs it is safe to do so. (1) it is important that unneeded medications not be kept in the home. (1) all medicine should be stored securely when in the home (1) To reduce the amount of waste pharmaceuticals: 1. Only purchase what you need. Why waste money on pharmaceuticals to just sit on the shelf and expire over time? 2. Say “No” to samples if you are not going to use them. You will only need to dispose of them later.

3. Stop junk mail. Take your name off mailing lists so you don't receive free sample products, such as pain relievers. If you don't use them, then you will need to dispose of them later. Visit www.des.nh.gov and search on "junk mail" to find out how.
4. Centralize all pharmaceuticals in one location. This may help to limit over purchasing of products you already have. (2)

CITATION
Ontario Palliative Care Network. Palliative Care Health Services Delivery Framework Recommendations for a Model of Care to Improve Palliative Care in Ontario Focus Area 1: Adults Receiving Care in Community Settings. 2019.
YEAR
2019
JURISDICTION
Canada
FOCUS OF SOURCE
The goal of the Delivery Framework is to recommend a model of care that delivers high-quality, culturally safe palliative care in Ontario. The Delivery Framework builds on the three strategic goals of the Declaration of Partnership–Quality, Population Health, and Sustainability. Specifically, the Delivery Framework will help us move towards a system that: a) Provides patients and their families with timely, equitable access to high-quality care as close to home as possible; b) Supports broader integration and coordination of healthcare resources to deliver seamless palliative care to patients and their families; and, c) Optimizes the use of health human resources. (7)
KEY FINDINGS
5. The patient will have 24/7 access to pain and symptom management from the Core Team or the on-call providers. This may occur in-person or via telemedicine (e.g., telephone support, virtual care, etc.). 5.6. Pharmacists, in consultation with the Core Team, will play a significant role in symptom management, medication safety and will support treatment decisions throughout the patient's journey. 5.7 Standardized symptom management kits and related policies/protocols will be available and safely stored in all community settings (e.g. patient's home, long-term care home) for management of unexpected, emerging, or worsening symptoms. (30-31) **Implementation Considerations for Management of Pain and Other Symptoms** • There is significant variation in access to medications for palliative care across the province. To support 24/7 access to palliative care, there needs to be reliable and equitable access to pharmacy services and expertise after hours. As well, a full range of palliative care medications and appropriate protocols on doses and dosing formats (oral and parenteral) should to be available to the Core Team. • Developing provincial standards for symptom management kits that allow for regional/local customization will be an important action. The key elements that need to be standardized include: a) the medications and doses, b) protocols for ordering and dispensing of the kits and monitoring their utilization, c) safety standards, and d) education for community nurses in the use of the kits. (31)

CITATION
World Health Organization. Safe management of wastes from health-care activities. 2nd edition. 2014.
YEAR
2014
JURISDICTION
Global
FOCUS OF SOURCE
the safe, sustainable and affordable management of health-care waste (1) Initially, the publication was intended for those directly involved in the creation and handling of health-care wastes: medical staff, health-care facility directors, ancillary health workers, infection-control officers and waste workers. This is no longer the situation. A wider range of people and organizations now have an active interest in the safe management of health-care wastes: regulators, policy-makers, development organizations, voluntary groups, environmental bodies, environmental health practitioners, advisers, researchers and students. (1)
KEY FINDINGS
Note: most information is hospital-level and assumes there is a facility involved rather than multiple home sites – very little information applicable to home care environment Box 2.4 lists some minor sources of health-care waste. However, it should be recognized that the quantities of waste from the home treatment of medical conditions and long-term home-based care are rising significantly in many countries. (10) Health-care waste-generation data are best obtained from quantitative waste assessments. An assessment entails defining goals, planning, enlisting the cooperation of staff, procurement of equipment (e.g. weighing scales, personal protective equipment), data collection, analysis and recommendations. The process of waste assessment provides an opportunity to improve current practices, sensitize health workers about waste, and determine the potential for waste minimization. Implementing rigorous segregation can avoid over-sizing of equipment and result in cost savings. (11) Where there is no national policy, legislation or guidelines, this should not prevent a hospital or health-care facility from commencing a modest programme of health-care waste management. A short document could be prepared that states the problems, sets out simple actions, identifies the stakeholders, and mobilizes them to carry out the actions. Initially, this is all that may be necessary. (48) Training should highlight the roles and responsibilities of each member of staff and how they contribute to the broader management policy to achieve good waste practices. Staff education programmes should include: • information on, and justification for, all aspects of the health-care waste policy;

• information on potential infection risks posed by health-care waste;
• information on the role and responsibilities of each staff member to follow waste-management procedures;
• technical instructions on the application of waste-management practices relevant to particular types of work
by some medical or support staff
• information on monitoring, record keeping and maintenance of equipment. (216)

training and public awareness programme should contain two aspects. The first is to create awareness and foster responsibility for good hygiene among all workers, patients and visitors at health-care facilities. The public awareness programme can go further and explain how good health-care waste management protects public health. The second aspect is to inform the public in general about the risks from poor hygiene and health-care practices, with particular regard to people living or working in close proximity to health-care facilities, families of patients treated at home, and scavengers working at disposal sites.
Various methods can be used to promote public education on health-care waste. Commonly used approaches include the following:
• Poster exhibitions can be used to educate about health-care waste issues, such as the risks involved in reusing syringes and hypodermic needles or the infection-control benefits of waste segregation and treatment.
• Medical staff can explain to new patients and visitors their personal responsibilities to help maintain good hygiene and safe waste management. This may be difficult to achieve with people who have entrenched views, and face-to-face discussion should be supplemented with diagrams, posters and leaflets
• Information signs and pictograms can be used in hospitals, at strategic points such as waste-bin locations, giving instructions on waste segregation. Signs should be explicit, using diagrams, illustrations and consistent colour coding to convey the message to a broad audience, including illiterate people and those with a lower educational capacity. (223)

CITATION
National Institute for Health and Care Excellence. Controlled drugs: safe use and management. NICE Guideline. 2016.
YEAR
2016
JURISDICTION
United Kingdom
FOCUS OF SOURCE
This guideline covers systems and processes for using and managing controlled drugs safely in all NHS settings except care homes. It aims to improve working practices to comply with legislation and have robust governance arrangements. It also aims to reduce the safety risks associated with controlled drugs.
KEY FINDINGS
NOTE: extracted data most pertinent to home care organizations **1.1 Developing and establishing systems and processes for organisations** *Governance arrangements and accountability* 1.1.1 Organisations should agree governance arrangements with clear lines of responsibility and accountability for controlled drugs in their contracts. 1.1.2 Designated bodies must appoint a controlled drugs accountable officer, who will quality assure processes for managing controlled drugs in their organisation, in line with Regulation 8 of the 2013 Regulations. 1.1.3 Consider appointing a nominated person in organisations that are not required by legislation to appoint a controlled drugs accountable officer, to: work in accordance with governance arrangements for the safe use and management of controlled drugs; make sure processes are in place for safe use and management of controlled drugs, and; the reporting and investigating of concerns liaise with the local NHS England lead controlled drugs accountable officer and local intelligence network members. (5-6) *Policies, processes and procedures* 1.1.4 Develop a controlled drugs policy and standard operating procedures for storing, transporting, destroying and disposing of controlled drugs. 1.1.5 Establish processes for developing, reviewing, updating, sharing and complying with controlled drugs-related standard operating procedures, in line with legislation and national guidance. Consider using a risk assessment when establishing processes. 1.1.6 Designated bodies must put in place the minimum standard operating procedures for processes relating to prescribing, supplying and administering controlled drugs, including clinical monitoring for people who have been prescribed controlled drugs, in line with Regulation 11 of the 2013 Regulations. 1.1.7 Ensure that national medicines safety guidance about controlled drugs, such as patient safety alerts, are incorporated into policy and acted on within a specified or locally agreed timeframe.

1.1.10 Consider putting processes in place to access prescribing data for all controlled drugs to identify: prescribing trends and potential risks of unintended use; the reasons for very high, increasing or very low volume prescribing. (6-7)

Processes and procedures for storage, stock checks and audits
1.1.11 When developing standard operating procedures for storing controlled drugs, ensure that they are in line with the Misuse of Drugs (Safe Custody) Regulations 1973, meet the needs of the service and take into account:

- the setting for use and whether the security setting is low, medium or high risk
- staff access to controlled drugs
- the storage environment, including temperature and space in the controlled drugs cabinet
- storage of stock (including unwanted or expired stock) and patients' own controlled drugs
- any additional storage needs for controlled drugs of different strengths with similar or 'lookalike' packaging. (7)

Providing information and advice to people taking or carers administering controlled drugs
1.5.9 Document and give information to the person taking the controlled drug or the carer administering it, including:

- how long the person is expected to use the drug
- how long it will take to work
- what it has been prescribed for
- how to use controlled drugs when sustained-release and immediate-release formulations are prescribed together
- how it may affect the person's ability to drive (see the advice from the Department of Transport on drug driving and medicine: advice for healthcare professionals)
- that it is to be used only by the person it is prescribed for.

1.5.10 Inform people who are starting controlled drugs that they or their representative may need to show identification when they collect the controlled drugs.

1.5.11 When prescribing controlled drugs in primary care for use in the community, advise people how to safely dispose of:

- unwanted controlled drugs at a community pharmacy
- used controlled drugs. (13-14)

Providing information and advice to people receiving controlled drugs
1.6.6 When supplying controlled drugs, advise people how to safely dispose of: unwanted controlled drugs at a community pharmacy; used controlled drugs. (15)

Providing information and advice on storage to people prescribed controlled drugs
1.8.2 Provide advice and information to people who are prescribed controlled drugs about how to store controlled drugs safely. Discuss storage options taking into account:

- the person's preference for a lockable or non-lockable storage box
- whether the controlled drugs will be accessible to people who should and should not have access to them
- whether the storage method could increase the risk of controlled drug-related incidents, including patient safety incidents. (19)

Safely destroying and disposing of controlled drugs

1.8.9 For stock controlled drugs, when disposing of bottles containing irretrievable amounts of liquid drugs:

- consider rinsing the bottle and disposing of the liquid into a pharmaceutical waste bin
- remove or obliterate labels and other identifiers from the container
- dispose of the clean, empty container into the recycling waste.

1.8.10 When a person has died in their home and controlled drugs need to be removed for destruction and disposal in primary care, consider:

- discussing the removal of controlled drugs with a family member or carer
- recording the action taken and details of the controlled drugs listed in the person's medical record or notes
- having a witness to the removal
- any requirements of the coroner to keep medicines in the person's home for a period of time
- taking the drugs to a health professional, such as a community pharmacist who is legally allowed to possess controlled drugs, for safe disposal at the earliest opportunity.

CRITICAL APPRAISAL

Guideline – Highest possible quality

APPENDIX C – Critical Appraisal Forms

Author(s)	de la Cruz M, Reddy A, Balankari V, et al.
Year	2017
Title	The Impact of an Educational Program on Patient Practices for Safe Use, Storage, and Disposal of Opioids at a Comprehensive Cancer Center
Reviewer	PM
Review Date	Oct 3, 2019

Key Question	Does the implementation of a patient education program improve the patterns of use, storage and disposal of opioids among cancer outpatients?

Refer to Analytic Study Critical Appraisal Tool Dictionary for complete criteria. Not all criteria will be applicable to all studies. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

Select Study Design									
Strong Design				**Moderate Design**				**Weak Design**	
RCT	NRCT	Lab	CBA*	CBA*	Cohort	Case Control	ITS* (adequate)	UCBA	ITS* (inadequate)
☐	☐	☐	☐	☐	☒	☐	☐	☐	☐

*See Table 1 and legend for "Algorithm - Naming the Type of Analytical Study" for decision regarding CBA or ITS.

Screening Question			
	Strong	**Moderate**	**Weak**
1. Research Question	Clearly focused. Highly relevant to Key Question. ☐	Fairly focused. Related to Key Question. ☒	Unclear or too broad. Unrelated to Key Question. ☐
Comments	Research question defines sample age limit, time period, use of opioids in last month, fluency in English and without cognitive impairment. Intervention is not entirely clear right away.		
Screening Decision	☐ Reject (if weak)		☒ Continue

Assessment of Study Population (Sample) and Sampling Method			
	Strong	**Moderate**	**Weak**
2. Study participants representative of target population	Multiple recruitment strategies used. Recruited/selected from a variety of locations or all of target population included. Participants (or lab sample) have targeted characteristics or appropriate database used.	Participants recruited/selected from a single source that may have excluded members of target population. Participants (or sample) seem to have targeted characteristics.	Participants are self-referred or volunteers. Participants (or sample) do not have targeted characteristics or it is not clear if they do.

	☐	☒	☐
3. Adequacy of control of selection bias	Random sampling used. Similar recruitment/selection process applied to all; similar baseline characteristics; participation rates ≥80% in each group. ☐	Random sampling not used. Similar recruitment/selection process applied to all; similar baseline characteristics; participation rates ≥80% in each group. ☐	Random sampling not used. Recruitment/selection process and some baseline characteristics may have differed. Less than 80% and/or different participation rates in groups. ☒
Comments	2. Sample characteristics are targeted but recruited from a single source. 3. Sample is not random.		

Assessment of Internal Validity			
	Strong	**Moderate**	**Weak**
4. Adequacy of control of misclassification bias	Strong intervention integrity with clear definitions applied. Clear temporal association. Objective measures used for exposure/ outcome status. No missing or inaccurate data. ☐	Strong intervention integrity with clear definitions. Clear temporal association. Some missing data or errors in measurement of exposure/outcome status likely created misclassification in only a few participants. ☐	Any one item: weak intervention integrity with unclear definitions, missing data or errors in measurement of exposure / outcome status likely created misclassification in many participants; unclear temporal association; or outcomes reported at aggregate level and unclear if individuals had intervention. ☒
5. Adequacy of control of information bias	Assessors blinded, trained in data collection and clearly adhered to procedures. Biases minimized with respect to data collection procedures and measures. Whether or not patients were blinded made no difference to data collected. ☐	Assessors were not blinded but trained in data collection and likely adhered to procedures. Biases reduced with respect to data collection procedures and measures. Patients were not blinded and this might have made a difference to data collected. ☒	Assessors were not blinded and unclear if trained in or adhered to data collection methods. Unclear if bias was sufficiently reduced. Patients were not blinded and it clearly made a difference to data collected. ☐
6. Validity and reliability of data collection instruments	Tools are known or were shown to be valid and reliable. ☐	No attempt to assess validity and reliability of tools. Content validity can be assumed based on questions asked and expert involvement. ☒	No attempt to assess validity and reliability of tools. Neither can be assumed. ☐
7. Adequacy of retention and follow-up	>90% of participants completed study. Similar dropout rates between groups with reasons unrelated to exposure. ☒	≥80% of participants completed study. Little difference in dropout rates between groups with reasons unrelated to exposure. ☐	Any one item: <80% of participants completed study; and/or major difference in dropout rates between groups; and/or dropout reasons were related to exposure. ☐

Comments	4. Members of control group may have received intervention from other sources (e.g. family, information media) – authors note this in Discussion section. 5. Safe to assume assessors were trained in data collection – they were part of the research team. 6. Very little information provided about data collection tool. Content validity can be assumed. 7. No evidence of participant dropout.

Assessment for Control of Confounding			
	Strong	**Moderate**	**Weak**
8. Comparability of control group and intervention group	Groups were similar at baseline and assessed concurrently. Appropriate controls used in case-control study. ☐	Groups were comparable at baseline with minor differences. Appropriate controls in case-controls study. ☒	Any one item: no control group or major differences existed between groups; or similarity of groups was not assessed. ☐
9. Adequacy of control of major confounders	Appropriate randomization to groups or appropriate matching / statistical analysis / lab conditions adequate for controlling confounding. Major confounders examined. ☐	Unclear / inadequate randomization or inappropriate matching but statistical analysis adequately controlled for confounding or lab conditions only partially controlled for confounding. Major confounders examined. ☒	No randomization to groups or appropriate matching. Statistical analysis or lab conditions did not control for confounding. Major confounders not examined. ☐
Comments	8. Groups were comparable, but with some minor differences. 9. Fisher's exact test and the Wilcoxon rank-sum test were used, confounders discussed (e.g. education from other sources).		

Ethics			
	Strong	**Moderate**	**Weak**
10. Adequacy of ethical conduct ☐ Not applicable	Study approved by appropriate ethics review board or sufficient details that conduct was ethical. Research report was not influenced. ☒	Not applicable	Insufficient details provided to draw conclusion on ethical conduct. Likelihood of research report being influenced could not be ruled out. ☐
Comments	10. Approved by institutional review board.		

Assessment for Control of Analysis			
	Strong	**Moderate**	**Weak**
11. Adequacy of interpretation of statistical testing	Statistical tests appropriate for level of data and hypothesis being tested. Probability values and confidence intervals interpreted correctly. ☒	Simple tests used correctly but data warranted more sophisticated tests. Control of confounding was limited. ☐	Tests were incorrect for data or information not given on tests used. Results not interpreted correctly. ☐
12. Power and sample size	Significant differences were found, thus sample size was sufficient or no significant differences found but researchers reported sufficient power. ☒	Significant differences not found and researchers reported that study power was insufficient. Sample size seemed reasonable. ☐	Significant differences not found and sample size was small. Adequacy of the study power not reported. ☐
Comments	11. P values provided and interpreted correctly. 12. Statistically significant differences were found.		

Assessment of Applicability			
☐ Not applicable ☐ Not appraised			
	Strong	**Moderate**	**Weak**
13. Generalizability of results	Study population characteristics very similar to group to which one wishes to generalize results. ☒	Study population characteristics somewhat similar to group to which one wishes to generalize results. ☐	Study population characteristics not at all similar to group to which one wishes to generalize results. ☐
14. Feasibility of implementation	Intervention is highly likely to be readily implemented in other settings. ☒	Intervention is somewhat likely to be readily implemented or exposure is very likely amenable to an intervention that can be readily implemented. ☐	Intervention is unlikely to be readily implemented or exposure is unlikely amenable to an intervention that can be readily implemented. ☐
Comments	13. Population is very similar to other populations of cancer patients prescribed opioids. 14. Intervention should be applicable to similar populations.		

Overall Conclusion
15. Summarize the results of the critical appraisal and complete the Evidence Summary Table. Note that you cannot make a recommendation based on a single study.

a) Identify the strength of study design
See "Select Study Design" at beginning of this tool.

☐ Strong ☒ Moderate ☐ Weak

b) Decision regarding quality of the study
Consider your ratings for appraisal items 2-12 and identify the appropriate rating for quality.

☐ High ☐ Medium ☒ Low

- **Rate the quality as HIGH if:** Most or all appraisal items were rated as strong, and none were rated as weak. In addition, there are no major threats to internal validity of the study or the ability to draw the conclusion that there is a clear association between the exposure and the outcome of interest.

- **Rate the quality as MEDIUM if:** Appraisal items 4 and/or 11 are rated as at least moderate, and the other appraisal items rated as weak or moderate are not sufficient to compromise the internal validity of the study. Also, these other items do not interfere with the ability to draw the conclusion that there is a probable association between the exposure and the outcome of interest.

- **Rate the quality as LOW if:** Appraisal items 4 and/or 11 are rated as weak, or if other items rated as weak are sufficient to interfere with the ability to rule out other explanations for the findings and draw a conclusion about the association of the exposure and the outcome of interest.

c) Decision regarding directness of evidence
Consider your ratings for appraisal items 2-12 and identify the appropriate rating for quality.

☒ Direct ☐ Extrapolation

Comments	Moderate study design Low quality – item 4 rated weak

Author	Fleming E, Proescholdbell S, Sachdeva N, et al.
Year	2016
Title	North Carolina's Operation Medicine Drop: Results from one of the nation's largest medication disposal programs.
Reviewer	PM
Review Date	Oct 9, 2019

Key Question	How many unit doses (pills) were collected at a medication disposal program in North Carolina from 2010 to 2014.

Refer to Descriptive Study Critical Appraisal Tool Dictionary for complete criteria. Complete only the section for the type of study design being appraised. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

A. Screening Question			
	Strong	**Moderate**	**Weak**
A1. Research Question	Clearly focused. Highly relevant to Key Question. ☒	Fairly focused. Related to Key Question. ☐	Unclear or too broad. Unrelated to Key Question. ☐
Comments	Research question describes exactly what the purpose of the study is.		
Screening Decision	☐ Reject (if weak) ☐ Continue		

B. Descriptive Exploratory Study			
	Strong	**Moderate**	**Weak**
B1. Study participants representative of target population	Random sampling and/or multiple recruitment / selection from various location or groups; >50% agreed to participate (or ≥80% of exposed were tested). ☐	Random sampling not used but multiple recruitment / selection strategies used. Single source of participants; 30-50% agreed to participate (or 60-79% of exposed were tested) ☐	Random sampling not used. Recruitment / selection processes limited. Participants were volunteers; <30% agreed to participate (or <60% of exposed were tested. ☒
B2. Data collection sources and methods	No missing data. Assessors trained and clearly adhered to procedures. Biases minimized with respect to data collection procedures and measures. Clear temporal association. ☐	Minimal missing/inaccurate data. Assessors trained and likely adhered to procedures. Biases reduced with respect to data collection procedures and measures. Clear temporal association. ☒	Any one item: substantial missing/ inaccurate data; unclear if assessors were trained; unclear if bias was reduced; or unclear temporal association. ☐
B3. Data collection instruments	Tools are known to be valid and reliable.	No attempt to assess validity and reliability of tools. Validity can be assumed based on questions	No attempt to assess validity and reliability of tools. Neither can be assumed.

	☐	asked and expertise of researchers. ☒	☐
B4. Ethics ☐ Not applicable (see dictionary)	Approved by appropriate ethics review board or content indicates ethical conduct was ensured. Research report was not influenced. ☐	Not applicable	Insufficient details provided regarding ethical conduct. Likelihood of research report being influenced could not be ruled out. ☒
B5. Statistics	Appropriate statistics used (descriptive). Narrow CI with all values having the same direction of effect. Clearly adequate power. Results interpreted correctly. ☐	Appropriate statistics used. Reasonably narrow CI with uncertain direction of effect. Power likely adequate. Results interpreted correctly. ☒	Any one item: statistics were incorrect for the data; CI was wide; power was inadequate; or results were not interpreted correctly. ☐
Comments	B1. Participants selected based on participation in take-back program. B2. Assessors likely adhered to procedures (Injury Prevention Research Centre) B3. Data collection tool was administrative database. No attempt to assess validity and reliability. B4. No details provided re: approval by ethics review board. B5. Only one descriptive statistic is reported. No need for CI.		

Overall Conclusion

a) Identify the strength of study design

☒ Weak (descriptive studies are weak by design)

b) Decision regarding quality of the study

Consider your ratings for appraisal items B1-B5 and identify the appropriate rating for quality.

☐ High ☒ Medium ☐ Low

- **Rate the quality as HIGH if:** most/all items rated strong, no weak items. Also, there are no major threats to the internal validity of the study or the ability to draw the conclusion that there is a possible association between the exposure and the outcome of interest.
- **Rate the quality as MEDIUM if:** either or both B2 or B5 were rated as moderate and neither rated as weak; other items rated as weak or moderate are insufficient to compromise ability to draw conclusions regarding a possible association between the exposure and the outcome of interest.
- **Rate the quality as LOW if:** either B2 or B5 was rated as weak; or other items rated as weak are sufficient to interfere with the ability to rule out other explanations for the findings

c) Decision regarding directness of evidence

☒ Direct ☐ Extrapolation	
Comments	Study is simple and descriptive but reports on exactly what the research question asked.

Author	Haughey CW, Lawson D, Roberts K, Santos M, Spinosa S.
Year	2019
Title	Safe Medication Disposal
Reviewer	PM
Review Date	October 9, 2019

Key Question	How does a small sample (n=15) of home care patients dispose of their unwanted or unused medications?

Refer to Descriptive Study Critical Appraisal Tool Dictionary for complete criteria. Complete only the section for the type of study design being appraised. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

A. Screening Question			
	Strong	**Moderate**	**Weak**
A1. Research Question	Clearly focused. Highly relevant to Key Question. ☐	Fairly focused. Related to Key Question. ☒	Unclear or too broad. Unrelated to Key Question. ☐
Comments	Research question is only fairly focused. Does not describe parameters of the study.		
Screening Decision	☐ Reject (if weak)	☒ Continue	

B. Descriptive Exploratory Study			
	Strong	**Moderate**	**Weak**
B1. Study participants representative of target population	Random sampling and/or multiple recruitment / selection from various location or groups; >50% agreed to participate (or ≥80% of exposed were tested). ☐	Random sampling not used but multiple recruitment / selection strategies used. Single source of participants; 30-50% agreed to participate (or 60-79% of exposed were tested) ☐	Random sampling not used. Recruitment / selection processes limited. Participants were volunteers; <30% agreed to participate (or <60% of exposed were tested. ☒
B2. Data collection sources and methods	No missing data. Assessors trained and clearly adhered to procedures. Biases minimized with respect to data collection procedures and measures. Clear temporal association. ☐	Minimal missing/inaccurate data. Assessors trained and likely adhered to procedures. Biases reduced with respect to data collection procedures and measures. Clear temporal association. ☐	Any one item: substantial missing/ inaccurate data; unclear if assessors were trained; unclear if bias was reduced; or unclear temporal association. ☒

B3. Data collection instruments	Tools are known to be valid and reliable. ☐	No attempt to assess validity and reliability of tools. Validity can be assumed based on questions asked and expertise of researchers. ☐	No attempt to assess validity and reliability of tools. Neither can be assumed. ☒
B4. Ethics ☐ Not applicable (see dictionary)	Approved by appropriate ethics review board or content indicates ethical conduct was ensured. Research report was not influenced. ☐	Not applicable	Insufficient details provided regarding ethical conduct. Likelihood of research report being influenced could not be ruled out. ☒
B5. Statistics	Appropriate statistics used (descriptive). Narrow CI with all values having the same direction of effect. Clearly adequate power. Results interpreted correctly. ☐	Appropriate statistics used. Reasonably narrow CI with uncertain direction of effect. Power likely adequate. Results interpreted correctly. ☒	Any one item: statistics were incorrect for the data; CI was wide; power was inadequate; or results were not interpreted correctly. ☐
Comments	B1. Participants were volunteers. No mention of any other selection criteria. B2. Cannot assume assessors adhered to data collection procedures without biases as these were nursing students not trained researchers. B3. No mention of assessing validity and reliability of tools. Survey was created and then administered. B4. No mention of ethical considerations B5. Appropriate statistics used. Only descriptive.		

Overall Conclusion

a) Identify the strength of study design

☒ Weak (descriptive studies are weak by design)

b) Decision regarding quality of the study

Consider your ratings for appraisal items B1-B5 and identify the appropriate rating for quality.

☐ High ☐ Medium ☒ Low

- **Rate the quality as HIGH if:** most/all items rated strong, no weak items. Also, there are no major threats to the internal validity of the study or the ability to draw the conclusion that there is a possible association between the exposure and the outcome of interest.
- **Rate the quality as MEDIUM if:** either or both B2 or B5 were rated as moderate and neither rated as weak; other items rated as weak or moderate are insufficient to compromise ability to draw conclusions regarding a possible association between the exposure and the outcome of interest.
- **Rate the quality as LOW if:** either B2 or B5 was rated as weak; or other items rated as weak are sufficient to interfere with the ability to rule out other explanations for the findings

c) Decision regarding directness of evidence ☒ Direct ☐ Extrapolation	
Comments	Very basic study with minimal details about methodology.

Author	Joyce BT, Berman R, Lau DT.
Year	2014
Title	Formal and informal support of family caregivers managing medications for patients who receive end-of-life care at home: a cross-sectional survey of caregivers.
Reviewer	PM
Review Date	October 10, 2019

Key Question	Using key characteristics previously identified as barriers to caregiving and managing medications, do caregivers have or lack additional formal/informal support with managing medications for elderly hospice patients. (1147)

Refer to Descriptive Study Critical Appraisal Tool Dictionary for complete criteria. Complete only the section for the type of study design being appraised. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

A. Screening Question			
	Strong	**Moderate**	**Weak**
A1. Research Question	Clearly focused. Highly relevant to Key Question. ☐	Fairly focused. Related to Key Question. ☒	Unclear or too broad. Unrelated to Key Question. ☐
Comments	Research question lacks clarity but is fairly focused.		
Screening Decision	☐ Reject (if weak)	☒ Continue	

B. Descriptive Exploratory Study			
	Strong	**Moderate**	**Weak**
B1. Study participants representative of target population	Random sampling and/or multiple recruitment / selection from various location or groups; >50% agreed to participate (or ≥80% of exposed were tested). ☐	Random sampling not used but multiple recruitment / selection strategies used. Single source of participants; 30-50% agreed to participate (or 60-79% of exposed were tested) ☐	Random sampling not used. Recruitment / selection processes limited. Participants were volunteers; <30% agreed to participate (or <60% of exposed were tested. ☒
B2. Data collection sources and methods	No missing data. Assessors trained and clearly adhered to procedures. Biases minimized with respect to data collection procedures and measures. Clear temporal association. ☐	Minimal missing/inaccurate data. Assessors trained and likely adhered to procedures. Biases reduced with respect to data collection procedures and measures. Clear temporal association. ☒	Any one item: substantial missing/ inaccurate data; unclear if assessors were trained; unclear if bias was reduced; or unclear temporal association. ☐
B3. Data collection instruments	Tools are known to be valid and reliable.	No attempt to assess validity and reliability of tools. Validity can be assumed based on questions	No attempt to assess validity and reliability of tools. Neither can be assumed.

	☐	asked and expertise of researchers. ☒	☐
B4. Ethics ☐ Not applicable (see dictionary)	Approved by appropriate ethics review board or content indicates ethical conduct was ensured. Research report was not influenced. ☒	Not applicable	Insufficient details provided regarding ethical conduct. Likelihood of research report being influenced could not be ruled out. ☐
B5. Statistics	Appropriate statistics used (descriptive). Narrow CI with all values having the same direction of effect. Clearly adequate power. Results interpreted correctly. ☒	Appropriate statistics used. Reasonably narrow CI with uncertain direction of effect. Power likely adequate. Results interpreted correctly. ☐	Any one item: statistics were incorrect for the data; CI was wide; power was inadequate; or results were not interpreted correctly. ☐
Comments	B1. Only one recruitment process was used. B2. One trained study investigator conducted all of the interviews. B3. Survey in its entirety was not validated, but researchers included validated tools within the survey (e.g. Center for Epidemiologic Studies Depression Scale—Short Form (CESD-10). B4. Study approved by the Institutional Review Board, an independent expert panel that reviews human subjects' research for ethical compliance B5. Univariate analysis using frequencies for categorical variables, means and standard deviations for continuous variables and bivariate logistical regression to determine associations.		

Overall Conclusion

a) Identify the strength of study design

☒ Weak (descriptive studies are weak by design)

b) Decision regarding quality of the study

Consider your ratings for appraisal items B1-B5 and identify the appropriate rating for quality.

☐ High ☒ Medium ☐ Low

- **Rate the quality as HIGH if:** most/all items rated strong, no weak items. Also, there are no major threats to the internal validity of the study or the ability to draw the conclusion that there is a possible association between the exposure and the outcome of interest.
- **Rate the quality as MEDIUM if:** either or both B2 or B5 were rated as moderate and neither rated as weak; other items rated as weak or moderate are insufficient to compromise ability to draw conclusions regarding a possible association between the exposure and the outcome of interest.

• **Rate the quality as LOW if:** either B2 or B5 was rated as weak; or other items rated as weak are sufficient to interfere with the ability to rule out other explanations for the findings **c) Decision regarding directness of evidence** ☒ Direct ☐ Extrapolation	
Comments	Overall, high quality study design, but limited participant recruitment methodology lowers quality to Medium.

Author	Latter S, Hopkinson JB, Richardson A, Hughes JA, Lowson E, Edwards D.
Year	2016
Title	How can we help family carers manage pain medicines for patients with advanced cancer? A systematic review of intervention studies
Reviewer	PM
Review Date	October 10, 2019

Key Question	(1) What are the pain medication management interventions for family carers of patients with advanced cancer that have been evaluated? (2) What were their effects, positive or otherwise, on family carers and on patients' pain? (3) Were any particular intervention characteristics or components (e.g., intensity, tailoring, timing, underpinning theoretical framework) associated with improved outcomes?

Refer to the Literature Review Critical Appraisal Tool Dictionary for complete criteria. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

Select Type of Literature Review		
☐ Meta-analysis	☒ Systematic review	☐ Narrative review

Screening Question			
	Strong	**Moderate**	**Weak**
1. Clear review questions / focus	Clearly focused. Highly relevant to guideline Key Question. ☒	Fairly focused. Related to guideline Key Question. ☐	Unclear or too broad. Unrelated to guideline Key Question. ☐
2. Included studies and critical appraisal of these studies	Studies relevant to Key Question included. Analytic studies included. Clear inclusion criteria. Studies appraised in a consistent systematic manner with clear results. ☒	Relevant studies included. Analytic studies included. Inclusion criteria may be unclear. Criteria for critical appraisal of studies unclear but results of critiquing were clear. ☐	Any one item: relevant studies not included; analytic studies not included; inclusion criteria are unclear; or did not report results of critical appraisal for each study. ☐
Comments	1. Research question is highly focused 2. Downs and Black checklist used for critical appraisal of studies. Clear inclusion criteria.		

Screening Decision	☐ Reject (if appraisal item 2 is weak) ☒ Continue Note: if appraisal item 2 is moderate or strong but item 1 is weak, then consider carefully the value of continuing

Assessment of Methodology			
	Strong	**Moderate**	**Weak**
3. Search for relevant studies	Comprehensive search of several databases, bibliographies, non-English and grey/unpublished articles. ☐	Comprehensive search of databases including non-English literature but may not have looked at bibliographies and grey/unpublished literature. ☒	Limited search of databases and non-English literature. Did not look at grey/unpublished literature. ☐
4. Rigour of review process	Included studies met inclusion and critical appraisal criteria. Screened and reviewed by more than one appraiser with same criteria and good agreement. ☒	Included studies met inclusion and critical appraisal criteria but screened and reviewed by only one appraiser or criteria were unclear. ☐	Did not use criteria for inclusion or critical appraisal or not clear if used. ☐
5. If meta-analysis, was it reasonable to do so? ☒ Not applicable	Combined studies did not differ considerably. Minimal heterogeneity among individual study results. Appropriate summary statistics used. ☐	Combined studies did not differ considerably. Significant heterogeneity among study results but was adequately addressed by authors. Statistics seem reasonable. ☐	Combined studies differed considerably. Significant heterogeneity exists among study results and was inadequately addressed. Statistics did not seem reasonable. ☐
Comments	3. Searches of MEDLINE, CINAHL, PsycINFO and AMED, bibliography search. No evidence of grey literature searching. 4. Included studies screened by two investigators. Decisions made by consensus. 5. Not applicable		

Methodology Decision
☐ **Reject** (if appraisal item 4 is weak, stop the appraisal). If items 3 and/or 5 are weak, then consider carefully the value of continuing. If the appraisal is discontinued, identify studies in the literature review that are relevant and appraise them individually. ☒ **Continue** (if appraisal items 3-5 are moderate or strong, continue with the appraisal).

Assessment of the Study Results (effect size)			
	Strong	**Moderate**	**Weak**
6. Study results description and interpretation (skip to 7 if meta-analysis) ☐ Not applicable	Correct interpretation of statistical significance and confidence interval (CI) or reasonable summary of trend and potential impact. ☒	Correct interpretation of statistical significance and CI or reasonable summary of trend but did not discuss potential impact. ☐	Did not correctly interpret the results. ☐
7. For meta-analysis only: magnitude and precision of treatment effect ☒ Not applicable	Overall CI of 95 or 99% reported. Minimal difference in treatment effect size and good overlap of CI of individual studies. Sufficient power. Correct interpretation of statistical significance and CI. ☐	Overall CI of 95 or 99% reported. Some difference in treatment effect size and some overlap of CI of individual studies. Power seemed sufficient. Correct interpretation of statistical significance and CI. ☐	Any one item (even if overall CI of 95 or 99% reported): large difference in treatment effect size and little or no overlap of CI of individual studies; insufficient power; or did not correctly interpret the results. ☐
Comments	6. Interpretation of study results appears correct. Trends and impacts discussed. 7. Not applicable.		

Decision Regarding Results		
I. Draw a conclusion as to whether there is sufficient evidence to make a recommendation for action:		
a) Is there a clear effect?	☒ Yes	☐ No
b) Is there consistency of results across studies?	☒ Yes	☐ No
c) Was the number of studies that contributed to the decision regarding a clear effect sufficient (four or more)?	☒ Yes	☐ No
d) Is the evidence direct?	☒ Yes	☐ No
e) Is the effect clinically meaningful?	☒ Yes	☐ No
f) If meta-analysis, were data appropriately pooled and statistical analysis properly conducted?	☐ Yes ☒ N/A	☐ No

- **If the answer to each is YES,** then appraisal for applicability with appraisal items 8 and 9 may be warranted.
- **If the answer to any item is NO,** then do not appraise items 8 and 9, go to appraisal item 10 and draw an overall conclusion, **do not state a recommendation.**

II. Decision regarding directness of evidence provided in the study
Draw a conclusion regarding directness of evidence:

☒ **Direct evidence** comes from studies that specifically researched the associated of interest ☐ **Extrapolation** is the inference drawn from studies that researched a different but related research question or researched the same question but in an artificial setting	
Comments	Clear effect.

Assessment for Control of Confounding			
	Strong	**Moderate**	**Weak**
8. Application of results to population of interest	Sample population and setting very similar to that of population of interest. ☒	Sample population and setting somewhat similar to that of population of interest. ☐	Sample population and setting not similar to that of population of interest. ☐
9. Applicability based on important outcomes (e.g. costs, stakeholder perspectives)	Intervention is highly likely to be readily implemented in other settings. ☐	Intervention is somewhat likely to be readily implemented in other settings. ☒	Intervention is unlikely to be readily implemented in other settings. ☐
Comments	8. Inclusion of patients with advanced cancer, diagnoses and treatment. 9. Intervention format is clear, but intervention content is still vague at end of review. NOTE: Include major weaknesses or limitations (e.g., important inconsistency of results, high probability of reporting bias, uncertainty about directness of evidence).		

Overall Conclusion and Evidence Summary Table			
10. Can a conclusion be drawn based on the evidence? ☒ Yes ☐ No			
If NO and unable to use the literature review as a whole, check the reason and appraise individual studies	**Rejected at screening** ☐	**Weak review methods** ☐	**Insufficient evidence to make a recommendation** ☐

If yes and there was sufficient evidence to make a recommendation and the results were applicable to the population of interest complete the following:

- **Strength of study design** (applicable to meta-analyses only): **Strong**
- Systematic and narrative reviews: No Rating

Decision regarding quality of study

The overall conclusion drawn should be about the quality (rigour) of the review methods as well as the quality of the research studies included in the literature review, and thus the credibility of the body of evidence covered by the literature review. Before making recommendations based on the literature review, one should

consider whether a clear association was found between exposure and outcome, and the samples in the studies covered by the literature review are similar to the group to whom one wishes to generalize results.

Consider your ratings for methodology and decision regarding results:

☐ **Rate the quality as HIGH if:** Decision regarding methodology was strong and the overall conclusion drawn about the association between the exposure and outcome of interest came from at least 4 or more studies of strong design and high quality.

☒ **Rate the quality as MEDIUM if:** Review methods were rated as moderate, or methods were rated as strong but fewer than 4 studies contributed to the overall conclusion, or the included studies were not strong designs and high quality.

Any literature review of weak methods should be considered as low quality and should have been rejected from further appraisal.

Recommendation	Use results in evidence synthesis.
Comments	Medium quality systematic review.

Author	Maeng DD, Snyder RC, Medico CJ, et al.
Year	2016
Title	Unused medications and disposal patterns at home: Findings from a Medicare patient survey and claims data.
Reviewer	PM
Review Date	October 10, 2019

Key Question	1. What specific medications may represent the most frequently left unused once purchased by sampled patients? 2. What fraction of these medications are left unused? 3. What methods are used to dispose of these medications? 4. Why were these medications left unused by patients?

Refer to Descriptive Study Critical Appraisal Tool Dictionary for complete criteria. Complete only the section for the type of study design being appraised. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

A. Screening Question			
	Strong	**Moderate**	**Weak**
A1. Research Question	Clearly focused. Highly relevant to Key Question. ☒	Fairly focused. Related to Key Question. ☐	Unclear or too broad. Unrelated to Key Question. ☐
Comments	Research question is clear and concise.		
Screening Decision	☐ Reject (if weak)	☒ Continue	

B. Descriptive Exploratory Study			
	Strong	**Moderate**	**Weak**
B1. Study participants representative of target population	Random sampling and/or multiple recruitment / selection from various location or groups; >50% agreed to participate (or ≥80% of exposed were tested). ☐	Random sampling not used but multiple recruitment / selection strategies used. Single source of participants; 30-50% agreed to participate (or 60-79% of exposed were tested) ☒	Random sampling not used. Recruitment / selection processes limited. Participants were volunteers; <30% agreed to participate (or <60% of exposed were tested. ☐
B2. Data collection sources and methods	No missing data. Assessors trained and clearly adhered to procedures. Biases minimized with respect to data collection procedures and measures. Clear temporal association. ☐	Minimal missing/inaccurate data. Assessors trained and likely adhered to procedures. Biases reduced with respect to data collection procedures and measures. Clear temporal association. ☒	Any one item: substantial missing/ inaccurate data; unclear if assessors were trained; unclear if bias was reduced; or unclear temporal association. ☐

B3. Data collection instruments	Tools are known to be valid and reliable. ☐	No attempt to assess validity and reliability of tools. Validity can be assumed based on questions asked and expertise of researchers. ☒	No attempt to assess validity and reliability of tools. Neither can be assumed. ☐
B4. Ethics ☐ Not applicable (see dictionary)	Approved by appropriate ethics review board or content indicates ethical conduct was ensured. Research report was not influenced. ☒	Not applicable	Insufficient details provided regarding ethical conduct. Likelihood of research report being influenced could not be ruled out. ☐
B5. Statistics	Appropriate statistics used (descriptive). Narrow CI with all values having the same direction of effect. Clearly adequate power. Results interpreted correctly. ☐	Appropriate statistics used. Reasonably narrow CI with uncertain direction of effect. Power likely adequate. Results interpreted correctly. ☒	Any one item: statistics were incorrect for the data; CI was wide; power was inadequate; or results were not interpreted correctly. ☐
Comments	B1. Random sample of 2000 drawn from database of Medicare Advantage members. Response rate was 46%. B2. Data collected by Geisinger Survey Research Unit (experienced interviewers). B3. Survey developed by researchers. Pretesting of instrument and feedback from trained interviewers. B4. The study was reviewed and approved by Geisinger Health System's Internal Review Board. B5. Descriptive statistics (e.g. frequency, averages) used.		

Overall Conclusion

a) Identify the strength of study design

☒ Weak (descriptive studies are weak by design)

b) Decision regarding quality of the study

Consider your ratings for appraisal items B1-B5 and identify the appropriate rating for quality.

☐ High ☒ Medium ☐ Low

- **Rate the quality as HIGH if:** most/all items rated strong, no weak items. Also, there are no major threats to the internal validity of the study or the ability to draw the conclusion that there is a possible association between the exposure and the outcome of interest.
- **Rate the quality as MEDIUM if:** either or both B2 or B5 were rated as moderate and neither rated as weak; other items rated as weak or moderate are insufficient to compromise ability to draw conclusions regarding a possible association between the exposure and the outcome of interest.

• **Rate the quality as LOW if:** either B2 or B5 was rated as weak; or other items rated as weak are sufficient to interfere with the ability to rule out other explanations for the findings **c) Decision regarding directness of evidence** ☐ Direct ☐ Extrapolation	
Comments	Weak study of medium quality.

CITATION:
National Institute for Health and Care Excellence. Controlled drugs: safe use and management. NICE Guideline. 2016.

DOMAIN 1: SCOPE AND PURPOSE

1. The overall objective(s) of the guideline is (are) specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments:
"This guideline covers systems and processes for using and managing controlled drugs safely in all NHS settings except care homes. It aims to improve working practices to comply with legislation and have robust governance arrangements. It also aims to reduce the safety risks associated with controlled drugs." (4)

2. The health question(s) covered by the guideline is (are) specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments:
See Appendix B: Scope, section 1.5 Key Issues and Questions

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments:
See 'Who is it for? (4)

DOMAIN 2: STAKEHOLDER INVOLVEMENT

4. The guideline development group includes individuals from all relevant professional groups.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments:
Can only find names of members of guidelines development group. Missing discipline, institution, etc. Some information available in 'Declaration of Interest' column.

5. The views and preferences of the target population (patients, public, etc.) have been sought.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments:
See https://www.nice.org.uk/guidance/ng46/history for stakeholder list and consultation methods and questions.

6. The target users of the guideline are clearly defined.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments:
See 'Who is it for?' (4)

DOMAIN 3: RIGOUR OF DEVELOPMENT

7. Systematic methods were used to search for evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments:
See https://www.nice.org.uk/process/pmg20/chapter/identifying-the-evidence-literature-searching-and-evidence-submission for overview of NICE literature searching methods.

8. The criteria for selecting the evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: See https://www.nice.org.uk/process/pmg20/chapter/identifying-the-evidence-literature-searching-and-evidence-submission for overview of NICE literature searching methods.						

9. The strengths and limitations of the body of evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: See Appendix C.2 – appraisal of evidence described in 'Review strategies column.						

10. The methods for formulating the recommendations are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: See https://www.nice.org.uk/process/pmg20/chapter/writing-the-guideline for description of how recommendations are formulated.						

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: See Appendix C for data tables.						

12. There is an explicit link between the recommendations and the supporting evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: Easy to make link between evidence and final recommendations. See Appendix C and recommendations in main body of guideline.						

13. The guideline has been externally reviewed by experts prior to its publication.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: See https://www.nice.org.uk/process/pmg20/chapter/the-validation-process-for-draft-guidelines-and-dealing-with-stakeholder-comments for stakeholder review process.						

14. A procedure for updating the guideline is provided.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: See https://www.nice.org.uk/process/pmg20/chapter/ensuring-that-published-guidelines-are-current-and-accurate. Guidelines are assessed every 5 years to see how much updating is required.						

DOMAIN 4: CLARITY OF PRESENTATION

15. The recommendations are specific and unambiguous.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments:						

Recommendations are clear and demonstrate recommended action, relevant population and have qualifying statements when necessary.

16. The different options for management of the condition or health issue are clearly presented.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: Different options for managing controlled drugs are provided within the recommendations (e.g. 1.8.10 is specific to situations in which the patient died at home).						

17. Key recommendations are easily identifiable.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: Recommendations are organized in descending lists.						

DOMAIN 5: APPLICABILITY

18. The guideline describes facilitators and barriers to its application.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: Barriers and facilitators to implementation are listed when appropriate, but seldom found in this document.						

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments: See “Putting this guideline into practice’ section in main report.

20. The potential resource implications of applying the recommendations have been considered.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: See “Putting this guideline into practice’ section in main report.						

21. The guideline presents monitoring and/or auditing criteria.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: Assessment strategies built in to “Putting this guideline into practice” section and throughout recommendations.						

DOMAIN 6: EDITORIAL INDEPENDENCE

22. The views of the funding body have not influenced the content of the guideline.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Comments: See Appendix A: Declarations of Interest.						

23. Competing interests of guideline development group members have been recorded and addressed.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments: See Appendix A: Declarations of Interest.

OVERALL GUIDELINE ASSESSMENT

1. Rate the overall quality of this guideline.

1 Lowest Possible Quality	2	3	4	5	6	7 Highest Possible Quality

2. I would recommend this guideline for use:

Yes	Yes, with modifications	No

NOTES: Guideline achieve a score of 7 on the majority of items and is of consistent high quality and transparency of process.

Author	Payne S, Turner M, Seamark D, et al.
Year	2015
Title	Managing end of life medications at home--accounts of bereaved family carers: a qualitative interview study.
Reviewer	PM
Review Date	October 10, 2019

Key Question	To explore how bereaved family members recall managing end of life medications when delivering care to a patient dying at home in England.

Refer to Descriptive Study Critical Appraisal Tool Dictionary for complete criteria. Complete only the section for the type of study design being appraised. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

A. Screening Question			
	Strong	**Moderate**	**Weak**
A1. Research Question	Clearly focused. Highly relevant to Key Question. ☐	Fairly focused. Related to Key Question. ☒	Unclear or too broad. Unrelated to Key Question. ☐
Comments	Fairly focused research question. Use of term "explore" is vague.		
Screening Decision	☐ Reject (if weak)	☒ Continue	

B. Descriptive Exploratory Study			
	Strong	**Moderate**	**Weak**
B1. Study participants representative of target population	Random sampling and/or multiple recruitment / selection from various location or groups; >50% agreed to participate (or ≥80% of exposed were tested). ☐	Random sampling not used but multiple recruitment / selection strategies used. Single source of participants; 30-50% agreed to participate (or 60-79% of exposed were tested) ☐	Random sampling not used. Recruitment / selection processes limited. Participants were volunteers; <30% agreed to participate (or <60% of exposed were tested. ☒
B2. Data collection sources and methods	No missing data. Assessors trained and clearly adhered to procedures. Biases minimized with respect to data collection procedures and measures. Clear temporal association. ☐	Minimal missing/inaccurate data. Assessors trained and likely adhered to procedures. Biases reduced with respect to data collection procedures and measures. Clear temporal association. ☐	Any one item: substantial missing/ inaccurate data; unclear if assessors were trained; unclear if bias was reduced; or unclear temporal association. ☒
B3. Data collection instruments	Tools are known to be valid and reliable.	No attempt to assess validity and reliability of tools. Validity can be assumed based on questions	No attempt to assess validity and reliability of tools. Neither can be assumed.

	☐	asked and expertise of researchers. ☐	☒
B4. Ethics ☐ Not applicable (see dictionary)	Approved by appropriate ethics review board or content indicates ethical conduct was ensured. Research report was not influenced. ☐	Not applicable	Insufficient details provided regarding ethical conduct. Likelihood of research report being influenced could not be ruled out. ☒
B5. Statistics	Appropriate statistics used (descriptive). Narrow CI with all values having the same direction of effect. Clearly adequate power. Results interpreted correctly. ☐	Appropriate statistics used. Reasonably narrow CI with uncertain direction of effect. Power likely adequate. Results interpreted correctly. ☐	Any one item: statistics were incorrect for the data; CI was wide; power was inadequate; or results were not interpreted correctly. ☒
Comments	B1. No random sampling used. Carers recruited though GP practices. B2. Unclear if assessors were trained or bias reduced. B3. Tools were pretested, but no attempt made to assess reliability or validity. B4. No mention of ethics review. B5. Limited use of statistics as this is a qualitative study. Table 1 displays characteristics of study population.		

Overall Conclusion

a) Identify the strength of study design

☒ Weak (descriptive studies are weak by design)

b) Decision regarding quality of the study
Consider your ratings for appraisal items B1-B5 and identify the appropriate rating for quality.

☐ High ☐ Medium ☒ Low

- **Rate the quality as HIGH if:** most/all items rated strong, no weak items. Also, there are no major threats to the internal validity of the study or the ability to draw the conclusion that there is a possible association between the exposure and the outcome of interest.
- **Rate the quality as MEDIUM if:** either or both B2 or B5 were rated as moderate and neither rated as weak; other items rated as weak or moderate are insufficient to compromise ability to draw conclusions regarding a possible association between the exposure and the outcome of interest.
- **Rate the quality as LOW if:** either B2 or B5 was rated as weak; or other items rated as weak are sufficient to interfere with the ability to rule out other explanations for the findings

c) Decision regarding directness of evidence

☒ Direct ☐ Extrapolation	
Comments	Weak study of low quality, but findings can still be useful as they provide examples of direct caregiver experience with managing end-of-life medications.

Author	Rantanen P, Parkkari T, Leikola S, Airaksinen M, Lyles A.
Year	2017
Title	An In-home Advanced Robotic System to Manage Elderly Home-care Patients' Medications: A Pilot Safety and Usability Study
Reviewer	PM
Review Date	October 11, 2019

Key Question	To examine "the safety profile and usability of an integrated advanced robotic device and telecare system to promote medication adherence for elderly home-care patients." (1054 - abstract)

Refer to Descriptive Study Critical Appraisal Tool Dictionary for complete criteria. Complete only the section for the type of study design being appraised. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

A. Screening Question			
	Strong	**Moderate**	**Weak**
A1. Research Question	Clearly focused. Highly relevant to Key Question. ☐	Fairly focused. Related to Key Question. ☒	Unclear or too broad. Unrelated to Key Question. ☐
Comments	Clear in abstract, but unclear in body of article.		
Screening Decision	☐ Reject (if weak)	☒ Continue	

B. Descriptive Exploratory Study			
	Strong	**Moderate**	**Weak**
B1. Study participants representative of target population	Random sampling and/or multiple recruitment / selection from various location or groups; >50% agreed to participate (or ≥80% of exposed were tested). ☐	Random sampling not used but multiple recruitment / selection strategies used. Single source of participants; 30-50% agreed to participate (or 60-79% of exposed were tested) ☐	Random sampling not used. Recruitment / selection processes limited. Participants were volunteers; <30% agreed to participate (or <60% of exposed were tested. ☒
B2. Data collection sources and methods	No missing data. Assessors trained and clearly adhered to procedures. Biases minimized with respect to data collection procedures and measures. Clear temporal association. ☐	Minimal missing/inaccurate data. Assessors trained and likely adhered to procedures. Biases reduced with respect to data collection procedures and measures. Clear temporal association. ☐	Any one item: substantial missing/ inaccurate data; unclear if assessors were trained; unclear if bias was reduced; or unclear temporal association. ☒
B3. Data collection instruments	Tools are known to be valid and reliable.	No attempt to assess validity and reliability of tools. Validity can be assumed based on questions	No attempt to assess validity and reliability of tools. Neither can be assumed.

	☐	asked and expertise of researchers. ☒	☐
B4. Ethics ☐ Not applicable (see dictionary)	Approved by appropriate ethics review board or content indicates ethical conduct was ensured. Research report was not influenced. ☐	Not applicable	Insufficient details provided regarding ethical conduct. Likelihood of research report being influenced could not be ruled out. ☐
B5. Statistics	Appropriate statistics used (descriptive). Narrow CI with all values having the same direction of effect. Clearly adequate power. Results interpreted correctly. ☐	Appropriate statistics used. Reasonably narrow CI with uncertain direction of effect. Power likely adequate. Results interpreted correctly. ☒	Any one item: statistics were incorrect for the data; CI was wide; power was inadequate; or results were not interpreted correctly. ☐
Comments	B1. Participants hand selected based on a nurse's assessment that they were motivated to take their medications. B2. Some missing data (frequency of visits by home nurses). B3. Use of machine data and structured interview survey. Survey not validated. B4. Approved by Helsinki University Hospital Coordinating Ethic Committee. B5. Appropriate descriptive statistics used (frequencies and percentages).		

Overall Conclusion
a) Identify the strength of study design ☒ Weak (descriptive studies are weak by design) **b) Decision regarding quality of the study** Consider your ratings for appraisal items B1-B5 and identify the appropriate rating for quality. ☐ High ☐ Medium ☒ Low • **Rate the quality as HIGH if:** most/all items rated strong, no weak items. Also, there are no major threats to the internal validity of the study or the ability to draw the conclusion that there is a possible association between the exposure and the outcome of interest. • **Rate the quality as MEDIUM if:** either or both B2 or B5 were rated as moderate and neither rated as weak; other items rated as weak or moderate are insufficient to compromise ability to draw conclusions regarding a possible association between the exposure and the outcome of interest. • **Rate the quality as LOW if:** either B2 or B5 was rated as weak; or other items rated as weak are sufficient to interfere with the ability to rule out other explanations for the findings

c) Decision regarding directness of evidence ☒ Direct ☐ Extrapolation	
Comments	Overall weak study design and quality, but results care still be useful to include.

Author	Reddy A, de la Cruz M, Rodriguez EM, et al.
Year	2014
Title	Patterns of storage, use, and disposal of opioids among cancer outpatients.
Reviewer	PM
Review Date	October 11, 2019

Key Question	"to determine the patterns of storing, using, and disposing of opioids among cancer outpatients in a tertiary cancer hospital."

Refer to Descriptive Study Critical Appraisal Tool Dictionary for complete criteria. Complete only the section for the type of study design being appraised. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

A. Screening Question			
	Strong	**Moderate**	**Weak**
A1. Research Question	Clearly focused. Highly relevant to Key Question. ☒	Fairly focused. Related to Key Question. ☐	Unclear or too broad. Unrelated to Key Question. ☐
Comments	Research question is clearly focused and relevant.		
Screening Decision	☐ Reject (if weak) ☒ Continue		

B. Descriptive Exploratory Study			
	Strong	**Moderate**	**Weak**
B1. Study participants representative of target population	Random sampling and/or multiple recruitment / selection from various location or groups; >50% agreed to participate (or ≥80% of exposed were tested). ☐	Random sampling not used but multiple recruitment / selection strategies used. Single source of participants; 30-50% agreed to participate (or 60-79% of exposed were tested) ☐	Random sampling not used. Recruitment / selection processes limited. Participants were volunteers; <30% agreed to participate (or <60% of exposed were tested. ☒
B2. Data collection sources and methods	No missing data. Assessors trained and clearly adhered to procedures. Biases minimized with respect to data collection procedures and measures. Clear temporal association. ☐	Minimal missing/inaccurate data. Assessors trained and likely adhered to procedures. Biases reduced with respect to data collection procedures and measures. Clear temporal association. ☒	Any one item: substantial missing/ inaccurate data; unclear if assessors were trained; unclear if bias was reduced; or unclear temporal association. ☐
B3. Data collection instruments	Tools are known to be valid and reliable.	No attempt to assess validity and reliability of tools. Validity can be assumed based on questions asked and expertise of researchers.	No attempt to assess validity and reliability of tools. Neither can be assumed.

	☐	☒	☐
B4. Ethics ☐ Not applicable (see dictionary)	Approved by appropriate ethics review board or content indicates ethical conduct was ensured. Research report was not influenced. ☒	Not applicable	Insufficient details provided regarding ethical conduct. Likelihood of research report being influenced could not be ruled out. ☐
B5. Statistics	Appropriate statistics used (descriptive). Narrow CI with all values having the same direction of effect. Clearly adequate power. Results interpreted correctly. ☒	Appropriate statistics used. Reasonably narrow CI with uncertain direction of effect. Power likely adequate. Results interpreted correctly. ☐	Any one item: statistics were incorrect for the data; CI was wide; power was inadequate; or results were not interpreted correctly. ☐
Comments	B1. Only one recruitment strategy was used. B2. No missing data mentioned. B3. Validity not assessed. CAGE questionnaire used in study is validated. B4. Approved by institutional review board. B5. Descriptive statistics and logistic regression analysis used. P-values reported.		

Overall Conclusion

a) Identify the strength of study design

☒ Weak (descriptive studies are weak by design)

b) Decision regarding quality of the study
Consider your ratings for appraisal items B1-B5 and identify the appropriate rating for quality.

☐ High ☒ Medium ☐ Low

- **Rate the quality as HIGH if:** most/all items rated strong, no weak items. Also, there are no major threats to the internal validity of the study or the ability to draw the conclusion that there is a possible association between the exposure and the outcome of interest.
- **Rate the quality as MEDIUM if:** either or both B2 or B5 were rated as moderate and neither rated as weak; other items rated as weak or moderate are insufficient to compromise ability to draw conclusions regarding a possible association between the exposure and the outcome of interest.
- **Rate the quality as LOW if:** either B2 or B5 was rated as weak; or other items rated as weak are sufficient to interfere with the ability to rule out other explanations for the findings

c) Decision regarding directness of evidence

☒ Direct ☐ Extrapolation

Comments	Weak study design of medium quality.

Author	Rosenberg JP, Bullen T, Maher K.
Year	2015
Title	Supporting Family Caregivers with Palliative Symptom Management: A Qualitative Analysis of the Provision of an Emergency Medication Kit in the Home Setting.
Reviewer	PM
Review Date	October 11, 2019

Key Question	"to examine the lived experience of caregivers who have supported a dying person at home. In particular, it explores caregivers' perceptions of receiving this care when supplied with an EMK." (485)

Refer to Descriptive Study Critical Appraisal Tool Dictionary for complete criteria. Complete only the section for the type of study design being appraised. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

A. Screening Question			
	Strong	**Moderate**	**Weak**
A1. Research Question	Clearly focused. Highly relevant to Key Question. ☒	Fairly focused. Related to Key Question. ☐	Unclear or too broad. Unrelated to Key Question. ☐
Comments	Clearly focused and highly relevant research question.		
Screening Decision	☐ Reject (if weak) ☒ Continue		

B. Descriptive Exploratory Study			
	Strong	**Moderate**	**Weak**
B1. Study participants representative of target population	Random sampling and/or multiple recruitment / selection from various location or groups; >50% agreed to participate (or ≥80% of exposed were tested). ☐	Random sampling not used but multiple recruitment / selection strategies used. Single source of participants; 30-50% agreed to participate (or 60-79% of exposed were tested) ☐	Random sampling not used. Recruitment / selection processes limited. Participants were volunteers; <30% agreed to participate (or <60% of exposed were tested. ☒
B2. Data collection sources and methods	No missing data. Assessors trained and clearly adhered to procedures. Biases minimized with respect to data collection procedures and measures. Clear temporal association. ☒	Minimal missing/inaccurate data. Assessors trained and likely adhered to procedures. Biases reduced with respect to data collection procedures and measures. Clear temporal association. ☐	Any one item: substantial missing/ inaccurate data; unclear if assessors were trained; unclear if bias was reduced; or unclear temporal association. ☐

B3. Data collection instruments	Tools are known to be valid and reliable. ☐	No attempt to assess validity and reliability of tools. Validity can be assumed based on questions asked and expertise of researchers. ☐	No attempt to assess validity and reliability of tools. Neither can be assumed. ☒
B4. Ethics ☐ Not applicable (see dictionary)	Approved by appropriate ethics review board or content indicates ethical conduct was ensured. Research report was not influenced. ☒	Not applicable	Insufficient details provided regarding ethical conduct. Likelihood of research report being influenced could not be ruled out. ☐
B5. Statistics	Appropriate statistics used (descriptive). Narrow CI with all values having the same direction of effect. Clearly adequate power. Results interpreted correctly. ☐	Appropriate statistics used. Reasonably narrow CI with uncertain direction of effect. Power likely adequate. Results interpreted correctly. ☐	Any one item: statistics were incorrect for the data; CI was wide; power was inadequate; or results were not interpreted correctly. ☐
Comments	B1. Participants were self-selected from a sample of 99 caregiver-patient dyads. B2. Interview transcripts reviewed by two researchers. B3. No mention of validity and reliability of interview questions. B4. Ethics approval was obtained from the relevant industry and University Human Research Ethics Committees to conduct this study. B5. N/A. No statistics used – strictly qualitative analysis of interview transcripts.		

Overall Conclusion
a) Identify the strength of study design ☒ Weak (descriptive studies are weak by design) **b) Decision regarding quality of the study** Consider your ratings for appraisal items B1-B5 and identify the appropriate rating for quality. ☐ High ☐ Medium ☒ Low • **Rate the quality as HIGH if:** most/all items rated strong, no weak items. Also, there are no major threats to the internal validity of the study or the ability to draw the conclusion that there is a possible association between the exposure and the outcome of interest. • **Rate the quality as MEDIUM if:** either or both B2 or B5 were rated as moderate and neither rated as weak; other items rated as weak or moderate are insufficient to compromise ability to draw conclusions regarding a possible association between the exposure and the outcome of interest.

• **Rate the quality as LOW if:** either B2 or B5 was rated as weak; or other items rated as weak are sufficient to interfere with the ability to rule out other explanations for the findings **c) Decision regarding directness of evidence** ☒ Direct ☐ Extrapolation	
Comments	Weak study of low quality. Automatically rated low on this tool because of lack of statistical analysis.

Author	Sheehy-Skeffington B, McLean S, Bramwell M, O'Leary N, O'Gorman A.
Year	2014
Title	Caregivers experiences of managing medications for palliative care patients at the end of life: a qualitative study
Reviewer	PM
Review Date	October 12, 2019

Key Question	To explore: • the impact of polypharmacy at the end of life, as perceived by caregivers; • the use of syringe drivers at home for palliative care patients; • the use of as-needed medications by informal caregivers; • other issues, perceived by caregivers, with managing medications for palliative care patients at home.

Refer to Descriptive Study Critical Appraisal Tool Dictionary for complete criteria. Complete only the section for the type of study design being appraised. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

A. Screening Question			
	Strong	**Moderate**	**Weak**
A1. Research Question	Clearly focused. Highly relevant to Key Question. ☒	Fairly focused. Related to Key Question. ☐	Unclear or too broad. Unrelated to Key Question. ☐
Comments	Research questions is clearly focused and highly relevant to the study.		
Screening Decision	☐ Reject (if weak)	☒ Continue	

B. Descriptive Exploratory Study			
	Strong	**Moderate**	**Weak**
B1. Study participants representative of target population	Random sampling and/or multiple recruitment / selection from various location or groups; >50% agreed to participate (or ≥80% of exposed were tested). ☐	Random sampling not used but multiple recruitment / selection strategies used. Single source of participants; 30-50% agreed to participate (or 60-79% of exposed were tested) ☐	Random sampling not used. Recruitment / selection processes limited. Participants were volunteers; <30% agreed to participate (or <60% of exposed were tested. ☒
B2. Data collection sources and methods	No missing data. Assessors trained and clearly adhered to procedures. Biases minimized with respect to data collection procedures and measures. Clear temporal association.	Minimal missing/inaccurate data. Assessors trained and likely adhered to procedures. Biases reduced with respect to data collection procedures and measures. Clear temporal association.	Any one item: substantial missing/ inaccurate data; unclear if assessors were trained; unclear if bias was reduced; or unclear temporal association.

	☐	☒	☐
B3. Data collection instruments	Tools are known to be valid and reliable. ☐	No attempt to assess validity and reliability of tools. Validity can be assumed based on questions asked and expertise of researchers. ☒	No attempt to assess validity and reliability of tools. Neither can be assumed. ☐
B4. Ethics ☐ Not applicable (see dictionary)	Approved by appropriate ethics review board or content indicates ethical conduct was ensured. Research report was not influenced. ☒	Not applicable	Insufficient details provided regarding ethical conduct. Likelihood of research report being influenced could not be ruled out. ☐
B5. Statistics	Appropriate statistics used (descriptive). Narrow CI with all values having the same direction of effect. Clearly adequate power. Results interpreted correctly. ☐	Appropriate statistics used. Reasonably narrow CI with uncertain direction of effect. Power likely adequate. Results interpreted correctly. ☐	Any one item: statistics were incorrect for the data; CI was wide; power was inadequate; or results were not interpreted correctly. ☐
Comments	B1. Sampling not random. Purposive sampling used. B2. Data collection is adequate. Simple data set (recorded interviews). B3. Validity and reliability not assessed. Validity assumed based on questions and expertise of researchers. B4. Study approved by institutional ethics committee and informed consent obtained from participants. B5. N/A. Qualitative study.		

Overall Conclusion
a) Identify the strength of study design ☒ Weak (descriptive studies are weak by design) **b) Decision regarding quality of the study** Consider your ratings for appraisal items B1-B5 and identify the appropriate rating for quality. ☐ High ☐ Medium ☒ Low • **Rate the quality as HIGH if:** most/all items rated strong, no weak items. Also, there are no major threats to the internal validity of the study or the ability to draw the conclusion that there is a possible association between the exposure and the outcome of interest. • **Rate the quality as MEDIUM if:** either or both B2 or B5 were rated as moderate and neither rated as weak; other items rated as weak or moderate are insufficient to compromise ability to draw conclusions regarding a possible association between the exposure and the outcome of interest.

• **Rate the quality as LOW if:** either B2 or B5 was rated as weak; or other items rated as weak are sufficient to interfere with the ability to rule out other explanations for the findings **c) Decision regarding directness of evidence** ☐ Direct ☐ Extrapolation	
Comments	Weak study of low quality. All qualitative studies will achieve this score using this tool because of lack of statistics.

Author	Welham GC, Mount JK and Gilson AM.
Year	2015
Title	Type and frequency of opioid pain medications returned for disposal.
Reviewer	PM
Review Date	October

Key Question	This study aims to (1) quantify the prescription opioids returned for disposal to a local take-back program, and (2) explore selected drug characteristics that may predict the quantity of unused opioids.

Refer to Descriptive Study Critical Appraisal Tool Dictionary for complete criteria. Complete only the section for the type of study design being appraised. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

A. Screening Question			
	Strong	**Moderate**	**Weak**
A1. Research Question	Clearly focused. Highly relevant to Key Question. ☒	Fairly focused. Related to Key Question. ☐	Unclear or too broad. Unrelated to Key Question. ☐
Comments	Research question is clearly focused and highly relevant.		
Screening Decision	☐ Reject (if weak) ☒ Continue		

B. Descriptive Exploratory Study			
	Strong	**Moderate**	**Weak**
B1. Study participants representative of target population	Random sampling and/or multiple recruitment / selection from various location or groups; >50% agreed to participate (or ≥80% of exposed were tested). ☐	Random sampling not used but multiple recruitment / selection strategies used. Single source of participants; 30-50% agreed to participate (or 60-79% of exposed were tested) ☐	Random sampling not used. Recruitment / selection processes limited. Participants were volunteers; <30% agreed to participate (or <60% of exposed were tested. ☒
B2. Data collection sources and methods	No missing data. Assessors trained and clearly adhered to procedures. Biases minimized with respect to data collection procedures and measures. Clear temporal association. ☐	Minimal missing/inaccurate data. Assessors trained and likely adhered to procedures. Biases reduced with respect to data collection procedures and measures. Clear temporal association. ☒	Any one item: substantial missing/ inaccurate data; unclear if assessors were trained; unclear if bias was reduced; or unclear temporal association. ☐
B3. Data collection instruments	Tools are known to be valid and reliable.	No attempt to assess validity and reliability of tools. Validity can be assumed based on questions	No attempt to assess validity and reliability of tools. Neither can be assumed.

	☐	asked and expertise of researchers. ☒	☐
B4. Ethics ☒ Not applicable (see dictionary)	Approved by appropriate ethics review board or content indicates ethical conduct was ensured. Research report was not influenced. ☐	Not applicable	Insufficient details provided regarding ethical conduct. Likelihood of research report being influenced could not be ruled out. ☐
B5. Statistics	Appropriate statistics used (descriptive). Narrow CI with all values having the same direction of effect. Clearly adequate power. Results interpreted correctly. ☒	Appropriate statistics used. Reasonably narrow CI with uncertain direction of effect. Power likely adequate. Results interpreted correctly. ☐	Any one item: statistics were incorrect for the data; CI was wide; power was inadequate; or results were not interpreted correctly. ☐
Comments	B1. Study participants were participants of a medications take back program (volunteers). B2. Data collected from information on returned pill bottles. Data recorded by trained pharmacy students. B3. Data collection tools not assessed for validity and reliability. Simple recording of pill bottle information. B4. Study exempted from review by the University of Wisconsin-Madison Social and Behavioral Sciences Institutional Review Board. B5. Descriptive statistics and linear regression used. P-values and confidence intervals reported.		

Overall Conclusion

a) Identify the strength of study design

☒ Weak (descriptive studies are weak by design)

b) Decision regarding quality of the study

Consider your ratings for appraisal items B1-B5 and identify the appropriate rating for quality.

☐ High ☒ Medium ☐ Low

- **Rate the quality as HIGH if:** most/all items rated strong, no weak items. Also, there are no major threats to the internal validity of the study or the ability to draw the conclusion that there is a possible association between the exposure and the outcome of interest.
- **Rate the quality as MEDIUM if:** either or both B2 or B5 were rated as moderate and neither rated as weak; other items rated as weak or moderate are insufficient to compromise ability to draw conclusions regarding a possible association between the exposure and the outcome of interest.
- **Rate the quality as LOW if:** either B2 or B5 was rated as weak; or other items rated as weak are sufficient to interfere with the ability to rule out other explanations for the findings

c) Decision regarding directness of evidence ☒ Direct ☐ Extrapolation	
Comments	Weak study of medium quality.

Author	Yanovitzky I.
Year	2016
Title	The American Medicine Chest Challenge: evaluation of a medication takeback and disposal campaign.
Reviewer	PM
Review Date	October 12, 2019

Key Question	"the primary goal of this study was to profile a national drug take-back program and to assess public exposure and response to a public communication campaign promoting this program in a single state (New Jersey), where this program was first implemented."

Refer to Descriptive Study Critical Appraisal Tool Dictionary for complete criteria. Complete only the section for the type of study design being appraised. Unless otherwise specified (by the phrase "any one item"), most or all of the applicable criteria listed for all ratings should be met for the item to get the identified rating.

A. Screening Question			
	Strong	**Moderate**	**Weak**
A1. Research Question	Clearly focused. Highly relevant to Key Question. ☒	Fairly focused. Related to Key Question. ☐	Unclear or too broad. Unrelated to Key Question. ☐
Comments	Research question is clearly focused and highly relevant.		
Screening Decision	☐ Reject (if weak)	☒ Continue	

B. Descriptive Exploratory Study			
	Strong	**Moderate**	**Weak**
B1. Study participants representative of target population	Random sampling and/or multiple recruitment / selection from various location or groups; >50% agreed to participate (or ≥80% of exposed were tested). ☐	Random sampling not used but multiple recruitment / selection strategies used. Single source of participants; 30-50% agreed to participate (or 60-79% of exposed were tested) ☐	Random sampling not used. Recruitment / selection processes limited. Participants were volunteers; <30% agreed to participate (or <60% of exposed were tested. ☒
B2. Data collection sources and methods	No missing data. Assessors trained and clearly adhered to procedures. Biases minimized with respect to data collection procedures and measures. Clear temporal association. ☒	Minimal missing/inaccurate data. Assessors trained and likely adhered to procedures. Biases reduced with respect to data collection procedures and measures. Clear temporal association. ☐	Any one item: substantial missing/ inaccurate data; unclear if assessors were trained; unclear if bias was reduced; or unclear temporal association. ☐

B3. Data collection instruments	Tools are known to be valid and reliable. ☐	No attempt to assess validity and reliability of tools. Validity can be assumed based on questions asked and expertise of researchers. ☒	No attempt to assess validity and reliability of tools. Neither can be assumed. ☐
B4. Ethics ☐ Not applicable (see dictionary)	Approved by appropriate ethics review board or content indicates ethical conduct was ensured. Research report was not influenced. ☒	Not applicable	Insufficient details provided regarding ethical conduct. Likelihood of research report being influenced could not be ruled out. ☐
B5. Statistics	Appropriate statistics used (descriptive). Narrow CI with all values having the same direction of effect. Clearly adequate power. Results interpreted correctly. ☒	Appropriate statistics used. Reasonably narrow CI with uncertain direction of effect. Power likely adequate. Results interpreted correctly. ☐	Any one item: statistics were incorrect for the data; CI was wide; power was inadequate; or results were not interpreted correctly. ☐
Comments	B1. Random sampling used, but response rate was low (20.1% for the landline sample and 10.7% for the cell phone sample). B2. Data collection completed by Rutgers–Eagleton Poll. Can assume high quality. B3. No mention of assessment of validity and reliability, but can assume validity based on questions asked and expertise of researchers. B4. The survey was approved by the Rutgers University Institutional Review Board, and all respondents consented to participate. B5. Appropriate statistics used, confidence intervals reported.		

Overall Conclusion
a) Identify the strength of study design ☒ Weak (descriptive studies are weak by design) **b) Decision regarding quality of the study** Consider your ratings for appraisal items B1-B5 and identify the appropriate rating for quality. ☐ High ☒ Medium ☐ Low • **Rate the quality as HIGH if:** most/all items rated strong, no weak items. Also, there are no major threats to the internal validity of the study or the ability to draw the conclusion that there is a possible association between the exposure and the outcome of interest. • **Rate the quality as MEDIUM if:** either or both B2 or B5 were rated as moderate and neither rated as weak; other items rated as weak or moderate are insufficient to compromise ability to draw conclusions regarding a possible association between the exposure and the outcome of interest.

• **Rate the quality as LOW if:** either B2 or B5 was rated as weak; or other items rated as weak are sufficient to interfere with the ability to rule out other explanations for the findings **c) Decision regarding directness of evidence** ☒ Direct ☐ Extrapolation	
Comments	Weak study of medium quality. Rated medium quality because only one selection process used. Also, low response rate because of telephone survey method.