

STANDARDS RESEARCH

Evaluating Best Practices and Gaps in Equipment and Medication Management in Home and Community Care Settings

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Executive Summary

This report addresses the considerations of safely providing equipment, supplies, and medications to individuals receiving health care at home and in community care settings. The report outlines best practices, identifies gaps, and provides recommendations and a standards roadmap to address those gaps.

The development of national standards and guidelines that address the many existing gaps and shortcomings in home and community health care will positively affect Canadians. The demand for care in the home is increasing steadily, and health technologies are making many additional types of care possible. These, in turn, bring challenges in terms of safe and effective implementation. The overarching theme of this report is to identify these challenges and propose effective approaches for addressing them.

The following list recounts some of the opportunities for developing standardization and guidance needed to help improve the safety and effectiveness of home and community care:

- A set of national standardized requirements on the eligibility, coverage, co-payment, and funding policies for provincial and territorial home and community care programs to facilitate efficient and equitable access to home health technologies.
- A standard to help ensure that the environment for the delivery of home care is safe and appropriate, that provides details on duties of owners and occupants; structures, facilities, plumbing, and space requirements; safety and personal security; lighting and electrical systems; thermal comfort, ventilation, and energy efficiency; moisture control, solid waste, and pest management; and chemical and radiological agents.
- A unified national guideline for the safe disposal from the home setting of medications, chemical hazards, and biomedical waste.
- Standards that address the criteria used in selecting home health technologies, intended for prescribing health care professionals and individuals who are making their own purchases.
- Standards, equivalent to those that address the management of hospital equipment in Canada, but for home health technologies, to include preparing equipment for reuse.
- Standardized guidelines for infection, prevention and control (IPAC) in home and community care settings, to counteract incomplete knowledge and training on cleaning, decontamination, disinfection and sterilization. Best practices should address risk-prioritized methods for screening and remediating risks and surveillance techniques in the home.
- A best practices guideline or standard that focuses explicitly on mitigating medication errors in home and community care would likely significantly prevent injuries and deaths and serve all Canadians. Risk factors that should be taken into account in the context of widely divergent home and community care clients include polypharmacy; medication scheduling; management of missed doses; interactions with other prescribed medications as well as with over-the-counter medications or supplements; and safe storage.

The report is divided into seven major sections, with each section addressing unique problems encountered in the home care environment that the recommended standards and guidelines aim to address.



"With the greater volume of health care delivered at home and in the community, and concomitant increased complexity of care, the risk of adverse events has also increased."

1 Introduction

As the Canadian population ages, the demand for home and community health care services is growing rapidly, driven in part by people's desire to receive care in familiar environments [1]. In many cases, home care[1] may alternate with periodic visits to the hospital to address changing health conditions. Community care homes also provide short- or long-term residential environments when neither the hospital nor the home are optimal. As the individual moves back and forth between these environments, and their condition changes, medications, supplies, and equipment may be changed and relevant information lost [2].

With the greater volume of health care delivered at home and in the community, and concomitant increased complexity of care, the risk of adverse events has also increased. In a hospital, the person receiving treatment is supported by a team of professionals – risk managers, infection prevention and control (IPAC) specialists, respiratory therapists, biomedical engineers, purchasing agents as well as physicians and nurses, or clinical caregivers – who are available as needed. These professionals are all guided by accreditation standards as well as professional licensing, registration, and credentialing requirements.

In contrast, caregivers at home or in community care have different levels of professional training and experience. In many cases, the primary caregiver is a family member who may have no training or experience in health care.

This report addresses the considerations for safely providing equipment, supplies, and medications to individuals receiving health care at home or in the community. The report outlines best practices, identifies gaps, and provides recommendations to address those gaps. This research included an extensive review of published peer-reviewed scientific papers, legislation, guidance documents and reports, and standards pertaining to the relevant topics.

Many of the issues to do with equipment, supplies and medications are inextricably interwoven. Much of the discussion deals with these issues together and frequently refers to them as health care technologies. Where appropriate, the report focuses more specifically on a particular category of technology. The issues associated with health technologies in the home are varied and complex. Every effort has been made to comprehensively address these issues in the Canadian context, based on the most recent material available.

To provide points of reference for the reader, textboxes in the various sections of the report describe the people in different scenarios who are prescribed equipment, supplies, and medications for various conditions.

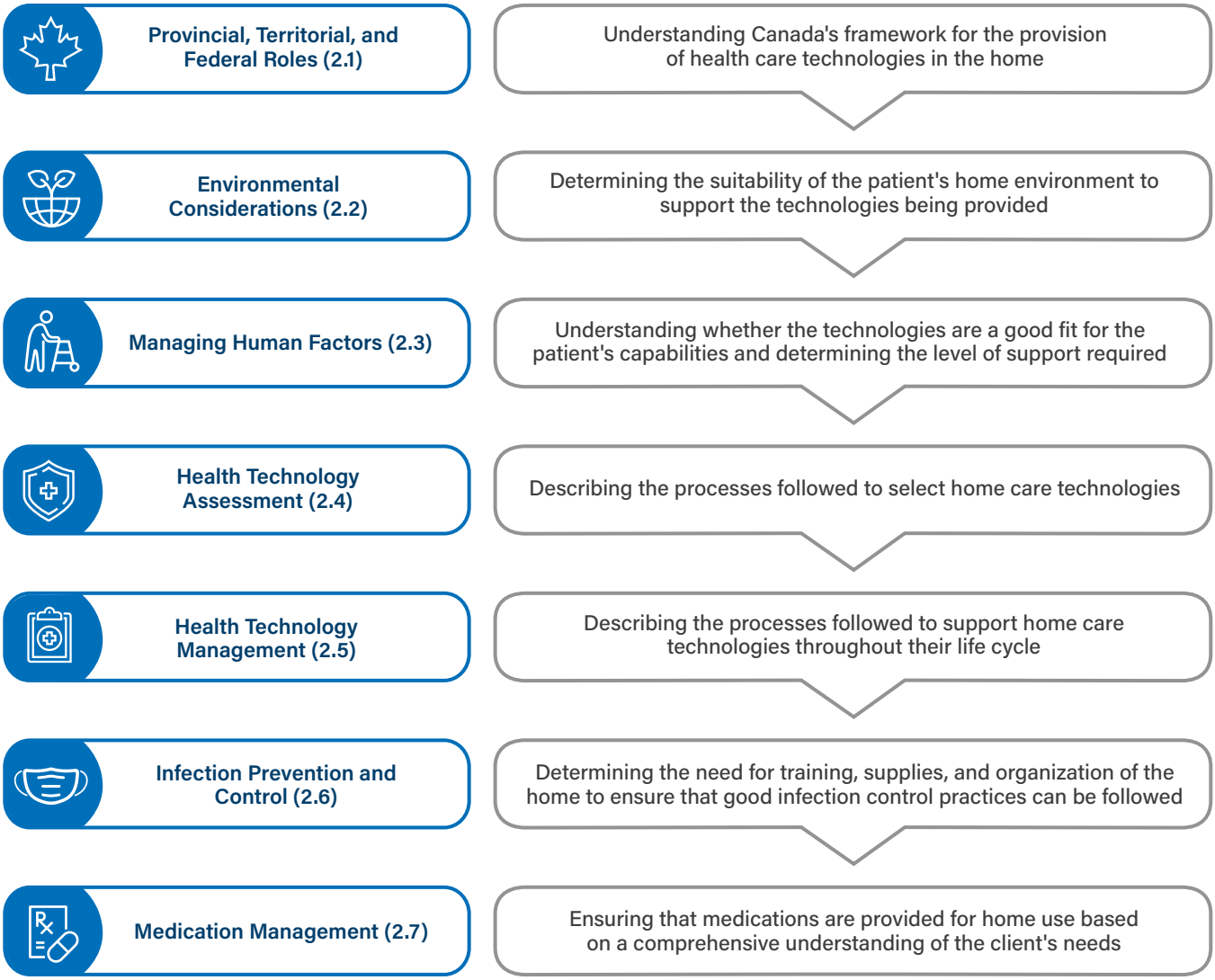
1 The use of "home care" or "home care settings" is intended to cover both home and community care settings. Where community care differences exist, such as shared dining or bathing areas, those will be addressed specifically.

The many gaps identified lead to recommended opportunities for the development of standards and guidelines. These are included as appropriate and are summarized in a standards roadmap in Appendix A. Best practices identified through this research are summarized in Appendix B. It is acknowledged that there may be variation in a client's/family's ability and willingness to follow these recommendations, and they have the right to opt out of any of them, assuming that the potential impact of that decision has been clearly explained to them.

2 Home Health Technology Overview

The following chart provides an overview of the topics covered by each section of this report.

Figure 1: Summary of topics covered in this report



2.1 Federal, Provincial, Territorial Legislation, Standards, Guidelines and Processes

2.1.1 Overview

Case Description: Territorial and Provincial Regulation Challenges

Jesse is 75 years old, has type 2 diabetes, and requires insulin, blood glucose monitoring strips and lancets, needles/syringes, and alcohol swabs, which are supplied by a private home care agency. With diabetic neuropathy in the feet and hands, Jesse is increasingly unsteady, and relies on a cane or a walker to move around indoors and a foldable wheelchair for trips to the doctor or store. Jesse also depends on a wide range of assistive devices for activities of daily life, such as a grasping device for items that fall, and special bathing, toileting, cooking, and eating utensils for safe handling. These must be ordered from a separate provincial assistive services agency. The diabetes has led to hypertension and kidney problems, with occasional episodes of incontinence, but there are repeated disputes over which agency will resupply the necessary disposable incontinence products.

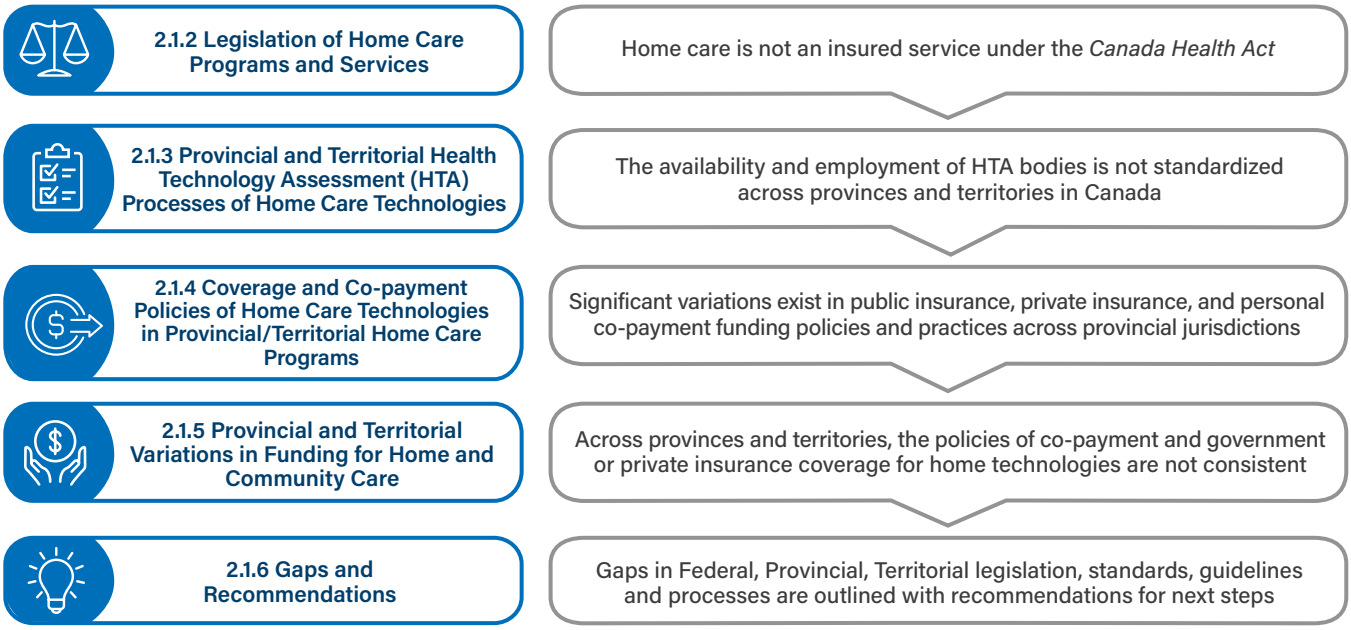
Home and community care has become one of the fastest-growing areas in Canadian health care over the past several decades. The growth has been driven by people's desire to receive care in familiar environments, public hospital systems' stretched resources and capabilities as the population ages, and the perceived greater cost-effectiveness of home and community care compared to hospital-based care [3, 4, 5].

This section compares home care legislation and program guidance across the provinces and territories. Each jurisdiction has its own distinct socio-economic, climate, cultural, and demographic characteristics. Differences and disparities exist in home care laws and practices in several areas, including federal, provincial, and territorial legislation pertaining to home care programs; provincial health technology assessment (HTA) processes for home health technologies; and coverage and co-payment policies of home use home health technologies in provincial and territorial home care programs.

2.1.2 Legislation of Home Care Programs and Services

The *Canada Health Act* (CHA), adopted in 1984, ensures that eligible residents of Canada have reasonable access to publicly funded health services each year

Figure 2: Summary of topics covered in Section 2.1



on a prepaid basis. The CHA establishes criteria and conditions related to insured health services that the provinces and territories must fulfill to receive federal funding under the Canada Health Transfer [6]. Home care is included as part of extended health care services described in the CHA [7]. As the five principles of the CHA do not apply to home care [8, 9], home care is not an insured service under the Act [10]. National legislation that specifically governs and funds home care, and the related federal regulations pertaining to the eligibility and cost to home care service programs in Canada, have yet to be established [9].

Because comprehensive federal legislation for home care does not exist, many localized provincial and territorial acts, regulations, and guidelines have emerged [9, 11]; these vary widely because they were conceived and implemented over different time periods to address the regions' specific cost-, equity-, or crises-driven needs [4. They are documented through various acts, orders-in-council, guidelines, and policies [3].

Similarly, each province and territory has developed home care definitions and services specific to the needs and available resources of their health ministry-led home care programs, and these have not been standardized across the country [3]. A 2012 report by Health Association Nova Scotia referred to the system of provincial and territorial home care services as "a patchwork quilt of services" [11].

Because the definition of home care varies, and the range, orientation, and model of delivery of services is diverse, comparing home care programs across provinces and territories is difficult [3, 7]. According to a 2009 policy brief by the Canadian Healthcare Association, there are four basic models of home care service delivery in Canada [9]:

- Manitoba, Northwest Territories, Nunavut, Prince Edward Island, Quebec, and Saskatchewan have a public-provider model; government employees manage and deliver both home care services (which include professional services such as nursing care) and home support services (which include services related to personal care, housework, meals, shopping, and respite care) directly. Intermediate agencies either play a limited role or have no role at all.
- In British Columbia, New Brunswick, and Newfoundland and Labrador, government employees deliver all professional home care services, but private agencies deliver home support services.
- In Alberta and Nova Scotia, both government and private employees provide professional home care services; government employees administer home care while the support services are contracted out to private contractors.
- In Ontario, Home and Community Care Support Services (HCCSS; previously referred to as Community Care Access Centre [CCAC]) staff employed by the government provide single-entry coordinating services, but all publicly paid professional home care and home support services are contracted to the private sector. A few HCCSS organizations deliver services through their government employees.

Appendix C provides a composite list of legislation applicable to publicly funded home care programs based on the 2011 report by Collier [3], updated with more recent laws and regulations. Appendix C identifies applications and implications for home care services and related home health technologies.

Considering the variations in legislation across jurisdictions, health care organizations have suggested nationwide legislation to facilitate comparison of safety, costs, and outcomes of provincial and territorial home care programs and to assess the efficacy and efficiency of the deployment and cost-effectiveness of home health technologies [9, 10]. Such legislation may provide a uniform and unified core federal, provincial, and territorial fiscal framework for home care. A cohesive core framework could guide the integration of home care into the local continuum of care, leaving sufficient flexibility for each province and territory to adapt and adopt local legislation that is suited to their socio-economic, geographic, societal, demographic, and other needs [9].

In 2016, the Canadian Home Care Association recommended that the federal government establish a set of harmonized national home care standards to ensure equitable access to high-quality home care for Canadians, regardless of where they live [12].

By establishing harmonized national legislation and standards, policymakers can develop and recommend baseline benchmark tools to help ensure accessible, equitable, and quality home care services and products across jurisdictions regardless of public or private funding [12].

2.1.3 Provincial and Territorial Health Technology Assessment Processes

HTA is a formal methodology used to support comprehensive, uniform, and systematically documented procurement processes for home health technologies. The HTA process helps ensure that, prior to purchasing any medical device, supply, or medication, a reasonably comprehensive analysis is completed to facilitate safe, reliable, affordable, and cost-effective lifetime use, and that competing alternatives have been similarly assessed. The HTA process helps avoid the acquisition of expensive, ineffective, or hazardous devices, medications, or supplies.

According to a 2015 report by the Institute of Health Economics:

- In Ontario and Quebec, HTA bodies are available at both provincial and local hospital levels;
- In Alberta, British Columbia, New Brunswick, Newfoundland and Labrador, and Saskatchewan, HTA bodies are available at provincial and regional levels;
- In Nova Scotia, HTA bodies were under development as of 2015; and
- In Manitoba, Nunavut, Prince Edward Island, Northwest Territories, and Yukon, there are no HTA bodies [13].

In addition, the HTA bodies may not focus on home health technologies because most HTA applications have been oriented to hospitals and other institutional health care settings.

The disparity in the availability of HTA bodies may be because of varying local HTA needs and legislation requirements. For example, provincial legislation in Quebec mandates that all teaching hospitals have an HTA body, while equivalent legislation may not exist in other jurisdictions [13]. Note that none of the HTA bodies directly address the use of technologies in home and community care settings.

The Canadian Agency for Drugs and Technologies in Health (CADTH) provides information on and resources in HTA, upon request, to the provinces (except Ontario and Quebec). Technologies may also be identified by provincial HTA processes through regular environmental scanning, passive surveillance, or by encouraging hospital administrators to flag technologies of concern or interest.

In the four most populous provinces (Alberta, British Columbia, Ontario, and Quebec – where approximately 86% of Canadians live), province-wide HTA processes have been established for new or existing technologies [13]. The information requirements and specifications of the HTA processes vary, but typically include:

- Disease burden or need;
- Comparative effectiveness;
- Budget impact and total health system costs;
- Evidence of cost-effectiveness;
- Equity of access;
- Feasibility of implementation; and
- Access in other jurisdictions.

Because there is neither a national process to recommend new health technologies for use in Canada nor a formal application process for medical device manufacturers to collaborate with each regional HTA process, regional HTA processes may not be consistently applied for every new medical device [13]. Such regionalized, autonomous, and non-standardized HTA methodologies may pose limitations and challenges in developing a comprehensive catalogue of home health technologies. By extension, this may affect the accessibility of home health technologies for home and community use. A further complication is that existing HTA methodologies do not specifically apply to home health technologies.

2.1.4 Provincial Coverage Policies

Along with the disparity in home care legislation and home care services offered by different provincial and territorial programs (Section 2.1.2 and Section 2.1.3), public insurance, private insurance, and personal co-payment funding policies and practices also vary significantly across jurisdictions. According to the 2009 Canadian Healthcare Association policy brief [9], there are substantial variations in who is responsible for

co-payments, participant income tests and thresholds, user fees, publicly funded services and products, and client self-payment for home health technologies. In one jurisdiction, many home health technologies may be free; in another, clients may incur substantial out-of-pocket costs.

Some home health technologies can be purchased and reimbursed through specific health ministry-led programs. For example, in Ontario, the Assistive Devices Program covers and provides some home health technologies. The Alberta Aids to Daily Living program provides some home health technologies. In British Columbia, some home health technologies are sourced through the PharmaCare Prosthetic and Orthotic Program. The New Brunswick Extra-Mural Program has a role in that province.

Some home care medications are provided or covered by provincial and territorial medication programs such as the Ontario Drug Benefit program and the Régie de l'assurance maladie du Québec in Quebec, but medications for home care are not uniformly covered across Canada.

A 2018 report by the North American Observatory on Health Systems and Policies has compared and categorized the assistive devices programs in all Canadian provinces and territories. The report identified four categories of assistive technologies [14]:

- Mobility aids, including wheelchairs, walkers, and crutches;
- Household aids, including hospital beds, stair lifts, bathroom devices, and transfer lifts;
- Respiratory aids, including continuous positive airway pressure (CPAP) machines and oxygen support; and
- Audio, visual, and communication aids, including bone-anchored hearing aids, adaptive telephones, and reading and writing devices.

Table 1 shows which government home care programs provide these categories of assistive devices.

2.1.5 Funding Policies

Policies of co-payment and government or private insurance coverage for home technologies are not consistent across Canada. According to the Canadian Home Care Association, only Ontario, Manitoba, Northwest Territories, Nunavut, and Yukon do not charge direct fees for home care services. The fees in

Table 1: Categories of assistive technologies provided by provincial and territorial home care programs [14]

Provinces/Territories	Mobility Aids	Household Aids	Respiratory Aids	Audio, Visual, and Communication Aids
Alberta	Yes	Yes	Yes	Yes
British Columbia	Yes	Yes	Yes	Yes
Manitoba	Yes	Yes	No	Yes
New Brunswick	Yes	Yes	No	Yes
Newfoundland and Labrador	Yes	No	Yes	Yes
Northwest Territories	Yes	Yes	Yes	Yes
Nova Scotia	Yes	Yes	Yes	Yes
Nunavut	Yes	Yes	Yes	Yes
Ontario	Yes	No	Yes	Yes
Prince Edward Island	Yes	Yes	No	Yes
Quebec	Yes	Yes	No	Yes
Saskatchewan	Yes	Yes	Yes	Yes
Yukon	Yes	Yes	Yes	Yes

the remaining eight provinces are based on income and generally apply to ongoing chronic support in the home [4].

Table 2 shows the various sources of funding for provincial and territorial home care programs for home health technologies. The funding sources may include public funds, private insurance funds, a mix of government coverage and private insurance coverage, and client out-of-pocket payments

Because of the variation in funding policies for home health technologies, Canadians may be forced to find the government agency, or combination of agencies, that provides the most comprehensive and flexible set of home care resources at the lowest cost to them or their family [14]. This can be a confusing and onerous task.

2.1.6 Gaps and Recommendations

2.1.6.1 Provincial and Territorial Legislation of Home Care Programs and Services

Gap: There is a lack of standardized, unified, and comprehensive national, provincial, and territorial legislation and regulations for home care services and products. Such legislation and related regulations would enable and help assure governmental oversight, assessment, and comparison of federal, provincial, and territorial home care programs.

Recommendation: Develop a model of guidance that addresses industry-wide unified home care benchmarks and assessment tools that could assist and accelerate federal, provincial, and territorial adoption and implementation. A set of national benchmarks that

Table 2: Funding policies for home health technologies by provincial and territorial ministry-led homecare programs [4, 9]

Provinces/Territories	Equipment	Supplies	Medication
Alberta	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds
British Columbia	Client payment	First 2 weeks of supplies publicly funded	Publicly funded
Manitoba	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds
New Brunswick	Use third party insurance wherever possible. If not possible, mix of private and public funds.	Use third party insurance wherever possible. If not possible, mix of private and public funds.	Use third party insurance wherever possible. If not possible, mix of private and public funds.
Newfoundland and Labrador	Publicly funded	Publicly funded	Publicly funded
Northwest Territories	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds
Nova Scotia	Client payment	Client payment	Publicly funded
Nunavut	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds
Ontario	Publicly funded	Publicly funded	Publicly funded
Prince Edward Island	Client payment	Client payment	Client payment
Quebec	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds
Saskatchewan	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds
Yukon	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds	Mix of client, private insurance, and public funds



"Policies of co-payment and government or private insurance coverage for home technologies are not consistent across Canada."

establish baseline quality, safety, equity, and efficacy levels could benefit all Canadian home care providers, recipients, families, clinicians, and other stakeholders and optimize client- and family-centric care.

2.1.6.2 Provincial and Territorial HTA Processes

Gap 1: The availability of HTA bodies varies across provinces and territories. Where HTA processes are in place, they are not consistently applied to existing (versus new) home health technologies. HTA bodies impose inconsistent requirements across jurisdictions and, in general, do not directly address the use of technologies in home and community care settings.

Recommendation 1: Develop a set of unified model legislation for provincial and territorial HTA processes for efficient identification, adoption, management, and deployment of home health technologies, dovetailed with similar model regulations for hospitals. Well-organized regional HTA guidelines and recommendations that provide a clear mandate and methodology will help ensure that Canadians have access to the safest, most effective, most appropriate, and cost-effective home care devices, supplies, and medications.

Gap 2a: Provincial and territorial HTA programs lack standardized national processes to identify, recommend, and review products as new home health technologies.

Gap 2b: Provincial and territorial HTA programs lack formal, consistent, and uniform application processes for manufacturers to use so that their home health technologies can be considered.

Recommendation 2: Develop a unified national and regional HTA process to identify and assess new devices, supplies, or medications for procurement and deployment as new home health technologies. Manufacturers could use the same pathway to apply to have existing technologies assessed if they develop novel home care uses.

2.1.6.3 Funding Policies

Gap: The eligibility, coverage, co-payment, and funding policies of provincial and territorial home and community care programs, including the programs for home health technologies, are inconsistent and vary across provinces and territories.

Recommendation: Develop a set of national standardized requirements regarding the eligibility, coverage, co-payment, and funding policies for provincial and territorial home care programs to facilitate efficient and equitable access of home health technologies in the home and community care settings.

2.2 Environmental Considerations for Safe Home and Community Care

2.2.1 Overview

Case Description: Internal Environmental Issues – Inadequate Wiring

Rose is fortunate enough to have a home oxygen concentrator and a portable pulse oximeter to help in recovery from COVID-19. However, Rose's apartment is in an older house that was divided into separate one-bedroom apartments long before she moved in. The wiring is old, and the house is equipped with ungrounded, two-prong outlets that are supplied by a fuse box in the basement. A neighbour helped modify the system to accommodate Rose's medical equipment by bypassing the ground prong, but this creates an electrical shock and fire hazard. Every couple of days the fuse blows when Rose plugs in the toaster, but she does not always notice if the concentrator has stopped. When Rose is not receiving oxygen from the concentrator, her oxygen saturation levels drop, leading to confusion and difficulty breathing.

The incidence of workplace injuries among health care workers is the highest of any industry in Canada [15]. Although data from the Association of Workers' Compensation Boards of Canada do not distinguish between home and hospital health care workers, it is reasonable to assume that an uncontrolled home environment presents significant risks to caregivers. In fact, research from Canada and the United States (US) has reported that home health care workers have one of the highest injury rates of any industry [16, 17, 18].

Two environmental aspects can affect home care safety for both caregivers and the individual receiving care: internal aspects within the home or community setting, and external aspects, such as climate or geography.

This section summarizes the internal environmental hazards that make it difficult to provide safe care when using equipment, supplies, and medications and identifies a wide range of risks to client and caregiver safety. The necessary infrastructure supports to permit the safe use of devices, supplies, and medications are discussed in depth in Sections 2.3, 2.4, and 2.5.

2.2.2 Internal Environmental Hazards

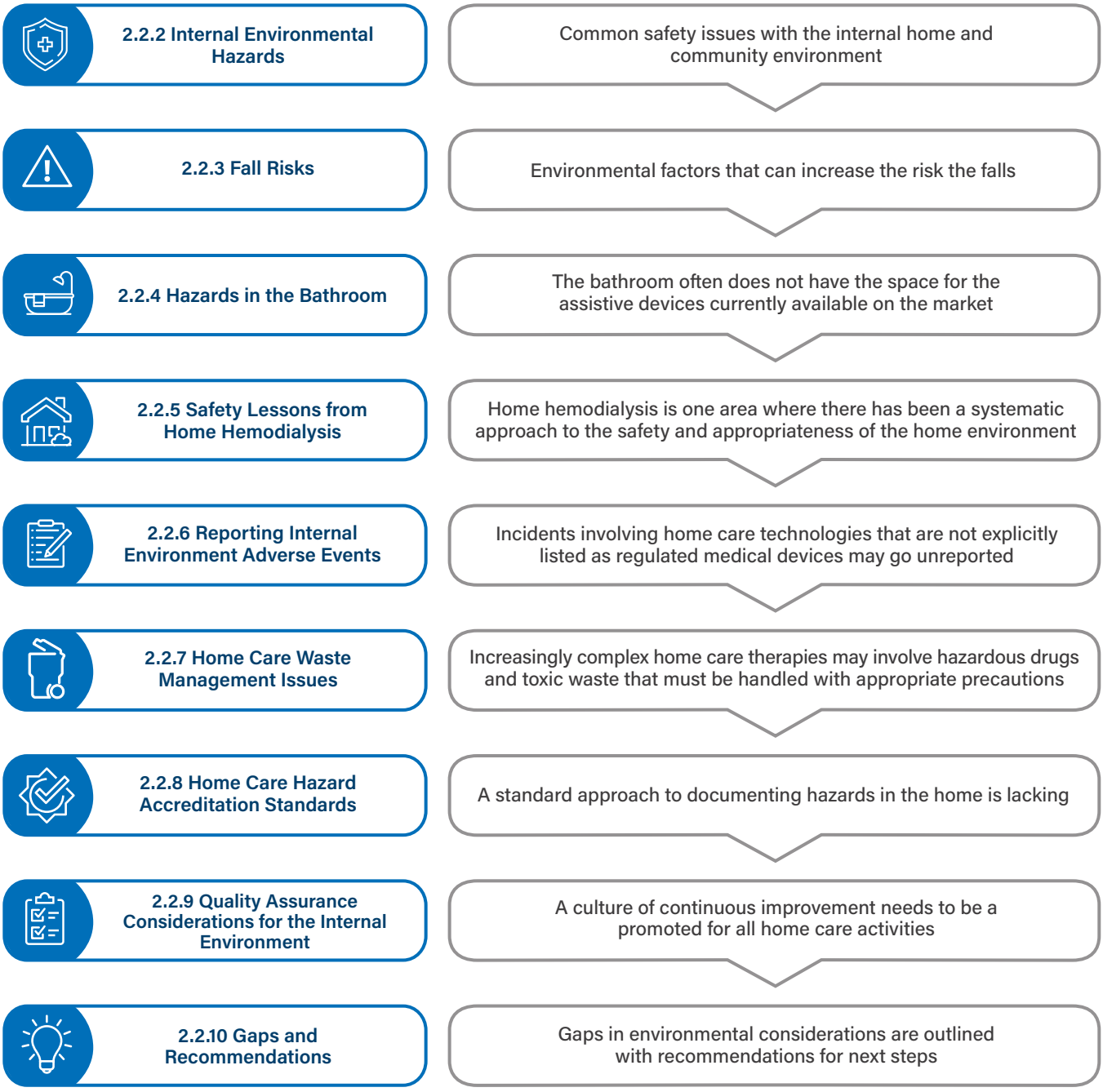
There is a widespread lack of standardized protocols to verify the safety of the home and community care environment into which home health technologies may be introduced. Safety issues may include:

- Buildings in disrepair, with rotting steps or crumbling ceilings [16];
- Faulty electrical wiring and circuit breakers or fuses and otherwise unsafe electrical systems;
- Lack of emergency sensors and alerts (e.g., smoke and carbon monoxide detectors and alarms);
- Lack of adequate heat, air conditioning, humidity, and ventilation;
- Lack of appropriate plumbing, running water, and a safe water supply;
- Lack of safe sanitation/waste disposal;
- Trip hazards in living, cooking, sleeping, entranceways or doorways, and common areas;
- Pets that may interfere with the operation of critical devices (e.g., pets may chew the device);
- Exposure to the outside elements from lack of repairs to the roof or exterior of the building; and
- Presence of pests, pollen, mould, chemicals, and other contaminants.

People's behavioural habits may also put them and their caregivers at risk. A notable fire hazard is smoking while on oxygen therapy [19]. Also, the home space may be too cramped to allow safe spacing and placement of necessary equipment.

The lack of standards or regulations that define a safe home environment for the delivery of health care needs to be urgently addressed. The National Building Code of Canada, which defines safe building standards, has evolved over time; much of Canada's housing stock was built many years ago and does not meet the current code requirements [20]. Also, up to one-third of households live in substandard conditions or in housing need [21].

Figure 3: Summary of topics covered in Section 2.2



2.2.3 Fall Risks

Case Description: Internal Environmental Issues – Falls

Jesse has lived in the same rental apartment in an old house for 40 years. It is very comfortable and the neighbourhood is safe and quiet, however Jesse now needs to use a large walker for support. The walker is too big to fit through the bathroom door, so Jesse leans on the door handle and the vanity to get to the toilet. Without adequate support, Jesse has had some bad falls onto the tiled floor after toileting and washing.

Approximately 30% of people aged over 65 and 50% of those aged over 80, living in the community, have been reported to fall at least once per year [22].

A clinical best practice guideline published by the Registered Nurses' Association of Ontario lists the following environmental factors that can affect the risk of falls [22]:

- Flooring (e.g., vinyl flooring is preferred over carpeting in geriatric rehabilitation hospitals);
- Adequate lighting;
- Heights of furniture (e.g., chairs, beds, side rails);
  - Note that bed side rails can be an entrapment hazard, if the person is caught between the bedrail and the mattress, and a fall hazard if the person attempts to climb over them [22].
- Safe, functional equipment (e.g., mechanical lift equipment, wheelchairs, bed type);
- Sufficient room (e.g., to move and use walking aids);
- Supports, such as hand holds and hand rails;
- Unit layouts.

2.2.4 Bathroom Hazards

In a dissertation focusing on caregiver safety, King documents many significant hazards associated with toileting and bathing [19]. The identified issues also affect the safety of the care recipient. The bathroom is the most cramped space in the home and does not usually have room for the assistive devices that a caregiver might typically use to safely lift and position a patient in a hospital. Modifying bathrooms in most home settings to accommodate hospital-scale devices is not always feasible, because of financial and time constraints, space limitations, or property rental contracts.

There is a need for new types of assistive devices to afford safe use by home and community care clients and their caregivers in constrained spaces, for example, the bathroom, without anyone risking injury.

An example of equipment that attempts to facilitate toileting is the raised toilet seat. There are three options currently available: the raised toilet seat, the commode chair, and an attachment that installs under the base of the toilet to raise the height of the toilet. All of these options have issues, either of cost or aesthetics. In addition, the caregiver is still at risk of musculoskeletal injury while assisting clients due to the need for awkward postures. The bidet seat has been shown to reduce this risk of injury by improving perineal cleaning, reducing the client's need for assistance. However, this is a costlier option that is not currently eligible for funding support [19].

2.2.5 Safety Lessons from Home Hemodialysis

Home hemodialysis is one area of home care where the approach to the safety and appropriateness of the home environment has been systematic because of the complexity of implementation and the need for ongoing technical support. As a life support technology, hemodialysis requires high standards of reliability and safety in terms of the electrical supply, the water supply, and wastewater handling, the scope of which is covered in CSA Z364.5-17, *Safe installation and operation of hemodialysis and peritoneal dialysis in a home setting* [23]. Prior to setup, qualified technologists from the base hospital that runs the home hemodialysis program assess the infrastructure of the home environment for safety and appropriateness.

Such technical expertise is not available for most home care services. Yet technologies that would benefit from a similar level of support include ventilators, infusion pumps, and oxygen concentrators. In many cases, these provide a level of life support similar to a hemodialysis machine.

2.2.6 Reporting Internal Environment Adverse Events in Home Care

The literature on home care includes many studies that report adverse events that occur in the home setting [24,25,26]. Many of these events – trips, falls, and infections – are caused by deficiencies in the environment [27]. The Canadian Institute for Health Information's Home Care Reporting System (HCRS) compiles Canadian statistics using the internationally validated Resident Assessment Instrument-Home Care (RAI-HC). The RAI-HC is a person-centred standardized clinical assessment for people with chronic and post-acute care needs. This tool informs and guides comprehensive care and service planning in home and community settings. However, "environmental/home safety" is only one of the 19 home care assessment domains covered by the RAI-HC [28].

The RAI HC instrument is designed primarily to assist in assessment and care planning, and to provide data to examine the effect of different combinations of services on client outcomes. As such, its utility in providing insights into issues with the home environment is limited.

For example, in a study of adverse events in home care in Canada, Doran et al. found that the rate of adverse events reported by the RAI-HC was 4% [27]. In a study published by the Canadian Patient Safety Institute that used multiple data sources, the rate of adverse events was 13% [29]. The main types of adverse events in this study were falls, medication incidents, and infections.

Health Canada has two formal programs for reporting adverse events; one is for medical devices and the other for medications. In 2011, Health Canada issued a requirement for mandatory reporting of adverse events [30]. The 2011 problem-reporting program was superseded on 23 June 2021 by a new incident-reporting program [31]. Under this program, the obligation for reporting lies with the medical device manufacturer or importer. Reporting relies on user reports, complaints, warranty claims, or other documentation.

An additional mandatory reporting program for hospitals, Vanessa's Law, was enacted in 2014 and came into effect on December 16, 2019. Vanessa's Law requires that health care institutions report "serious adverse drug reaction[s] … or medical device incident[s] that [involve] a therapeutic product" [32].

There is no corresponding legislation to cover reporting of adverse incidents related to drugs or other medical technologies used in the home or community care environment. Despite published reports describing significant prevalence of adverse events in home care, few examples can be found in the Health Canada databases.

For home health technologies (aside from medications), the many gaps in reporting may be because of:

- A lack of a mandate for home care users, caregivers, or agencies to report incidents to the manufacturer;
- Unclear chain of ownership versus use, because a home care device such as a hospital bed or oxygen concentrator may be supplied, loaned, rented, or resold numerous times;
- A layperson's inability to identify, describe, and document an incident and the actual cause of an incident;
- Fear of home care stakeholders being blamed or sued if the manufacturer deems an incident to be a "use error", which has a specific definition in the 2021 regulation that can eliminate the device or design as the cause; and
- Many home health technologies, such as consumer blood pressure monitors, may not be formally listed as a medical device and would therefore be excused from this incident-reporting program.

In contrast, all Canadians are encouraged to report incidents to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) to reduce and prevent harmful medication incidents [33]. Health Canada maintains a consumer-facing information page about this program [34]. In this program, medication incidents are reported directly to the government, making the manufacturers accountable to the government. A recent example is COVID-19 vaccine adverse-event reporting, through the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) [35], which has produced rich, immediate, and valuable information to identify and analyze harm [35]. However, in the home and community care environments, there is no requirement to report medical device problems and incidents either to Health Canada or to the manufacturer.

Other aspects of home care medication management are discussed in more detail in Section 2.7 and aspects of home health technology assessment and management are discussed in Sections 2.4 and 2.5, respectively.

2.2.7 Home Care Waste Management

Case Description: External Environment and Waste Management Factors

Ikhlas has irritable bowel syndrome, causing extreme and frequent bouts of fecal incontinence. He frequently eats foods that aggravate his diarrhea, as his cataracts make it hard to read the fine print on food labels.

Ikhlas is receiving sufficient quantities of disposable incontinence products, to wear during the day and to use on the bed at night. He's registered with a company that collects used incontinence products, but they only collect one full garbage bag every two weeks, from the curbside. In between collection days, he stores the used products in a box in his bathroom. He's unhappy about soiled products accumulating in his home but he does not know what else to do.

Hazardous waste and waste management are important causes for concern when delivering health care in the home and community. There are two issues: 1) many devices, supplies, and medications, such as, needles and syringes, create significant volumes of waste as does the related packaging; and 2) increasingly complex home care therapies may involve hazardous drugs and toxic waste that must be handled with due caution, depending on the substance, and which must also be accounted for in soiled incontinence products and discarded personal protective equipment (PPE).

The World Health Organization (WHO) classifies medical waste into the categories shown in Table 3 [36]. The recommended practice for disposal of each type of waste varies across Canada [37, 38]. The disposal method for each category of waste, as recommended by the Ontario Ministry of the Environment, Conservation and Parks, for example, is also shown in Table 3 [39]. Less detailed provincial standards exist for Alberta [40], British Columbia [41], and Quebec [42]. In addition, each municipal jurisdiction may interpret these standards differently.

Of the waste types listed in Table 3, only the general waste, Item 8, is safe to dispose of as regular garbage. All other categories require various special handling procedures.

2.2.7.1 Hazardous Waste Management

Intravenous (IV) chemotherapy treatment involves the use of cytotoxic drugs that are subsequently excreted in the urine and feces. If individuals receiving the therapy need to use incontinence products, the handling of these products after their use requires strict precautions and the effective use of PPE. The individuals receiving therapy, family members, and caregivers need guidelines and training on how to handle these waste products [44].

Researchers have found traces of hazardous drugs on many surfaces in the home environment, indicating a lack of effective PPE use [45]. In addition, people can continue to excrete chemotherapy drugs at low levels through urine, feces, and breath for more than 4 days after treatment. The risk of accidental spills of either the hazardous drug or urine and feces is higher in the home setting, and the person receiving the therapy or a family member or other caregiver may be tasked with cleaning up such spills.

People are also at risk of exposure to any infectious material in the medical waste stream. This can include used syringes, blood and other body fluids, as well as discarded PPE (e.g., masks, gloves, gowns, bed pads, diapers, gauze bandages, facial tissues, wipes). Examples of infectious substances include *Escherichia coli (E. coli),* Methicillin-resistant *Staphylococcus aureus (MRSA), Clostridioides difficile (C. diff),* SARS-CoV-2, hepatitis B or C virus (HBV, HCV), human immunodeficiency virus (HIV), and tuberculosis.

Hospitals have waste management departments with staff who have the necessary training and experience to handle such substances safely. Many guidelines have been published to assist with staff training. One developed by Ontario Health (previously Cancer Care Ontario) deals with the safe handling of cytotoxins at any point in the medication circuit including in the

Table 3: WHO medical waste categories

	Category of Waste (WHO)	Example of a disposal method or container as recommended in Ontario
1	Sharps waste including needles, scalpels, broken glass and razors	Reusable or single-use container with yellow biohazard label that conforms to CAN/CSA Z316.6:20 [43]
2	Infectious waste – anything that may be contaminated with pathogens, such as excreta, and materials that have been in contact with people with highly infectious diseases	Single-use container with red biohazard label
3	Pathological waste – human or animal tissue, body parts, blood, and fluids	Reusable or single-use container with red biohazard label
4	Pharmaceutical waste – unused and expired drugs or medications, including creams, pills, antibiotics	Ontario Regulation 298/12 places the responsibility on the producer (e.g., the pharmacy) for the collection of the pharmaceutical from consumers who bring the pharmaceutical to the collection locations
5	Cytotoxic drugs and other hazardous toxic waste that is carcinogenic, mutagenic, or teratogenic, including sharps and tubing	Reusable or single-use container with red cytotoxic label
6	Chemical waste, including expired disinfectants, waste with high content of heavy metals such as batteries, and broken thermometers	Leak proof container and delivered to a municipal hazardous or special waste depot
7	Radioactive waste, including any waste potentially containing radioactive materials, such as urine and excreta from patients treated or tested with radionuclides when undergoing nuclear medicine diagnostic procedures or procedures for cancer treatment	The Canadian Nuclear Safety Commission licenses, regulates, and monitors radioactive waste management activities
8	General/other waste – waste that does not pose any biological, chemical, radioactive, or physical hazard	Black plastic bag and into municipal waste

Abbreviation: WHO, World Health Organization

home setting [46], [47]. Recommendation 9 in this guideline addresses the issues for health care workers and people receiving cytotoxic drug treatment in the home. This recommendation includes the necessity of having a specialized spill kit readily available of educating caregivers and individuals receiving therapy and their family in the handling of cytotoxic waste, and of providing everyone involved with a process for appropriate disposal of the cytotoxic waste [46].

Provincial occupational health and safety (OHS) regulations aim to protect workers from the hazards of cytotoxins and other toxic substances. For example, WorkSafeBC "OHS Regulation Part 6: Substance Specific Requirements" deals with worker safety when handling or disposing of hazardous substances including cytotoxic drugs [48]. However, family and informal caregivers as well as the individuals receiving the therapy are not considered workers subject to these regulations – which points to a safety gap.

The regulation of biomedical waste in Canada is a responsibility that is handled by the provincial ministries of the environment and often delegated to the municipalities. Safe management of such waste is therefore inconsistent across the country.



"It is essential to promote a culture of continuous improvement for all home care activities."

2.2.8 Home Care Hazard Accreditation Standards

Three accreditation bodies in Canada address the delivery of home health care: Accreditation Canada, the Commission on Accreditation of Rehabilitation Facilities (CARF), and the Canadian Centre for Accreditation [49, 50, 51]. Accreditation Canada's *Home Care Services* [49] deals with home hazards in Section 14.0 "Client and team safety is promoted within the service environment."

In Section 14.0, Accreditation Canada Required Organizational Practice (ROP) 14.2 recommends conducting a safety risk assessment for clients receiving services in their homes that includes a review of internal and external physical environments. This risk assessment would include chemical, biological, fire, and fall hazards; medical conditions requiring special precautions; client risk factors; and emergency preparedness. Guideline 14.5 addresses the reporting of safety risks in the home, such as problems with equipment, spills, and client behaviour. Despite these recommendations, a standard approach to documenting such hazards in the home is lacking.

2.2.9 Quality Assurance Considerations for the Internal Environment

It is essential to promote a culture of continuous improvement for all home care activities. Procedures to identify incidents and near misses and action plans to implement improvements are necessary to any quality improvement program. The concepts of CAN/CSA-ISO 9001:16 (R2020), *Quality management systems - Requirements* can be adapted to the internal and external environmental and waste management challenges for home and community health care discussed in this section [52]. Several important opportunities include:

1. National and local standards for these issues change as scientific and medical literature evolve. Because of these changes, all standards must be periodically reviewed, and practices updated to account for such changes. Some examples:
   - Electrical safety standards and technologies for safe wiring, circuit breakers, and fault-exception protection are periodically improved as new products and safety risks are identified. In 2015, the Canadian National Electrical Code was modified to require arc fault circuit interrupters in new construction [53]. Compatibility of arc fault circuit interrupters with the wide variety of home health technologies should be part of indoor environmental management practice revisions.
   - There has been a tremendous increase in use of disposable PPE (e.g., masks, gloves, and gowns), and products such as oxygen tubing and administration sets during the COVID-19 pandemic. This has highlighted the many environmental threats these products pose because many PPE and disposable tubing products are not biodegradable, recyclable, or safely combustible. Routine operating procedures – and user instructions – for preventing harm to the environment must be regularly updated as such problems emerge.

- As the number of persons receiving home and community health care continues to expand, the numbers and types of hazardous waste increases. Procedures based on current best scientific and occupational safety practices need to be regularly updated to avoid risks to all parties.

2. In keeping with the continuous quality improvement (CQI) mandate of CAN/CSA-ISO 9001 [52], unambiguous, reliable, and consistent reporting of problems is key to identifying emerging risks and remediation needs. As new problems are identified, such as PPE disposal, focused problem-reporting and remediation programs may be instituted.
3. Employees and contractors need initial and ongoing training so that they are aware of, competent in, and compliant with current and updated standards and practices. Written records documenting staff training and competence are essential. Training omissions or oversights should be remediated in a timely manner. Checklists may be used to train and remind clients and also serve as a means of documenting employee intervention and follow-up.
4. Senior management of all the parties providing home and community health care technologies have significant challenges and obligations. All too often, assumptions are made about who is responsible for compliance and management, as waste management may fall under different provincial and local regulations. Senior management is responsible for the organization's quality processes and tracking methods, and for alignment of personnel and user training with local requirements.

2.2.10 Gaps and Recommendations

Opportunities exist to develop standards and guidelines for the home health care environment based on work done in other countries. The fact that Canada's national residential building code applies to new construction presents such an opportunity. For example, the *National Healthy Housing Standard,* issued in 2014 by the National Center for Healthy Housing and the American Public Health Association, has health-based provisions to fill the gaps where no property maintenance policy exists [54]. This US standard complements policies already in use by local and state governments and federal agencies for the upkeep of existing homes.

The *National Healthy Housing Standard* covers the following topics on the use of home health technologies [54] that would be relevant to a Canadian standard:

- Duties of owners and occupants;
- Structures, facilities, plumbing, and space requirements;
- Safety and personal security;
- Lighting and electrical systems;
- Thermal comfort, ventilation, and energy efficiency;
- Moisture control, solid waste, and pest management; and
- Chemical and radiological agents.

It is recommended that a similar standard be developed for Canada that provides details on these topics to help ensure that the home care and community care environment is safe and appropriate.

The safe handling and disposal of hazardous biomedical, biological, and infectious waste produced in the home and community setting lacks a uniform approach across the country and even within provinces and territories.

While most of CSA Z317.10-21, *Handling of health care waste materials* [55] addresses the handling of waste in health care facilities, the document does include a section on the home environment. This section outlines the duties of the home care provider and the client. It also includes a sample checklist for home care services in an appendix.

There is a need for more extensive guidelines, checklists, and oversight programs that focus specifically on home care. These could be adopted by municipal waste collection agencies and disseminated to home care users and caregivers.

It is recommended that a unified national guideline for the safe disposal of medications and other biomedical waste that focuses specifically on home care be developed based on CSA Z317.10, *Handling of health care waste materials* [55].

2.2.10.1 Internal Environmental Issues and Hazards

Gap: Building codes have evolved over time and do not address older infrastructure or the ongoing maintenance of Canadian housing. Existing standards do not address home health technology needs.

Recommendation: Develop and publish a unified set of national, provincial, and territorial guidelines and corresponding checklists, in collaboration with home care industry stakeholders, to establish a uniform minimum acceptable indoor environmental standard for safe use of technologies in the home. Such guidelines and checklists will recognize cultural differences in Canada's population.

2.2.10.2 Falls Prevention

Gap: There is a lack of comprehensive guidelines, or templates, for creating falls prevention programs that incorporate the safe use of home health technologies by caregivers and clients.

Recommendation 1: Home care agencies to provide falls prevention education programs and checklists for home care clients, and for caregivers, that incorporate the safe use of technologies.

Recommendation 2: Visiting home care staff to routinely assess, identify, and where possible, make recommendations to remediate the hazards that may cause falls in the home and community care environment in scenarios where home health technologies are present.

2.2.10.3 Bathroom Hazards

Gap: There is a lack of guidelines, and related checklists, on how to mitigate bathroom hazards and ensure safe home care. There is also little in the way of assistive devices appropriate for the home environment.

Recommendation 1: Develop and publish minimum national guidelines in collaboration with industry stakeholders and government agencies to mitigate home care bathroom hazards.

Recommendation 2: Incentivize industry stakeholders to develop, in collaboration with government agencies, assistive devices and home health technologies that minimize bathroom hazards.

2.2.10.4 Home Hemodialysis Experience

Gap: There is a lack of uniform national systematic safety assessment guidelines, related checklists, and education to help home care providers identify deficiencies in each home environment that would affect the use of intended home health technologies.

Recommendation 1: In collaboration with the home care industry, develop, publish, communicate, and monitor safe home care environmental requirements.

Recommendation 2: Private and public home care agencies or administrative oversight bodies (e.g., health care authorities) to provide uniform, checklist-based, initial and routine safety assessments of the home and community care environment in a manner that is on par with the assessments for home hemodialysis.

2.2.10.5 Reporting Adverse Events

Gap: Current medical device incident-reporting programs are not visible to all Canadian stakeholders. Home care stakeholders are not aware of the opportunities, importance, or mechanism for reporting incidents other than for medications. Incidents involving home health technologies that are not explicitly listed as regulated medical devices may go unreported.

Recommendation: Develop a roadmap in coordination with the home care industry and individual stakeholders that leads to guidelines, practices, checklists, promotion, and education that parallel the existing Canadian medication incident-reporting system and Vanessa's Law for all home health technologies.

2.2.10.6 Home Care Medical Waste Management

Gap 1: Canada does not have a consistent national medications disposal program. Instead, there exists a patchwork of provincial, municipal, and community programs [38]. In contrast, the US has national legislation, which is overseen by the US Drug Enforcement Agency [56].

Gap 2: There are virtually no standardized infectious or biological waste management protocols suitable for home and community environments. Although some municipalities publish guidelines for the disposal of hazardous waste [57], these guidelines are not universally available and they are not necessarily followed where they do exist. Consumers tend to dispose of unused and expired medications in regular waste or down the drain. There is a need for a process to define the best practice in each location and a process to ensure that it is followed.

Recommendation: Develop guidelines and checklist-driven protocols and documentation, for all home care stakeholders, to support individual and community safety when handling hazardous wastes used or produced during care or therapy in the home. These guidelines may mimic the relevant OHS guidelines that exist for workers to the extent possible given the different circumstances of the individuals involved. The resulting guidelines also help ensure the safety of municipal sanitation workers.

2.2.10.7 Accreditation standards

Gap: There is a lack of standardized, uniform, and checklist-based approaches to documenting, training, overseeing, and remediating environmental hazards associated with home care and home health technology hazards.

Recommendation: In collaboration with the home care industry, develop a minimum national standardized baseline approach, based on checklist-driven methodologies, to document and manage home care and home health technology hazards for the occupants, while taking into account the preferences and constraints that limit the feasibility of implementing some remediations.

2.3 Managing Human Factors for Home Health Technologies

2.3.1 Overview

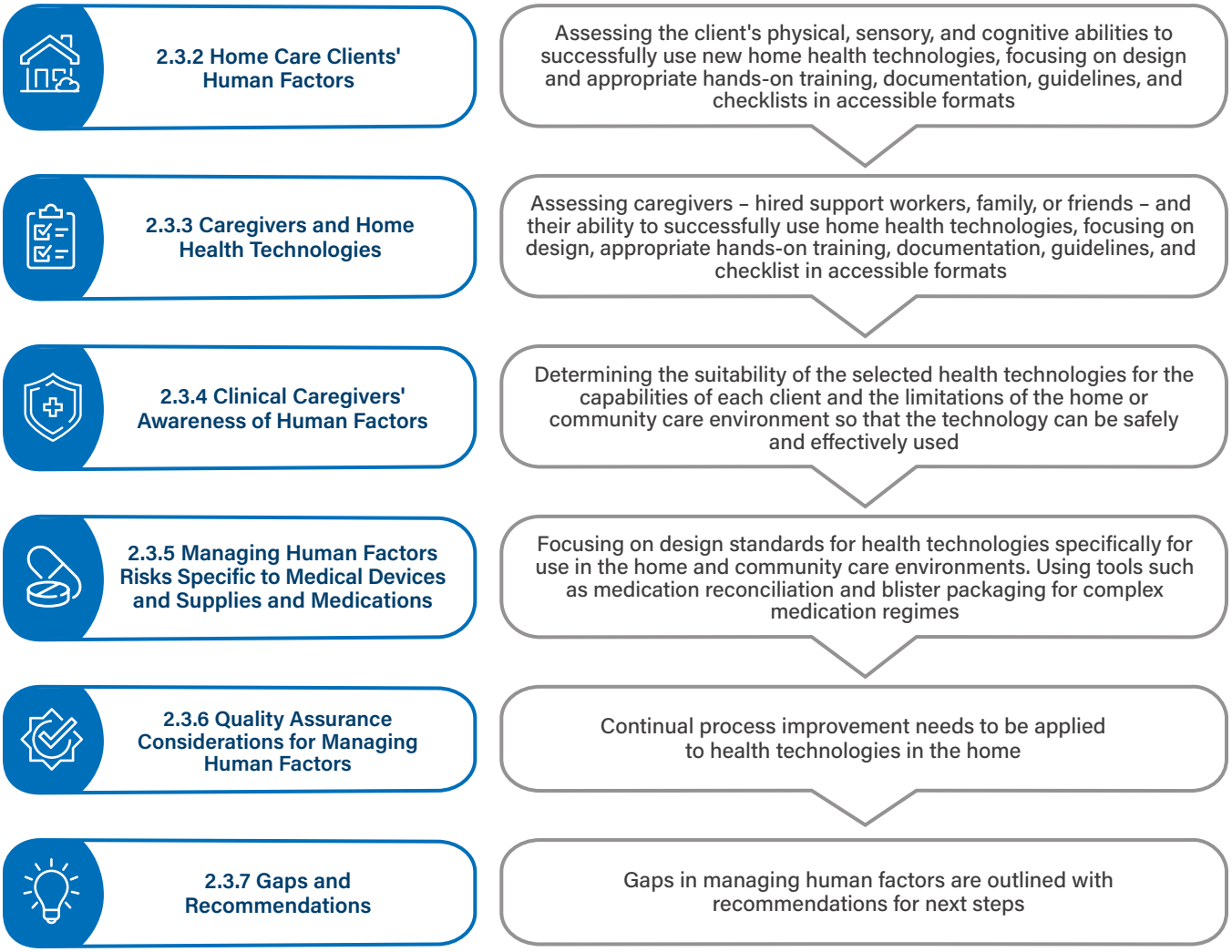
Case Description: Human Factors Challenges

Jan has been experiencing periods of high heart rate and blood pressure causing periodic nausea. Jan purchased a non-invasive blood pressure monitor from the hospital dispensary to measure blood pressure three times a day and record the results on a paper log to bring at each visit to the doctor. Like other models on the market, this monitor must be operated according to the manufacturer's directions for the readings to be accurate. But the small, low-power LCD display is difficult to read, particularly in daylight, and the blood pressure cuff is painful and even causes bruising. Jan is not sure that that's how the monitor is supposed to work, but the instructions are in very fine print and difficult to make out.

Human factors is a scientific discipline that aims to help people do their best work, improve resilience and overall system performance, and minimize errors. Human factors methods draw heavily on psychology and engineering to understand how human beings perform in complex situations, enabling the design of devices and environments that reduce the likelihood of errors and minimize their severity when they occur [58]. Human factors-based solutions make it easy to do things right and hard to do things wrong. When errors do occur, they are less likely to lead to harm [58].

A study of Canadian acute care hospital data from the year 2000 extrapolated that the incidence of preventable adverse events resulting in patient death was between 9,000 and 23,000 [59]. Studies in other countries have revealed similar rates of error, leading to the conclusion that health care processes are complex and often poorly designed from the perspective of safety.

Figure 4: Summary of topics covered in Section 2.3



Human factors applications in health care have predominantly focused on high-acuity institutional settings where the impacts of adverse events can be extreme. The rise in high-acuity treatments in the home has increased the potential for adverse events in that setting. Examining the provision of home and community care from a human factors perspective could identify opportunities to design and implement safer systems of care. The impact of human factors knowledge and thinking can be considered in terms of:

- The home care recipient or client;
- Caregivers in the home;
- Clinical personnel overseeing the client's care in the home; and
- The devices, supplies, and medications provided for use in the home.

This section examines each of these areas, in turn, through the lens of human factors, yielding some insights into approaches that may help to improve the level of safety of health care in the home and community environment.

2.3.2 Home Care Clients' Human Factors

Institutional users of medical devices, supplies, and medications – clinical caregivers such as physicians, nurses, and other health care practitioners – have been trained and licensed to use medical technologies and devices. This may not be the case for people in home and community settings. Many home care recipients are children who may not be able to safely operate complex devices unaided or recognize if a process is not going as intended. Adults, too, may have limitations to do with vision, hearing, cognition, balance, memory, strength, and physical dexterity, as well as the ill effects of one or more diseases.

In addition, the Canadian Expert Panel on Health Literacy estimated that 42% of Canadians aged over 16 and 88% of individuals over 65 scored below Level 3 on the International Adult Literacy and Skills Survey (IALSS) health literacy scale [60].

Powered medical devices display alarm warnings that assume a certain level of clinical knowledge, such as "line occlusion" for an infusion pump delivering intravenous medication. To someone with limited literacy, this can be meaningless; "flow stopped" is more likely to be understood. Given that most devices are designed for institutional settings, the average person in the home or community setting may face significant barriers to using them effectively. The usability of most health care devices is low when compared with that of typical home appliances such as microwave ovens and telephones [61].

A person's ability to use a medical device and willingness to learn how to use new devices and adapt to new devices in the home depends on [62]:

- Physical abilities, such as their size, strength, stamina, dexterity, flexibility, and coordination;
- Sensory capabilities, including vision and hearing and sometimes touch;
- Cognitive abilities, including memory, literacy, language skills, knowledge, and experience base;
- Mental and emotional state;
- Cultural background; and
- History of and experience with home and community-based health care and medical care.

To some degree, these limitations can be addressed by providing user-appropriate hands-on training with the device and by providing instructions in accessible formats written in plain language and with pictorial diagrams.

Ideally, medical devices and supplies for use in the home and community should be designed for those environments, with the needs of the typical user considered at each stage of the process. To ensure that the final product is suited to the skills and abilities of the people who will be using it, regular formative human factors evaluations should be conducted during an iterative design development phase, with laypeople hired to test the device and the use instructions at each step. These evaluations would culminate in a summative evaluation as part of the device-licensing process [63].

Training on the safe use of medical devices should be hands-on. The training should be provided by trainers with an understanding of home and community care environments, experience in teaching people with no clinical background, and expertise in the technology. Effective training includes allowing the home or community user to practice the entire use process, as if they were alone with the device at home, to help ensure that they understand all aspects of set-up and ongoing operation and maintenance so that they can safely complete this when alone.

Training resources for home and community settings should [63]:

- Use large font sizes with high contrast;
- Include clear illustrations that are appropriate to the age range of the users;
- Use plain language and avoid jargon;
- Be available in more than one language; and
- Be available in different forms, for example, some people may prefer video- or web-based instructions over written documentation;
- Be written at the Grade 7 education level or lower [64, 65].

The onus to provide much of this material lies with the manufacturer. Nevertheless, staff in home and community care agencies or device-issuing agencies may have to supplement manufacturers' materials to meet the needs of specific populations.

2.3.3 Caregivers and Home Health Technologies

The same broad assumptions made about home and community care recipients can be applied to caregivers: that they may have no clinical training and limited technical knowledge; and that their ability to use or learn to operate home health technologies may be hampered by their physical, sensory, and cognitive abilities, their mental and emotional state and willingness, their cultural background, and their personal history and experience with home and community-based health care and medical care. This may compromise caregivers' ability to support home care, making it potentially more dangerous for the care recipient and themselves.

The extent to which a home care recipient relies on caregiver support depends on their ability to manage the devices, supplies, and medications provided to them and the level of medical support available to them. For example, it would be unwise to expect a person living with dementia to manage a complex medical device without the support of a caregiver, be it a hired support worker, family, or friends who live in the home or close by and are able to provide ongoing, often daily support.

This being the case, caregivers may require training on how to use medical devices, administer medical supplies, and manage medication routines to competently and safely support the processes of care. The medical teams providing care for the client need to determine whether this approach is feasible and should periodically monitor caregivers to ensure that they are able to provide effective support. In addition, the medical team may need to determine if the caregiver is physically and emotionally able to support the client with their care needs. Recognizing the stress that can be associated with caregiving in the home, the Canadian Patient Safety Institute has published a resource guide for supporting home caregivers [66] that provides best practice guidelines for distress prevention, caregiver distress screening, and caregiver distress prevention education and tools.

2.3.4 Clinical Caregivers' Awareness of Human Factors

Clinical caregivers, or medical caregivers, are the physicians, nurses, or other health care practitioners based in institutions who oversee the discharge and ongoing care of people in home and community settings. Home settings vary tremendously; it is important for clinical caregivers to assess the ability of a person to care for themselves in the home, taking into account the overall complexity of the required care, the home health technologies and supports they will need, and whether the home environment can support the required level of care.

For example, discharging a person home with powered life support equipment when the home environment does not have a stable source of electrical power can result in serious injury or death. Pets can chew through intravenous lines, and family members may inadvertently disconnect equipment from a power source or trap lines under heavy objects in the room.

Clinical caregivers should also consider human factors issues in terms of home and community care clients and caregivers (see Sections 2.3.2 and 2.3.3) as these factors affect safe management of necessary home health technologies. It is best to determine significant deficits prior to setting up home and community care arrangements.

2.3.5 Home Health Technologies

2.3.5.1 Medical Devices and Supplies

Most medical devices and associated supplies are designed for use in institutions. In hospitals, almost all devices are operated by clinical caregivers – physicians, nurses, and allied health professionals – all of whom have received extensive training in patient care, and many of whom have had specialized training on how to operate the medical devices and supplies in their units.

The standards governing the design, manufacture, and sale of medical devices and associated supplies assume the same homogeneous clinical environment of use – for example, that the person connected to a

ventilator is in an environment where knowledgeable staff are available at all times to set it up and adjust it, where support is available in the event of a malfunction or failure, and where the sources of oxygen and electricity are reliable and uninterrupted. These supports are not necessarily in place in home and community care settings, and the level of care much less predictable.

Human factors methods help to systematically identify the risks associated with providing care in a home and community setting, and point to the steps to reduce those risks.

In recognition of the growing number and complexity of medical devices in use in the home, CSA C22.2 No. 60601-1-11 [67] provides useful contextual information about the specific issues that can arise when designing, manufacturing, and deploying medical devices in the home and community environment [67]. The adoption of this International Electrotechnical Commission (IEC) standard in Canada is an important step toward the development of safer home and community care devices.

Accreditation Canada's *Home Care Services* identifies ROPs as essential practices that an organization must have in place to enhance client safety and minimize risk [19]. This document includes several guidelines for the safe and effective provision of care in the home. It identifies, in Section 3.8, an ROP describing the need for a documented and coordinated approach to infusion pump safety that includes training, evaluation of competence, and a process to report problems with infusion pump use. This focus reflects the high incidence of errors associated with infusion pumps in health care.

A number of other medical devices that have the potential to cause serious harm, such as ventilators, are in use in the home and community environments, and it is recommended that this focused approach be extended to all high-risk medical device usage in home and community care settings.

It is also important to focus on seemingly simple devices. For example, with more than 70,000 needlestick injuries per year in Canada, a series of steps have been identified to minimize the likelihood of their occurrence [68, 69]. Effective training and appropriate supplies need to be provided to those who deliver injections in the home and community.

Similarly, Luer connectors, which are commonly used on medication infusion lines, are also on blood pressure cuffs. Inadvertently connecting a blood pressure cuff pressurization line to a venous infusion line can result in air being pumped into the person with potentially catastrophic results. Also, many Luer connectors do not lock into place and their tapered friction fit which can come loose during use, with the result that medication is not delivered. The Food and Drug Administration (FDA) has issued guidance on *Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications* [70]. Providing technologies that are as safe as possible and training on the technologies' uses and limitations to those who operate them in the home and community are important steps in providing a safe environment.

While CSA C22.2 No. 60601-1-11 [67] is an important step toward acknowledging the growing use of medical equipment in the home and community care settings, it does not guarantee that the devices sent home with patients on discharge are suited for use in the home and community environment. As described in Section 2.3.4, there is a pressing need for those involved in issuing medical devices and supplies for home and community care to take into account the special challenges and the variability in the home environment.

ANSI/AAMI HE75:2009/(R)2018, *Human factors engineering – Design of medical devices* acknowledges the distinct challenges that exist in the home care environment with the inclusion of Chapter 25: Home health care [63], as described in Section 2.3.2.

The medical devices issued to home and community care clients are, for the most part, licensed and tested for safety. However, many of the growing number of over-the-counter medical devices, such as pulse oximeters and blood pressure monitors, are bought directly by consumers or their families or friends. Over-the-counter medical devices are unregulated, and so it is unclear whether they perform safely and appropriately, whether they can be operated by the

typical consumer, or whether the accompanying instructions adequately describe how to correctly use and maintain the device.

When designing medical devices and supplies for the home and community environment, the following universal design principles should be followed [62]:

- Equitable use, so that everyone can use the same device;
- Flexibility in use, so that the device accommodates the full range of individual preferences and abilities;
- Simple and intuitive design, so that the device is easy to understand regardless of individual experience, knowledge, language skills, or current concentration level;
- Perceptible information, so that the device communicates necessary information effectively, regardless of ambient conditions or the user's sensory abilities;
- Tolerance for error, to minimize hazards and the adverse consequences of accidental or unintended actions;
- Low physical effort, so that the user can operate the device efficiently, comfortably, and with minimal fatigue; and
- Size and space for approach and use, regardless of the user's body size, posture, or mobility.

Section 2.4 provides an extensive equipment and supplies management program to address the issues identified here.

2.3.5.2 Medications

People can be on multiple concurrent medications, some of which may need to be kept under specific conditions, for example, refrigerated or stored in the dark at room temperature, and taken in different ways, for example, once or several times per day, with or without food, at the same time as other medications or not, or taken as needed. Keeping track of these variations can be an onerous task.

The Pan-Canadian Home Care Study team determined through multiple data sources that the annual incidence of an adverse event in the home in Canada was 13%, with injurious falls, injuries not caused by falls, medication events, and infections the most common [29]. The Canadian Home Care Association released a guidance poster entitled *Using Your Medications Safely* that shows that 50% of people in Canada do not take their medications correctly; 13,000 prescription and non-prescription drugs are on the Canadian market; and 21.5% of adverse events that occur in the home involve medications [71]. The poster stresses the importance of a person knowing what medications they are taking, keeping a medication list or medication record and sharing it with family and care teams, and reviewing and updating that information each time they meet with a health care professional. Still, keeping track of each medication can be a complex and confusing task when dealing with multiple prescriptions [49].

Accreditation Canada identifies, in *Home Care Services,* Section 8.6, an ROP on medication reconciliation conducted in partnership with clients and families for a target group of clients. Reconciliation is applicable when medication management is a component of care (or deemed appropriate through clinician assessment) to communicate accurate and complete information about medications [49].

One approach that helps to reduce confusion when keeping track of complex medication pill regimes is to package pills in customized blister packs, aggregating pills into clusters for times of the day and days of the week to try to reduce confusion. Many Canadian pharmacies provide this service on request.

Section 8.6 in Home Care services [49] provides an extensive medication management program to address the issues identified here.

2.3.6 Quality Assurance Considerations for Managing Human Factors

In health care, continual process improvement has become the norm. Process improvement can be equally effectively applied to health technologies in the home. CAN/CSA-ISO 9001 provides a universally accepted quality management methodology for all forms of health care [52].

The human factors methods described in Section 2.3 are intended to be applied systematically to the use of home



"An approach that helps to reduce confusion when keeping track of complex medication pill regimes is to package pills in customized blister packs, aggregating pills into clusters for times of the day and days of the week to try to reduce confusion."

health technologies, to achieve consistent high-quality outcomes. These methods should be incorporated into overall CQI programs, where they can help ensure that health technologies manufactured and selected for use in the home care environment are optimal.

There are several key areas where human factors methods can play an important role in the safe and effective use of health technologies:

1. During the design cycle of a new product;
2. During the selection of a product for purchase; and
3. During the use of an existing purchased product.

The examples of scenarios below show the impact that a quality assurance approach can bring to these three stages of the product lifecycle.

1. **During the design cycle of a new product:** A manufacturer is designing a pulse oximeter for use in the home and conducts a series of usability tests on prototype designs, recruiting typical users. Early testing reveals that many of the testers are confused about the placement of the on/off button and fail to identify it as such. The design team decide to relocate the button and provide additional labelling. Subsequent testing shows that typical consumers no longer experience problems with this issue.
2. **During the selection of a product for purchase:** A home care organization decides to purchase new non-invasive blood pressure monitors to issue to clients with diabetes. They identify several competing products and assemble a panel of typical users. Usability tests reveal that one manufacturer's product has lettering, symbols, and screen displays in small size fonts. A significant number of the panel of testers find it difficult to read this information. As a result, this product is removed from further consideration for purchase.
3. **During the use of an existing purchased product:** Home care clients are frequently not able to operate an oxygen concentrator. A human factors expert conducts observational analyses of a number of users interacting with this device in their home settings. The expert finds that the instructions for use are poorly worded, making them difficult to understand, and lengthy, discouraging most from reading. She redesigns the instructions for use, placing emphasis on appropriate literacy levels and using graphics to illustrate the steps required. These new instructions are reviewed with users in the home. Follow-up shows a much higher rate of successful use in the home.

These three examples illustrate the benefits that can be achieved when human factors methods are applied in a quality improvement context at various points. Other positive impacts can occur.

The most important point is to apply human factors methods systematically, to try to ensure safe and effective use of technologies, and to apply them to identify any deficiencies so that these are remedied in an effective manner.

2.3.7 Gaps and Recommendations

The rapid increase in the use of health care technologies in Canadian homes helps to support a much wider range of care than previously possible. The factors driving this change point to this trend growing with hospitals seeking to discharge those who can manage at home and people exert their preferences to receive treatment in their home.

Challenges in home and community care settings include the design of medical devices and technologies and suitable training for lay operators, the lack of on-site and on-demand technical support, the variations in home settings, the hazards that can be present in the home, and effective cleaning and sterilization of medical devices and supplies in the home.

Chapter 25 of ANSI/AAMI HE75:2009 (R2018) [63] focuses specifically on issues that should be addressed when designing medical devices and supplies for use in the home. While ANSI/AAMI HE75 focuses on device design, CSA C22.2 No. 60601-1-11 [67] is broader in scope and refers to many of the issues raised in this report, with Annex A of CSA C22.2 providing a rationale that addresses these points. While both standards focus on designing medical devices for the home and provide significant insight into the issues that should be considered during the design process, they contain limited guidance on the selection process and the training support for intended users.

There is a significant opportunity to develop standards that address the criteria used in selecting health technologies for use in the home. The target audience for these standards should be the health care professionals who either issue medical devices or provide guidance to clients on their selection and purchase. The standards should explain the issues in the home environment to try to make sure that the selected technology can be safely used in this specific case, taking into account the lay operator's skills and abilities and the level of support available to them.

Health technology selection will always be limited to the items that are currently available in the location of care. It would therefore be useful to have additional standards guidance on preparing suitable training materials and delivering suitable hands-on training for each client and their caregivers. As with selecting health technologies, the focus of the standard should be on the health care provider team supporting the care of the client in the home.

In some circumstances, a client acquires health technologies for use in the home without the support of a health care team. Standards should include guidance on direct purchases, for health care team members who visit the home, so that they can assess whether a directly acquired technology poses a significant risk to a client in a given situation and how to mitigate that risk.

To summarize, in the context of the human factors issues, practical implementation guidance would help improve the safety and efficacy of health care technology use in the home care environment, at selection (as discussed in Section 2.2) and during ongoing management (as discussed in Section 2.3):

- Designing technologies that are suited to lay operators – home care clients and caregivers – in the home.
- Selecting technologies appropriate for the challenges lay operators face in the home.
- Assessing the technologies that clients directly acquire for their safety in the home.
- Designing and supplying appropriate training and training materials on using health care technologies in the home.

To be effective, guidance on these points needs to be framed in a manner that addresses the practicalities of implementation, providing clear direction on what steps need to be taken to address each issue.

2.3.7.1 Managing Home Care Clients' Human Factors Limitations and Risks

Gap 1: Home health technologies can have inconsistent, confusing, unsafe, and frustrating designs, labelling, features, and operational characteristics that are unsuitable for lay operators without clinical or technical experience.

Recommendation 1: Manufacturers, home care agencies, and issuing agencies comply with the requirements of ANSI/AAMI HE75:2009 [63], and with CSA C22.2 No. 60601-1-11:15 [67].

Gap 2: Home and community care clients face significant barriers in safely and effectively using medical equipment and supplies designed for institutional use because of limited clinical and technical knowledge and possible physical, sensory, and cognitive limitations.

Recommendation 2a: Select home health technologies for the intended consumer in the intended use environment.

Recommendation 2b: Remediate any human factors deficiencies with easy-to-comprehend checklist-driven instructions and diagrams.

Gap 3: Most training materials and device-operating manuals are targeted at clinical users—physicians, nurses, and other health professionals—and are inadequate and inappropriate for home care users.

Recommendation 3a: Manufacturers, home care and issuing agencies, and technology suppliers review and enhance their training methods and documentation using plain language and accessibility principles (e.g. [72]) so that home care clients can safely and effectively use home health technologies.

Recommendation 3b: Manufacturers, home care and issuing agencies, and technology suppliers provide user-appropriate checklist-driven guidelines and documentation written in plain language with pictorial diagrams in accessible formats suitable for the intended user, on:

- How to safely and effectively use the relevant home health technologies;
- How to identify unexpected failures and risks;
- How to mitigate common problems; and
- How to obtain emergency assistance, if needed.

2.3.7.2 Managing Caregivers' Human Factors Limitations and Risks

Gap 1: Caregivers may face significant barriers to safely and effectively using all relevant home health technologies if they have limited clinical and technical knowledge and any physical, sensory, and cognitive limitations.

Recommendation 1: The manufacturer, home care and issuing agencies, and technology suppliers provide home and community care caregivers with user-appropriate hands-on training and checklist-driven documentation and guidelines written in plain language, with pictorial diagrams and in accessible formats, on:

- How to safely and effectively use the relevant home health technologies;
- How to identify unexpected failures and risks;
- How to mitigate common problems; and
- How to obtain emergency assistance, if needed.

Gap 2: Home caregivers may not have the mental, physical, or emotional capacity to provide adequate, safe, and effective use of home health technologies and avoid risk or harm to themselves or care recipients.

Recommendation 2: The clinical teams who provide care for home and community care clients routinely assess and document caregiver skills and knowledge. Where appropriate, the clinical teams give timely re-education or other remediation to help the caregivers use and manage technologies safely and effectively.

2.3.7.3 Clinical Caregivers' Management of Human Factors Risks

Gap: Real world settings vary in complexity, and home and community care environments may lack, for example, stable power and water supplies, which pose significant barriers to the level of care that can be provided to home care clients.

Recommendation: Clinical caregivers routinely assess and remedy potential issues that may impede the safe management and operation of home health technologies within the specific home and community care environments to the extent possible.

2.3.7.4 Managing Human Factors Risks – Medical Devices and Supplies

Gap 1: Most medical equipment and supplies are designed and manufactured for institutional use.

Recommendation 1a: The home and community care agencies and the agencies issuing medical devices and supplies provide clients and caregivers with appropriate resources, such as checklist-driven operating instructions and guidelines written in plain language, with pictorial diagrams and in accessible formats, on how to safely and effectively use the issued home health technologies.

Recommendation 1b: The agencies issuing medical devices and supplies take into account the challenges and degree of variability in the home and community care environments and adopt the use of environment-appropriate devices and supplies.

Gap 2: Over-the-counter medical devices, for example, personal blood pressure monitors, scales, pulse oximeters, or assistive products, are not necessarily equivalent to regulated medical devices and supplies with similar functions.

Recommendation 2: Preference is given for the selection and use of medical devices and supplies that are designed and developed specifically for use in the home and community care environments.

2.3.7.5 Managing Human Factors Risks – Home Care Medications

Gap: Clients and caregivers in home and community care settings may not be able to safely and effectively manage their medications because of the complexity of taking multiple concurrent medications with different storage requirements and administration schedules.

Recommendation 1: Medication-issuing agencies provide clients and caregivers with appropriate resources, such as a medication list or record in an accessible format, that is routinely reviewed and updated by health care professionals.

Recommendation 2: The home care agencies and medication-issuing agencies implement medication reconciliation programs to communicate accurate and complete information about the medication used by their home and community care clients.

Recommendation 3: Medication-issuing agencies package medication in a way that facilitates effective and simple management for home and community care clients and caregivers.

2.4 Health Technology Assessment for Safe Home and Community Care

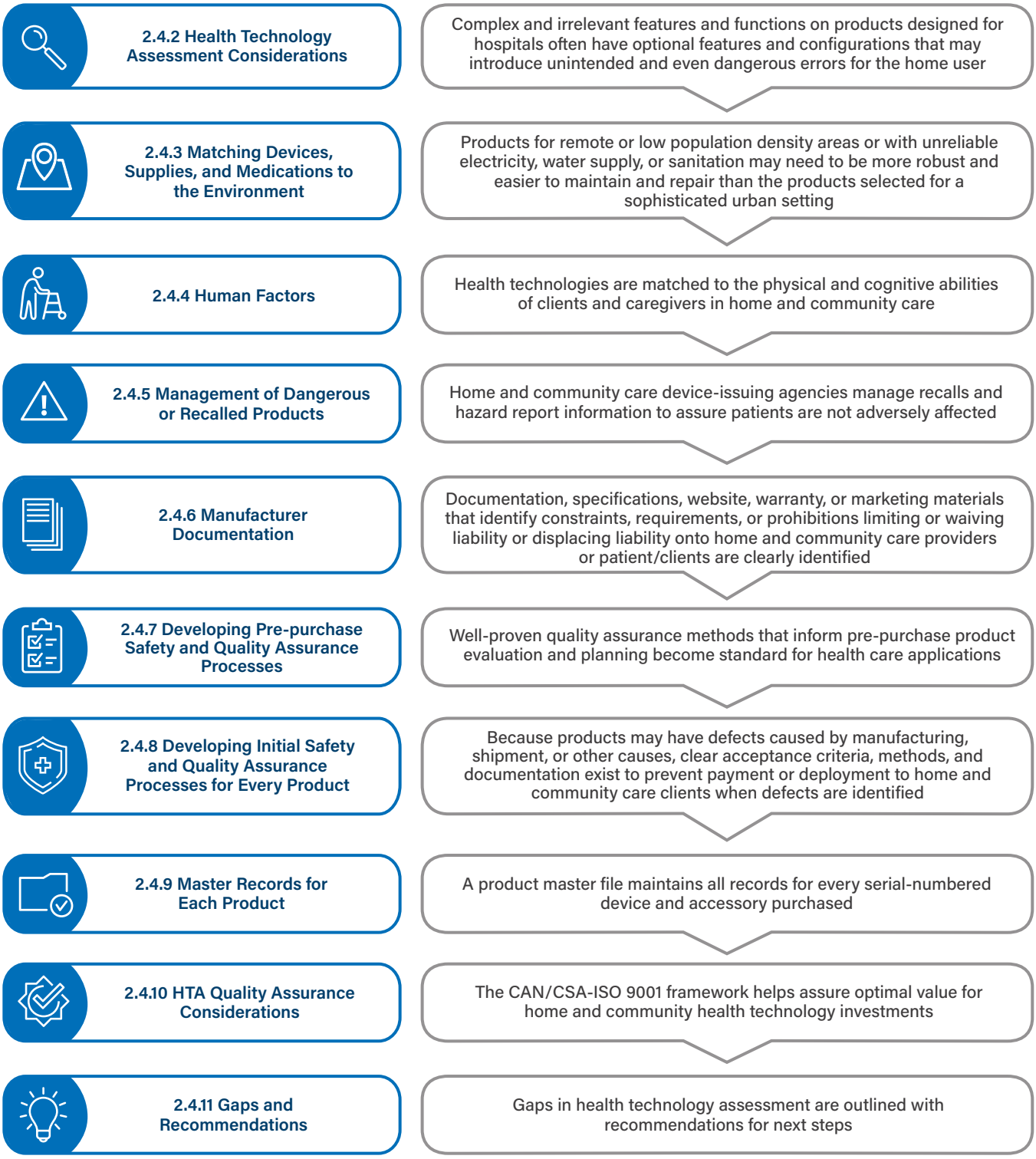
2.4.1 Overview

Case Description: Health Technology Assessment Challenges

Dana has difficulty breathing, and the hospital has provided her with an oxygen concentrator and a portable pulse oximeter as well as a BiPAP ventilator system to help with sleep apnea. When Dana is not receiving oxygen from the concentrator, her oxygen saturation drops, which can result in confusion. If she fails to use her BiPAP machine, she experiences heart pain and palpitations. The provincial home care program recently bid out a 5-year purchasing contract for a single brand and model of concentrator and BiPAP device. There is no latitude to substitute some of the inventory with newer, slimmer, more lightweight products that would fit safely and meet Dana's needs in her small apartment.

HTA focuses on providing the right product to the person who needs it. As described in Section 2.1, the field of HTA is relatively well developed for hospital applications throughout Canada and elsewhere. However, health technologies designed for use in hospitals are not necessarily appropriate for use in home and community settings by people without clinical experience.

Figure 5: Overview of the topics covered in Section 2.4



2.4.2 Health Technology Assessment Considerations

Device categories, brands, models, and even versions, can have widely divergent features, performance, reliability, maintainability, usability, and other unique factors. As is common in consumer products, manufacturers strive for novel product characteristics to differentiate themselves in competitive market niches.

Products designed for hospital applications often have many optional features and configurations. Complex and irrelevant features and functions may introduce unintended and even dangerous errors for the home care recipient and caregiver using the product. Some examples include:

- Extensive and programmable audible and visual alarms and alerts on products that reset to defaults whenever a product is turned off or unplugged;
- Multiple ways of configuring products with numerous optional accessories to suit different situations, for example, certain wheelchairs, nebulizers for inhaled medications and respiratory treatments, or non-invasive ventilators for people with sleep apnea;
- Numerous small adapters and connectors, most of which are inappropriate for the intended user;
- Bulk medications, vitamins, and other supplements that have expiration dates, variable labelling, and sometimes complicated prescribed uses that vary depending on the day, time, other medications being taken, foods, individual reactions, interactions, and side effects. Law and liability concerns often require prescription medication labelling to include extensive generalized warnings about use and misuse that can be difficult to interpret or remember.

In addition, products may be used at home differently from hospital applications. Technologies may be used intermittently or as needed to compensate for or overcome acute episodes or only during recuperative phases of care. People with multimorbidity or chronic diseases may experience long periods of remission, during which they may forget how to use a product. In other cases, products may be personalized and tailored to an individual's needs (e.g., customized wheelchairs, uniquely configured disposable supplies and accessories, or hand-compounded medications).

Medications can also vary widely, especially as generic substitutes have become common in Canada but manufacturers may only be required to demonstrate chemical equivalence of the active ingredient in tablets, capsules, or liquid formulations. There may be few controls on the non-medicinal ingredients each manufacturer uses to make their version, irrespective of where they are sourced. Medication packaging can also vary, with different containers, caps, security seals, dose administration, and labelling for each manufacturer's generic variant. (Medication distribution alternatives are discussed in Section 2.7.5, but bulk, monthly, and unit-dose packaging all have advantages and disadvantages for home use, depending on the user, the medication, and the situation.)

Many people take assorted products and supplements that may be categorized as nutraceuticals or homeopathic medicines or identified by an herbal or extract name [73]. Some of these substances can interfere with or amplify prescription and over-the-counter medications in risky ways. For example, *Ginkgo biloba* may interact with anticoagulation medications [74, 75]. Also, there are very few constraints on labelling, dosage, purity, or therapeutic claims, and the body of evidence-based literature and controlled clinical trials varies. Very little organized HTA literature is available on these products, but they should not be ignored.

HTA processes focus on identifying and sourcing the product that is best suited for the intended application. As discussed in Section 2.3, human factors considerations for home and community care differ from those for institutional settings in terms of the technologies used. The unique human factors needs and constraints affect appropriate packaging, labelling, safety features, and many other aspects of HTA such as safe installation and disposal.

The recommendations in Section 2.4 have been developed based on established Canadian, US, and international accreditation standards for hospitals and long-term care facilities plus numerous professional HTA organizations in the health care industry [76].

Specific documents and publications are listed below:

- Health Quality Ontario: *Health Technology Assessments: Methods and Process Guide* [77];
- CADTH: *Health Technology Assessment and Optimal Use: Medical Devices; Diagnostic Tests; Medical, Surgical, and Dental Procedures* [78];
- CADTH: HTA Excel Tools [79];
- Alberta Health: *Reusable & single-use medical devices standards: Standards for the reprocessing of reusable medical devices and for the use of single-use medical devices in all health care facilities and settings* [80];
- Public Health Ontario: *Best practices for cleaning, disinfection and sterilization of medical equipment/ devices in all health care settings, 3rd ed.* [81];
- European Patients' Academy on Therapeutic Innovation (EUPATI): *Health Technology Assessment process: Fundamentals* [82];
- WHO: *Health Technology Assessment of Medical Devices* [83];
- National Information Center on Health Services Research and Health Care Technology: *HTA 101: Introduction to Health Technology Assessment* [84];
- Ziken International: *Guide 3: How to procure and commission your healthcare technology* [85];
- Accreditation Canada: *Home Care Services, Ver. 14* [49];
- The Canadian Medical and Biological Engineering Society: *Clinical Engineering Standards of Practice – 2014* [86];
- Health Canada: Consumer Product Safety Program (CPSP) [87];
- *Clinical Engineering Handbook, 2nd ed. [*88];
- FDA: MAUDE reporting database [89];
- Medicines and Healthcare Products Regulatory Agency: *Managing Medical Devices: Guidance for health and social care organisations* [90];
- Emergency Care Research Institute (ECRI): *2021 Top 10 Health Technology Hazards* [91];
- ECRI: "Report a Device Problem" database [92].

2.4.3 Matching Devices, Supplies, and Medications to the Environment

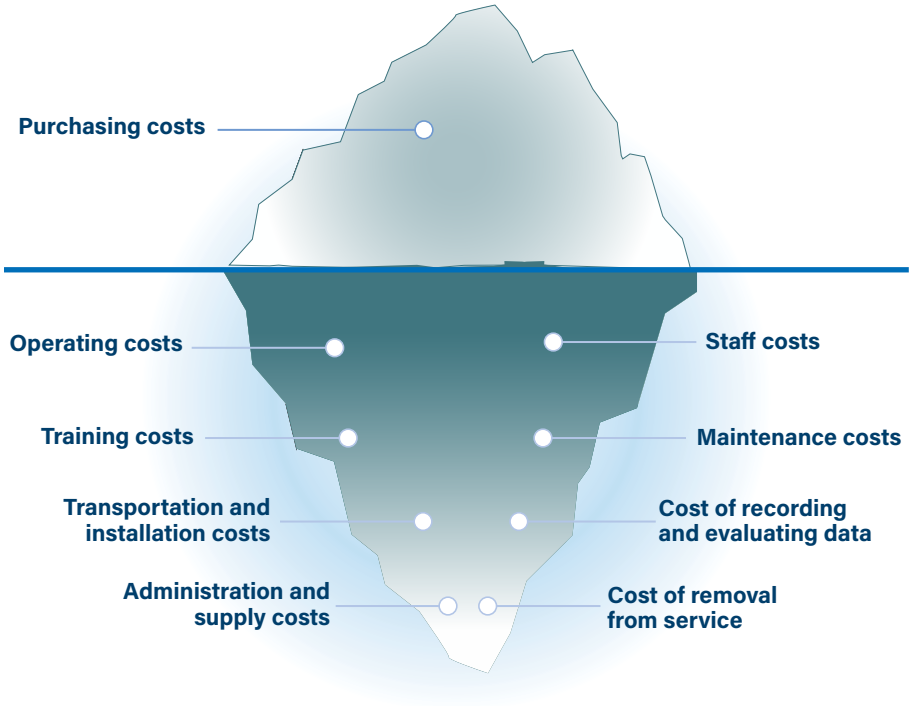
The initial purchase cost of any health technology is only a small fraction of its long-term operating cost [85]. The costs of installation, training, supplies, maintenance, and repairs – known as life cycle costs – accumulate over time (see Figure 6). Because these life cycle costs can accumulate so quickly, careful research and analysis is needed to select the best product for specific applications. Of course, the initial motivation for purchase is meeting a clinical need, so a careful and complete inventory of necessary features, functions, and relevant supplies and accessories is necessary to begin the full life cycle HTA. In the home and community environment, specific environmental, waste, and other constraints must also be accommodated, as described in Section 2.2.

In a thorough HTA, several key aspects must be considered:

- All clinical requirements are correct and validated for the intended use;
- The manufacturer or vendor has disclosed all pricing, maintenance, repair, and related costs;
- An adequate method is available – or is in the process of development – to verify that the product and ancillary supplies, accessories, and medications meet the published specifications;
- All foreseeable preventive maintenance, repair, and warranty considerations are documented and accurately budgeted at the outset;
- All user, maintenance, and repair documentation, tools, and supplies are provided and all related costs, including technical staff training, are identified;
- The technology's suitability at meeting human factors needs and limitations of home and community care users has been assessed; and
- The technology and ancillary supplies, accessories, and medications can eventually be safely disposed of.

Each home and community care agency should have a competent HTA process or program that can analyze and account for their local, regional, and provincial or

Figure 6: Illustration of the hidden life cycle costs of medical equipment



territorial internal and external home and community care environmental features and limitations, and incorporate them in the HTA processes. For example, products for use in remote areas, with a low population density or unreliable electricity and water supply or sanitation may need to be more robust and easier to maintain and repair than similar products selected for an urban setting.

Responsibility for the selection, procurement, deployment, warehousing, critical supplies, etc., of health technologies also needs to be clearly delineated. For example, should the responsibility lie with one or more referring physicians or clinical caregivers or with a purchasing agent? Should it be the home and community care agency, the rental/leasing company, or the provincial or federal funding agency who is responsible?

HTA processes and programs for home and community care products should ensure that they meet the typical or baseline internal and external environmental demands.

2.4.4 Human Factors

Each home and community care setting is unique, necessitating a site assessment to ensure that the required resources – safety, space, access, electrical supply, water supply, sewage and toxic/biological waste disposal, storage, communication, and related resources – are available to be able to use the intended home health technologies. Each client is also unique, with strengths and limitations in terms of cognition, mobility, visual and hearing acuity, and verbal communication, all of which may vary during the course of home and community care, because of effects of disease, medications, stress, or other complications. Many issues related to site-specific HTA needs are identified in the following sections and in Section 2.2.

2.4.5 Management of Dangerous or Recalled Products

Every year, thousands of devices, medical supplies, and medications are recalled. Hazards are reported in the press, in manufacturers' notices, and in government

reports and databases. Health Canada, FDA, and other organizations manage various programs for reporting problems with products. However, the majority of the regulations and reporting methods focus on traditional hospital and clinical settings. Where mandatory or voluntary reporting exist, the obligations do not focus on home and community care clients and caregivers.

Further, problem reports and forensics analysis for hospital and clinical settings assume that the environments of use are sufficiently engineered and routinely managed. Home settings are rarely as robust, stable, consistent, or safe. Problems with products may not be noticed or may be masked by blaming environmental or use failures rather than product deficiencies. In addition, the reports and notices about product failures and recalls are not promulgated to home and community care providers. To make up for this, HTA processes should include active research to identify, remediate, and prevent client and caregiver risks and harm.

Parties should negotiate appropriate contract terms at the procurement phase regarding warranty, parts, service, field replacement, or product upgrades. Manufacturers' standard form commercial purchase/sale documents may include undesirable, limiting "as is" clauses, disclaimers about "fit for purpose", and language stipulating that the sale contract "supersedes any prior written or oral representations" about the product.

Very few medical products are defect free through many years of use. Device-issuing agencies should develop ways to identify and act on information about product failures and recalls in a timely way. Although manufacturers have an obligation to either notify device owners or to report problems to Canadian, US, or European regulatory agencies, or all of them, there is a risk that problems could be improperly attributed by manufacturers to user error and may be deleted from public reports.

In addition, people with or without clinical experience may not be able to properly analyze, identify, describe, or document product failures, injuries, or deaths, which also contributes to the gap in reporting.

Finally, manufacturer acquisition and bankruptcy, brand acquisition, product resale, and failure to register purchase can make it difficult or impossible for the manufacturer to provide timely notification to the home and community care agency when a recall or hazard report is issued. Unless the problem is reported in the media, the responsible agency may not know it exists. Screening of manufacturer websites and reports from Canadian, US, European, and independent programs such as the one run by ECRI may help identify important problems quickly.

2.4.6 Manufacturer Documentation

Most medical equipment, supplies, and medication are intended for use in hospitals. The expectation is that they are operated and managed by licensed clinicians – physicians, nurses, or allied health professionals. Because licensed clinicians are rarely, if ever, present in the home care environment, manufacturers may attempt to limit liability by documenting restrictions, waivers, and admonitions in print and on their websites. In addition, durable medical equipment such as beds, ventilators, monitors, wheelchairs, and lifts are often reclaimed and reused at different homes over many years. Unused or surplus supplies and accessories may also be re-deployed to other homes.

Home settings vary, and contamination with body fluids, mould, or chemicals that exceed hospital norms or infestation by pests can occur. Manufacturers rarely, if ever, document methods to detect or manage such problems, which the device-issuing agency must take into account when assessing health technologies. A thorough HTA may identify one product's superiority over others for home applications or identify novel costs, training, or procedures necessary for successful, safe, and affordable procurement and deployment.

Note that the examination of product features, limitations, and manufacturer stipulations must be done before procurement, during the HTA process. This may be the only opportunity to identify exceptional costs, labour, or risks, to develop affordable and sustainable mitigation processes, or to negotiate special terms and conditions with the manufacturer to reduce or eliminate potential problems.

2.4.7 Developing Pre-purchase Safety and Quality Assurance Processes

Because most manufacturers of medical devices, supplies, and medications do not explicitly design or document products for home use, the onus of managing safety and efficacy for initial and ongoing home use falls on the home and community care agency. These responsibilities can and must be anticipated and remediated effectively during the HTA process to avoid unplanned risks and problems.

Quality, safety, reliability, affordability, and other desirable features of medical products cannot easily be retrofitted into products, especially after purchase. All the expected and necessary desirable features should be identified and understood prior to purchase. Inevitably, some limitations or deficiencies may exist, but once identified, remediation analysis and decisions should be made or another product considered or recommended instead.

2.4.8 Developing Initial Safety and Quality Assurance Processes for Every Product

Every medical device, supply, and medication is different. Each manufacturer uses discretion and ingenuity to differentiate their products from their competitors', and no two brands of oxygen concentrator, nebulizer, or medication, etc., are exactly the same. Even within brands, model-to-model differentiation, market positioning, and pricing can lead to significant differences.

Before purchasing a product, a device-issuing agency must assess and analyse the product's strengths, weaknesses, and ongoing support requirements. The agency may have little or no choice about purchase and deployment because provincial and territorial regulations or clinician prescriptions leave little latitude; in such cases, the agency must match the requirements or possibly forego the contract.

If, after careful HTA, significant concerns about a specific brand and model become apparent, some provinces or territories and clinicians may be open to appeal, discussion, or suggestions for alternative products. Successful resolution may depend on the quality and completeness of the HTA process.

From a liability perspective, manufacturers often focus on ensuring the product leaves their possession in compliance with good manufacturing practices (GMP). Once the product leaves their factory, the owner/user becomes part of the liability chain. If the buyer does not confirm safe and complete operation on receipt, the responsibility for defects may be on them and not the manufacturer.

"First do no harm" is a good rubric to follow; it guides and informs prudent actions rather than allowing home and community care agencies to assume that products are intrinsically safe when received.

2.4.9 Master Records for Each Product

Every product's life cycle starts when the procurement decision is made. Whether they ultimately accept or approve the purchase of a product or device, the device-issuing agency should create a permanent paper or electronic file for all relevant documentation. This file is an initial master record for each product. In the health technology management (HTM) process, every subsequent instance of purchase of the equipment, supply, or medication should be recorded and retained in the traceability system (see Section 2.5).

A product or device master file should be created and maintained for every serial-numbered device and accessory that is purchased. For devices and accessories, documentation related to ongoing testing, maintenance, approved repair, update, damage, warranty repair/replacement, and eventual disposal should be maintained in this device master record. This master file of all records is important in case of product changes or manufacturer sale or mergers.

For durable devices and accessories, a permanent asset control identifier tag or indelible marking should also be attached to the product, because many manufacturers, brands, and models use similar or identical serial numbers (e.g., a serial number starting with 00001 may be used by most manufacturers when they launch new products) [93, 94].



"Electromedical devices wear out, and new problems, risks, and vulnerabilities accumulate."

2.4.10 HTA Quality Assurance Considerations

The virtues, necessity, and best practices of quality management are well documented in CAN/CSA-ISO 9001. Although HTA may not seem a likely target of such quality management practices, several opportunities and needs should not be overlooked. One example is the constant evolution of health and home health technologies, with more of such technologies used outside of hospitals to provide important health care. Electromedical devices wear out, and new problems, risks, and vulnerabilities accumulate. Last year's home oxygen concentrator may require service twice per year, but next year's model may need an annual service. The costs and reliability of the newer oxygen concentrator may ultimately suggest changing the HTA acceptance criteria for such devices and, as appropriate, may support removal and replacement of the now-obsolete device. In HTA, such decisions are not binary yes/no considerations. A fresh HTA of an older oxygen concentrator may identify useful niches for use, for example, as a backup device in a remote location or as a short-term loaner while periodic repairs are made to the primary device.

In all cases, the CAN/CSA-ISO 9001 framework of senior management responsibility and accountability, attention to identification and reduction of defects and errors, and assurance of the verification and validation for all processes and methods serves to help assure optimal value for home and community health care technology investments.

There are many similarities between quality assurance processes for HTA and for HTM. These are both covered in detail in Section 2.5.8.

2.4.11 Gaps and Recommendations

The process, practice, and discipline of HTA is a primary foundation for assuring safe, efficient, and cost-effective medical care. Skipped, incomplete, or inappropriate HTA inevitably leads to problems. Nevertheless, established HTA methods have largely focused on hospital applications, where the environment is relatively controlled (as described in Section 2.2) and access to trained technical staff is regulated.

Home and community care relies on safe, effective, reliable, and reasonably affordable technologies in locations that can be quite remote and inhospitable compared to hospital settings. Because home and community health care are growing segments of Canadian health care, there exists an opportunity to develop best practice guidelines or standards for HTA to assure optimum health technology selection for home and community care settings.

Components of such a national HTA guideline or standard should include:

- A consistent core description of HTA processes as applied to home and community care settings, placing special emphasis on internal and external environmental limitations and challenges, and the human factors needs of people without clinical or technical experience;

- A clear focus on the life cycle costs and labour for supporting technologies outside of the traditional hospital setting, including relevant aspects of supplies, accessories, medications, installation, training, troubleshooting, maintenance, and repair;
- An enduring and consistent process to ensure that manufacturers are obligated to provide necessary repair and operational parts, user and service documentation, and warranty fulfillment resources for safe, affordable, and clinically effective use;
- A sensitivity to and incorporation of likely site-specific modifications that a particular health technology may require in the home or community care setting, such as special electrical or water provisions, waste management, and supply chain support for all consumable items, routine maintenance, and repairs;
- Consistent documentation of HTA process, including appropriate senior management oversight, review, and intervention;
- Consistent and continuous HTA process improvement, based on CAN/CSA-ISO 9001 quality management methods, which require that changes in device specifications, changes in home and community care applications, and ongoing maintenance and failure histories are all used to routinely improve each product's HTA as a means of maximising safety, reliability, and clinical efficacy; and
- Frequent, regular, and consistent reviews of appropriate Canadian, the FDA/MAUDE and ECRI databases to avoid acquiring products with pre-existing recalls or other deficits, and a periodic review of those sources on a timely basis.

Although it may not be feasible to initially create a single national guideline or standard, it may be an opportunity to bring stakeholders together to begin harmonizing provincial HTA regulations, standards, and practices toward the goal of establishing national best practices for HTA for home and community health care.

2.4.11.1 Matching Devices, Supplies, and Medications to the Environment

Gap 1: In addition to a lack of clear or complete home and community care environment standards or regulations, there is a lack of guidance on how to support acceptable and safe performance of health technologies in the intended environment.

Recommendation 1: Guidance on how to support acceptable and safe performance in the actual environment of home and community care needs to be developed and organized by categories/types of technologies (e.g., a ventilator has different environmental requirements than storage of chemotherapy medicines). In addition, the RAI-HC assessment methodology [28, 95] may help inform or serve as a template for such guidance.

Gap 2: There is a lack of clarity on the delineation of responsibilities for the selection, procurement, deployment, warehousing, critical supplies, etc., of health technologies.

Recommendation 2: Roles, responsibilities, and authorities are clearly documented in writing, and are consistent across all provinces and territories, in order that they be actionable and enforceable. The definition of roles/actors must also be consistent across all provinces and territories. If exceptions are needed for particular technologies, they are limited and consistent across provinces and territories (e.g., if pain or morphine pumps have unique profiles, or if certain hospice or chemotherapy protocols represent exceptions).

Gap 3: Assessment of appropriate HTA processes needs to include packages of associated home health technologies required for treatment (e.g., nebulizer, tubing, masks, and medications must all be supplied and be compatible for safe care, and with the home environment in terms of storage, refrigeration, freezing, or space requirements).

Recommendation 3: Packages and assemblages are clearly identified. Acceptable, unacceptable, or optional substitutions or exclusions must be clear to all parties. A home or community care client should not be a position where, for example, an IV pump is delivered without sufficient cassettes, tubing, or medications.

Gap 4: There is no clear delineation of who is responsible for remediating internal environments in terms of supply of electricity and water, sewage and waste disposal, storage, security, access, and communication services. If the burden falls solely on the client and their family, important safety risks may be ignored.

Recommendation 4: Necessary home and community care environmental modifications cannot be overlooked or ignored. If electrical power updates are needed, it needs to be determined who pays, who arranges, who manages, and who signs off on the work to ensure it meets or exceeds minimum required criteria.

2.4.11.2 HTA of Human Factors

Gap: There is a lack of complete and appropriate human factors standards for home and community care applications.

Recommendation 1: Site and client assessments are made to facilitate safe and effective care.

Recommendation 2: If product substitutions or field adjustments are needed, and feasible, all details are documented and approved before leaving technology or supplies with the client and their families and caregivers.

Recommendation 3: Home and community care provider roles are clearly delineated, and personnel with the appropriate training and skills conduct all aspects of delivery, installation, training, and troubleshooting, and document these aspects.

Recommendation 4: Any gaps, such as missing accessories, shortages of items, resupply logistics, schedules for follow-up visits, training, audits, safety checks, scheduled product service, or other aspects are affirmatively managed and documented before leaving technologies with the client and their families or caregivers.

2.4.11.3 HTA Process for Management of Dangerous or Recalled Products

Gap: Health Canada and the FDA/MAUDE systems do not have extensive coverage of problems reported with home and community care devices or applications. Standards that focus on hospitals or clinical practices may not describe or thoroughly assess products designed for or used in home and community care settings.

Recommendation 1: All recalls, hazard reports, or other known deficiencies are identified from manufacturer, government, or other reliable resources, and a decision is made whether this may affect the product under consideration with respect to the home environment, the client, their family, their caregivers, etc.

Recommendation 2: If specific remediation is identified, an assessment is conducted to determine if it is feasible.

Recommendation 3: If there is a new recall or hazard for existing inventory, a process is initiated to ensure the affected products are managed to help assure client and caregiver safety as well as clinical efficacy.

2.4.11.4 HTA of Manufacturer Documentation

Gap: Manufacturer documentation, specifications, and labelling are rarely targeted to home settings. In fact, manufacturers document restrictions, waivers, and admonitions in print and on their websites. Documents may contain broad cautions such as avoiding using near fluids or restricted temperature ranges that simply cannot be controlled at home. Stipulations about using manufacturer-certified or manufacturer-trained technicians or repair at factory-authorized sites, or using manufacturer-labelled tools tests, or supplies may be infeasible due to cost, availability, geography, or other practical constraints. Manufacturers are also unlikely to foresee or document risks that may be unavoidable in the home care setting.

Recommendation 1: Manufacturer documentation for each product is inspected for warnings that may affect home care settings, clients and caregivers.

Recommendation 2: A suitably qualified individual makes sure that formal pre-procurement processes are developed and followed.

Recommendation 3: Unless manufacturer documentation is adequate, a suitably qualified writer develops local, agency-specific alternative procedures that support adequate remediation.

Recommendation 4: Documented training and audit procedures are planned and initiated to make sure that all affected personnel can and do follow these procedures.

Recommendation 5: Senior management approves all procedures and cost estimates for compliance before approving procurement.

2.4.11.5 HTA for Developing Pre-purchase Safety and Quality Assurance Processes

Gap 1: All health technologies and products are subject to risks and variable manufacturing, distribution, storage, labelling, handling, etc. Liability and client safety assurance fall on the device-issuing agencies as the actual owner or intermediary owner of the products. Product liability, responsibility, and risk are amplified and perpetuated if the home health technologies are allocated to many different home and community care sites and users.

Gap 2: The manufacturer may not provide adequate documentation and support to the device-issuing agency other than mandatory warranty services, which may diminish once they have shipped or delivered the product;

Gap 3: Quality programs and procedures, by their nature, evolve. Product features, uses, repairs, and wear characteristics change with time, requiring timely changes to documentation as appropriate.

Recommendation 1: The agency develops, and senior management approves, written pre-purchase quality assurance policies that encompasses all products. Each policy covers customer complaints, atypical product failures, and incidents involving serious injury or death, and includes appropriate reporting to government and manufacturers. All such quality assurance policies include continuous quality assurance concepts commonly followed in all health care sectors, such as CQI, total quality management (TQM), statistical process control (SPC), ISO9001, GMP, etc.

Recommendation 2: If the product is completely new to the agency, the agency plans and conducts bench and site testing to identify potential problems. In addition, the device-issuing agency conducts independent interviews of other comparable users to identify use, training, maintenance, warranty, supplies, parts, or medication-specific issues.

Recommendation 3: All vendor product documentation (written and online/electronic) is carefully analyzed to understand proprietary and/or generic accessories, supplies, medication, or other recommendations or explicit requirements to make sure that the product can be successfully supported in the intended home and community care application.

Recommendation 4: Senior management reviews and approves each procedure, evaluation, and assessment in advance of product purchase.

2.4.11.6 Developing Initial Safety and Quality Assurance Processes

Gap: From a liability perspective, manufacturers focus on ensuring the product leaves their possession in compliance with GMP. After the product leaves the factory, the owner/user becomes part of the liability chain. Health technologies and products can have defects caused in manufacturing, and also during shipping, storage, handling, etc. If the buyer assumes that the product is safe when they receive it, and does not confirm safe and complete operation, then they may bear disproportionate responsibility for defects or damage.

Recommendation 1: Device-issuing agencies establish product-acceptance criteria in advance, in writing. These criteria are approved by senior management of the agencies.

Recommendation 2: All labelling, documentation, accessories, and any testable features (and methods) are clearly identified in writing by the manufacturer.

Recommendation 3: Product acceptance criteria also identify minimum qualifications and authority of the personnel who are authorized to perform and document tests of all relevant safety and performance procedures.

Recommendation 4: Without exception, every device, supply, or medication is inspected upon receipt by the device-issuing agencies to help assure full compliance with specifications and purchase agreement details.

The device-issuing agencies fully test devices and their accessories prior to release to clients to help assure proper and safe operation. Safety processes are developed to help assure that no untested products are inadvertently sent to patients prior to such testing.

2.4.11.7 Master Records for Each Product

Gap: GMP obligates manufacturers to track devices and accessories by serial number, and supplies and medications by lot/batch/Unique Device Identification (UDI) numbers. While this is the most logical and viable way for the device-issuing agencies to track and manage products, many manufacturers use the same numbering schemes, so devices and accessories need permanent identification unique to the home and community care agency.

Recommendation 1: A paper or electronic master file is created for each approved product. All purchase documentation, purchase orders, requests for proposal, requests for information, bid documents, product specifications, and warranty/service or replacement agreements as well as details on ongoing testing, maintenance, repairs, updates, damage to, and eventual disposal are included in the master file. This master file and any authorized exceptions are reviewed and approved by senior management.

Recommendation 2: A unique, indelible asset control identification is attached to every durable device and accessory.

2.4.11.8 HTA Procedures, Practices, and Documentation Quality Assurance

Gap: Product features, uses, repairs, and wear characteristics change with time, requiring timely quality documentation changes by the device-issuing agencies as appropriate.

Recommendation: All HTA procedures are reviewed regularly by the device-issuing agencies, with senior management approving each review, in writing.

2.5 Health Technology Management for Safe Home and Community Care

2.5.1 Overview

Case Description: Health Technology Management Challenges

On discharge for treatment for COVID-19, the hospital provided Akira with an oxygen concentrator and a portable pulse oximeter, for daily use, as well as a small portable liquid oxygen system that allows him to leave his apartment and go shopping. Without oxygen from the concentrator, Akira's saturation drops, leading to extreme confusion. There is no one nearby that can check, repair, adjust, or refill the liquid oxygen system and the oxygen system is often empty when Akira needs to go out. Although oxygen is considered to be a drug, this problem with the oxygen system is a combination of drug, device, and supply issues. Nobody seems to know who is responsible for assessing and fixing the problem, and Akira is increasingly afraid of going out and collapsing, and as a result is becoming more reclusive.

Health technology management (HTM) is the process of supporting safe and effective use of medical devices, supplies, and medications throughout their life cycle. For reusable health technologies, for example, devices, accessories, and some supplies, the life cycle may be months or years of repeated use. In the case of mechanical beds, wheelchairs, and patient lifts, the safe and useful lifetime may exceed a decade. Some accessories, for example, power supplies or control pendants, may only last a few years, and reusable or semi-disposable items such as manual suction pumps or alternating pressure pad mattress overlays may only last a few months. Suction tips and other such disposable items might be reused for a short time if their use is infrequent and not too demanding. Many other supplies, such as airway tools, urinary catheters, or gloves, are strictly single-use only. Further, supplies

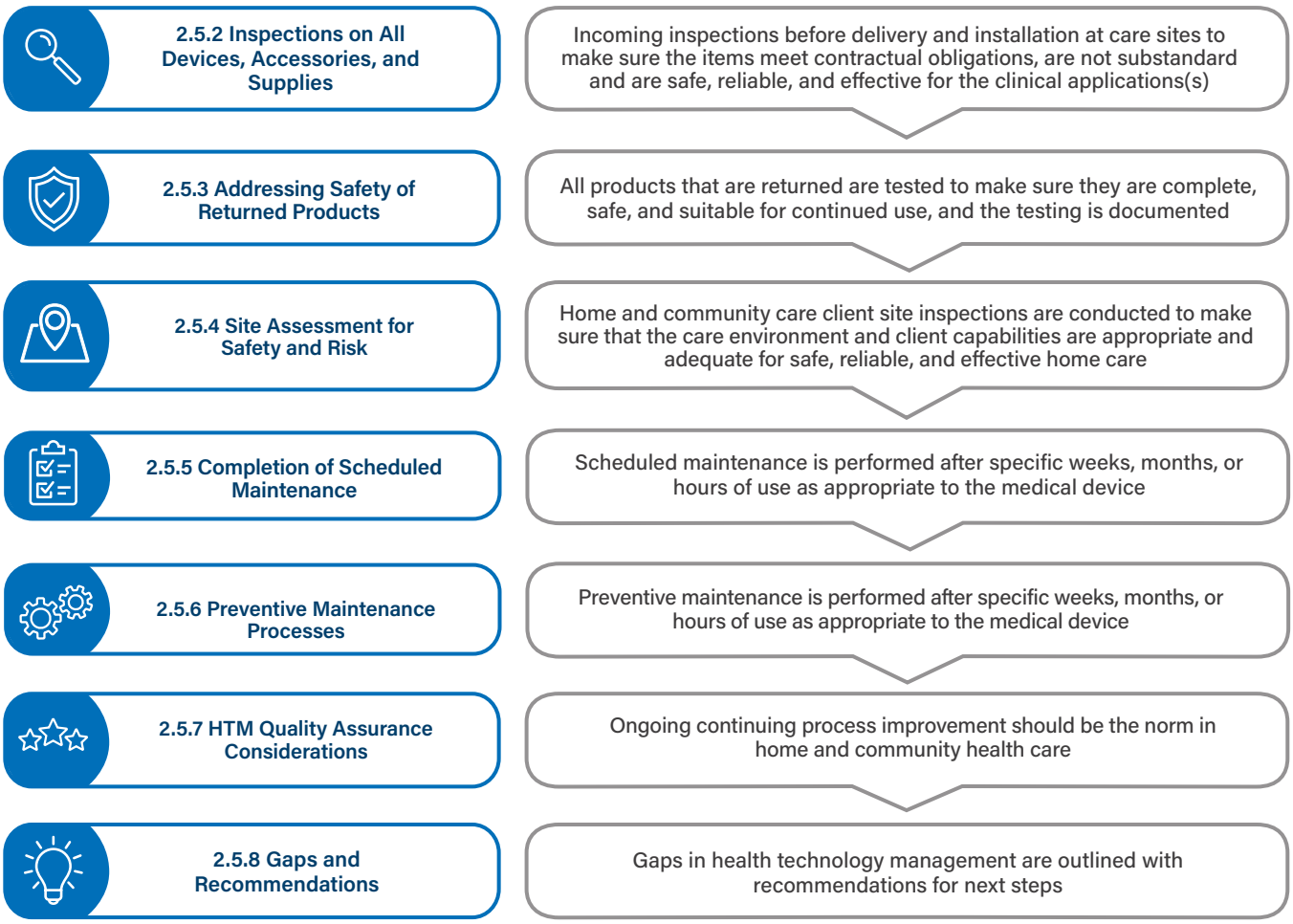
distributed in sterile packaging must be discarded once the package has been opened.

All medications have specified storage, reuse, and expiration characteristics that must be managed. In addition, some custom-blended medications and parenteral feeding solutions are not packaged with assured sterility. These need to be carefully stored, possibly refrigerated, and used relatively quickly prior to expiration dates.

Regardless of the length of a product's life cycle, home care or community care clients may not be trained or equipped to understand or manage complex technologies, supplies, and medication beyond go/no-go decisions. While many people can change a standard consumer-grade battery, wash and dry a nebulizer cup, replace an easily accessible external air filter, or reorder and discard an expired medication, others in the home and community care environment may have cognitive, mobility, sensory, memory, or other limitations that prevent completing such tasks.

The research conducted for this report did not identify a body of best practices or standards that addresses HTM in home and community care. Fortunately, there is a large body of literature on HTM of medical equipment and supplies in hospitals. The Clinical Engineering Standards of Practice – 2014 is aligned with global norms [86]. More Canadian documentation as well as sources from the United Kingdom, WHO, and published book chapters are cited in Section 2.5.9.

Figure 7: Summary of the topics covered in Section 2.5



2.5.2 Inspections of All Devices, Accessories and Supplies

Although manufacturers and distributors follow regulatory guidelines for assembly and distribution, incorrect and incomplete assembly or storage or shipping issues can result in sub-par products. Sometimes the problems are subtle, such as, software or hardware revisions that no longer match the labels or accompanying instructions. Sometimes manufacturers rely on third parties for parts, and batches may be inferior or incorrect for the intended application. Either way, we cannot assume that medical equipment and supplies are always safe and function as intended. Documented inspection and, where applicable, documented assembly, testing, and adjustment are required, not least when providing equipment and supplies to home care clients.

Health care technologies used in home and community care are often returned to the issuing agencies and reused. The health care technologies remain the property of the provincial and territorial health ministries, the purchaser, or the supplier. This makes good fiscal sense, but it also means that the technology-issuing agency must check that each product and the related supplies and accessories are correct, complete, safe, and in good working order before delivery to another home or community care setting.

All medical equipment must be fully tested and undergo safety and performance inspection (SPI) by qualified personnel before delivery and installation in the client's home. As explained in Section 2.4, the responsibility for providing safe and efficacious products lies with the device-issuing agency, before the first client's use and for every other person's use thereafter.

Development and management of such HTM procedures and practices requires and presumes that the agency has hired appropriately trained, qualified, and equipped technicians and engineers for that purpose.

2.5.3 Addressing Safety of Returned Products

Health care technologies require the same sort of scrutiny as a rental car or tool, as they can also be damaged during use or transport. In addition, a home care client may have accepted, adapted, or tolerated product deficiencies. Leaking water gaskets, overheating power supplies, noisy operations, or erratic alarms may not seem out of the ordinary to non-technical users. In addition, some products may be subject to recalls, periodic updates, or refurbishment. A careful inspection, and possibly testing, may be an important documented step before any other tasks are undertaken.

2.5.4 Site Assessment for Safety and Risk

Because every home may be unique, site-specific risk assessment and remediation is often necessary. *HSO 35001:2015:2015 – Home Care* identifies the obligation to help assure and manage a safe home care environment as ROP 14.2, and specifies that a home safety risk assessment should be conducted to enhance the safety of clients, families, and caregivers [49]. The requirement for controlling and creating a safe care environment is also in many other Canadian and international accreditation standards. This concept is broadly referred to as the "Environment of Care" by the Joint Commission [96]. Specific environmental issues, risks, and standards are discussed in Section 2.2.

To develop, maintain, and manage a sound health technology program, a qualified and trained technician – a clinical engineer, clinical engineering technologist, certified health technology manager, or factory-certified technician – should assess each home and community care site. The technician should be trained in health care technology support and know how to safely operate these systems in home care environments. Their assessment should identify risks and potential problem areas for mitigation. Examples could include worn-out electrical outlets that do not retain plugs or cause intermittent power failures when devices are repositioned. Replacement of wall outlets is a largely affordable way of providing a more reliable operation. Some home settings do not have sufficient or secure storage space for supplies or medication, but providing modestly priced shelving or lockable storage cabinets could overcome such problems. With substantial new telehealth and telemedicine expansion as a result of the COVID-19 pandemic, provision or repair of wired or wireless Internet access may also be a necessity. Other internal and external environmental risk examples are discussed in Section 2.2.

The home and community care employee(s) conducting the site visit and audit must be competent and qualified to perform the site evaluation. The person should have clear instructions on how to report problems, when and how to proceed with product provision, and how to arrange necessary remediation approval and action, including, if approved, contacting approved, qualified tradespeople, such as plumbers or electricians.

If a home and community care client is unable or unwilling to accommodate recommended changes, senior management of the home and community care agencies should explain the risks and make reasonable attempts to mitigate the identified issues. Senior management should know and approve when and where exceptions are made that may increase risk to the home care client.

2.5.5 Completion of Scheduled Maintenance

Some products and technologies require relatively simple maintenance that can be conducted by the home care client or caregiver user. Devices and accessories may require periodic washing and drying, simple air filter cleaning or replacement, or replacement of commonly used batteries. For example, most oxygen concentrators have an easily accessible external air filter to prevent dust from entering the actual oxygen generation subsystem.

Scheduled maintenance is conducted by trained technicians, at regular intervals or as one-time tasks, and includes inspections, adjustments, regular service, and planned shutdowns that are given deadlines [97].

Determining the optimal and least disruptive interval for scheduled maintenance may not be easy. Home environments may be relatively harsh compared with hospital settings, and detrimental to medical technologies and products. On the other hand, the equipment may be used less frequently and relocated less often than in a busy hospital. Thus, determining intervals and procedures for scheduling maintenance of home and community care products may need to be customized to maximize product safety, reliability, and durability.

Making technology management decisions like these generally requires access to service histories to enable careful and complete statistical analysis. Computerized maintenance management systems (CMMS) have become common in hospitals, and the device-issuing agencies that manage large fleets of devices may find CMMS more efficient and effective than paper- or spreadsheet-based methods.

2.5.6 Preventive Maintenance Processes

Some medical equipment requires preventive maintenance, by technical specialists, to support safe and reliable operation. Internal lubrication, part replacement or renewal, or specialized calibration tasks may be recommended. For example, the control actuators of many electric and manual beds require regular lubrication for smooth and safe operation. Most oxygen concentrators require periodic replacement of the “molecular sieve” components inside the device, or little or no oxygen will be generated.

Home health technologies may be in use in environments that are harsh and detrimental to equipment compared with hospital settings. Likewise, they may be operated and relocated less frequently than in a busy hospital. As such, the intervals and procedures for preventive maintenance need to be customized to maximize product safety, reliability, and durability for home and community care uses.

As for scheduled maintenance, making technology management decisions like these requires access to service histories to enable careful and complete statistical analyses. As mentioned in Section 2.5.5, CMMS have become common in hospitals, and the device-issuing agencies that manage large fleets of devices may find such systems more efficient and effective than paper- or spreadsheet-based methods. Failure to provide competent oversight, management, and execution of preventive maintenance of all home health devices, be it a hospital bed or a ventilator, may void warranties and also lead to unsafe, uneconomical, unreliable, and unsustainable product behaviours. For example, a simple compressor nebulizer can become a fire hazard if the wiring is inadequate or an infection hazard if filters are not cleaned regularly or if the tubing has started to accumulate water condensate.



"Management of certain home health technologies in community care settings may differ from that in an individual home setting, so HTM best practice guidance or standards may need to accommodate both situations."

2.5.7 HTM Quality Assurance Considerations

In health care, ongoing continuing process improvement is the norm. Process improvement can also be applied to home and community care. CAN/CSA-ISO 9001 provides a universally accepted quality management methodology for all forms of health care [52]. Other viable quality assurance systems include CQI [98], TQM [99], Kanban [100], and SPC [101]. Some systems are designed to be used on their own, and others may be combined to meet local needs [52]. The goal of all these approaches is multifold, including that:

- Defects do not persist, but are routinely identified and reduced;
- Quality processes follow documented procedures;
- Quality processes are valid for their intended application;
- Quality processes evolve and constantly improve outcomes; and
- Senior management is aware of and responsible for quality assurance.

For example, non-invasive blood pressure monitors can be issued with a request that clients take daily blood pressure readings and bring the results to their next medical appointments. Such monitors have internal rechargeable batteries sealed inside them that cannot be easily replaced when they begin to fail; this means the device can perform erratically and give inadequate results, making it impossible to keep a full record of blood pressure trends. Setting up a periodic battery replacement process for any home health device with internal batteries would address this problem. For example, clients could be asked to bring their monitor to each medical appointment, and the batteries could be evaluated or changed or the unit could be exchanged for one with fresh batteries.

2.5.8 Gaps and Recommendations

Home and community care requires an HTM best practices guideline or standard that focuses explicitly on their needs. The following are useful sources:

- *Clinical Engineering Standards of Practice – 2014* [86];
- *Guide 4: How to Operate your Healthcare Technology Effectively and Safely* [93];
- *Guide 5: How to Organize the Maintenance of your Healthcare Technology* [94];
- *Home Care Services, Ver. 14* [49];
- *Clinical Engineering Handbook, 2nd ed.* [88];
- *Managing Medical Devices: Guidance for health and social care organisations* [90].

The two Ziken guides, Guide 4 [93] and Guide 5 [94] and the guidance from the United Kingdom [90] have common public domain uses, and may be easier to adapt. Older US Army and US Air Force manuals that cover similar topics may also have public use status.

Management of certain home health technologies in community care settings may differ from that in an individual home setting, so HTM best practice

guidance or standards may need to accommodate both situations. In community care settings, for example, it may be necessary to address novel infection prevention and control, default start-up settings, and post-use cleaning and configuration differently from home care settings. This applies to devices, such as infusion pumps, blood pressure monitors, and medication nebulizers; to reusable and disposable supplies, such as ventilator humidifiers, oxygen nasal cannula; and to PPE, such as masks and face shields. It may also apply to certain bulk medications and dispensers for drugs in pill, powder, or liquid form.

To support such an effort, development and adoption of a Canadian HTM nomenclature would be extremely helpful. The COVID-19 pandemic highlighted the lack of a robust way to describe and identify products. Too many similar products have been assigned conflicting names, making identification, prescription, acquisition, recalls, management and, ultimately, proper disposal difficult or impossible. For example, ventilators are sometimes mistakenly called respirators or resuscitators or even reanimators. A consistent, hierarchical nomenclature system would solve such problems, such as, "Ventilator, Emergency", "Ventilator, Pediatric", "Ventilator, Neonatal", "Ventilator, ICU", "Ventilator, Portable", "Ventilator, Non-Invasive, Positive Airway Pressure", etc. WHO has a high-priority project that might help Canada fill this void [102]. The two existing systems, the Universal Medical Device Nomenclature System (UMDNS) and the Global Medical Device Nomenclature (GMDN), are incomplete and incompatible, and both have copyright constraints.

Another need for guidelines or standards would be "clinical use cases". Specific clinical home care applications can be grouped together with focused best practices. For example, home care oxygen concentrator management involves filter replacement, humidification, and oxygen concentration and flow rate verification, and periodic major product refurbishment. Home chemotherapy infusion, home pain management infusion, home COVID-19 pulse oximeter, and ventilator care are other examples of well-known non-treatment-specific applications that could benefit from best practices. Such guidelines or standards need not be overly brand-, model-, or situation-specific, but can set minimum recommended best practices based on representative clinical use cases. An accepted and documented open-source Canadian clinical care book, *Clinical Procedures for Safer Patient Care* [103], could be used for many of these use cases and could also serve as a template to develop HTM guidance for other common clinical use cases. Rather than attempting to write manuals for all possible scenarios and technologies, the home care industry, together with appropriate government bodies, should collaborate to identify high-risk, high-cost, and high-benefit home care use cases for such an effort.

2.5.8.1 Inspections of All Devices, Accessories, and Supplies

Gap 1: New medical equipment and supplies are received with defects that could cause serious harm or death. While it is standard practice for hospitals to inspect all incoming medical products, there are no published standards to do with managing medical products in home and community care settings.

Recommendation 1: Adapt well-known hospital best practices to home and community care uses. Documented incoming and purchase inspection procedures are needed for every product, by serial/lot/batch number, with each procedure approved by senior management.

Gap 2: There are no published standardized guidelines on documenting SPI procedures for home and community care in Canada.

Recommendation 2: Develop documented SPI procedures prior to use, with senior management of the device-issuing agencies approving each procedure.

2.5.8.2 Addressing Safety of Returned Products

Gap: Many home health technologies are returned to the issuing agency for reuse. It would be imprudent and risky to assume all these products were safe for immediate reuse, irrespective of client complaints, as home care clients and caregivers without clinical experience may have been unaware of and tolerated product deficiencies and not noted any problems.

Recommendation 1: Conduct and document SPI procedures after the return of any product from use in a home or community care setting.

Recommendation 2: Assess and analyze causes of problems and determine appropriate remediation procedures.

Recommendation 3: Establish an appropriate expiration date for the SPI for each product and record this on the relevant SPI documentation. Recency of SPI procedures might be used to validate release of the product to the next home care client without a complete inspection.

Recommendation 4: Approve all the above procedures in writing by senior management.

2.5.8.3 Site Assessment for Safety and Risk

Gap: Each home environment is likely to be unique, and the safety and maintenance standards applied to hospitals may not be possible in the home. The home and community care agency and the device-issuing agency should not assume that products and technologies can be operated or stored safely and as-directed.

Recommendation 1: Senior management develops and approves written delivery and installation site inspection procedures.

Recommendation 2: Clearly define “red flag” site deficiencies that would likely prevent safe, reliable, or effective clinical care in written policies. Clearly write appropriate communication chains of command or decision points for exceptions that are understood by all staff and approved by senior management. In addition, the RAI-HC assessment methodology [28, 95] may help inform or serve as a template for site assessments.

2.5.8.4 Completion of Scheduled Maintenance

Gap: There is a lack of standardized deployment of CMMS or equivalent maintenance management systems for medical equipment and technologies by home and community care agencies.

Recommendation 1: Develop written procedures for scheduled maintenance by home and community care agencies, taking into consideration manufacturer recommendations, actual service, and failure patterns to support safe, reliable, and effective care.

Recommendation 2: Clearly identify, document and communicate in writing the qualifications necessary for a person to be authorized to perform scheduled maintenance.

Recommendation 3: Implement a manual or electronic tracking system to help support scheduled maintenance of products in clients' homes.

Recommendation 4: Implement procedures for swapping out the product or scheduling field maintenance in the home.

Recommendation 5: Conduct and document a complete SPI at each scheduled maintenance.

Recommendation 6: Senior management of the device-issuing agencies approves all scheduled maintenance procedures and any subsequent changes, in writing.

2.5.8.5 Preventive Maintenance Processes

Gap: Preventive maintenance documentation provided by manufacturers may not adequately address home and community care usage or situations.

Recommendation 1: Develop written preventive maintenance procedures, taking into account manufacturer recommendations, actual service, and failure patterns to support safe, reliable, and effective care.

Recommendation 2: Clearly identify, document and communicate in writing the qualifications necessary for a person to be authorized to perform preventive maintenance.

Recommendation 3: Senior management of the device-issuing agencies approves all the preventive maintenance procedures and any subsequent changes, in writing.

2.5.8.6 HTM Quality Assurance

Gap: Products, quality programs, and procedures, by their nature, evolve. Product features, uses, repairs, and wear characteristics change with time, requiring timely quality documentation changes, as appropriate.

Recommendation: Review all above HTM procedures periodically, at no less than 12-month intervals, with senior management approving each review in writing.

2.6 Infection prevention and control in home and community care environments

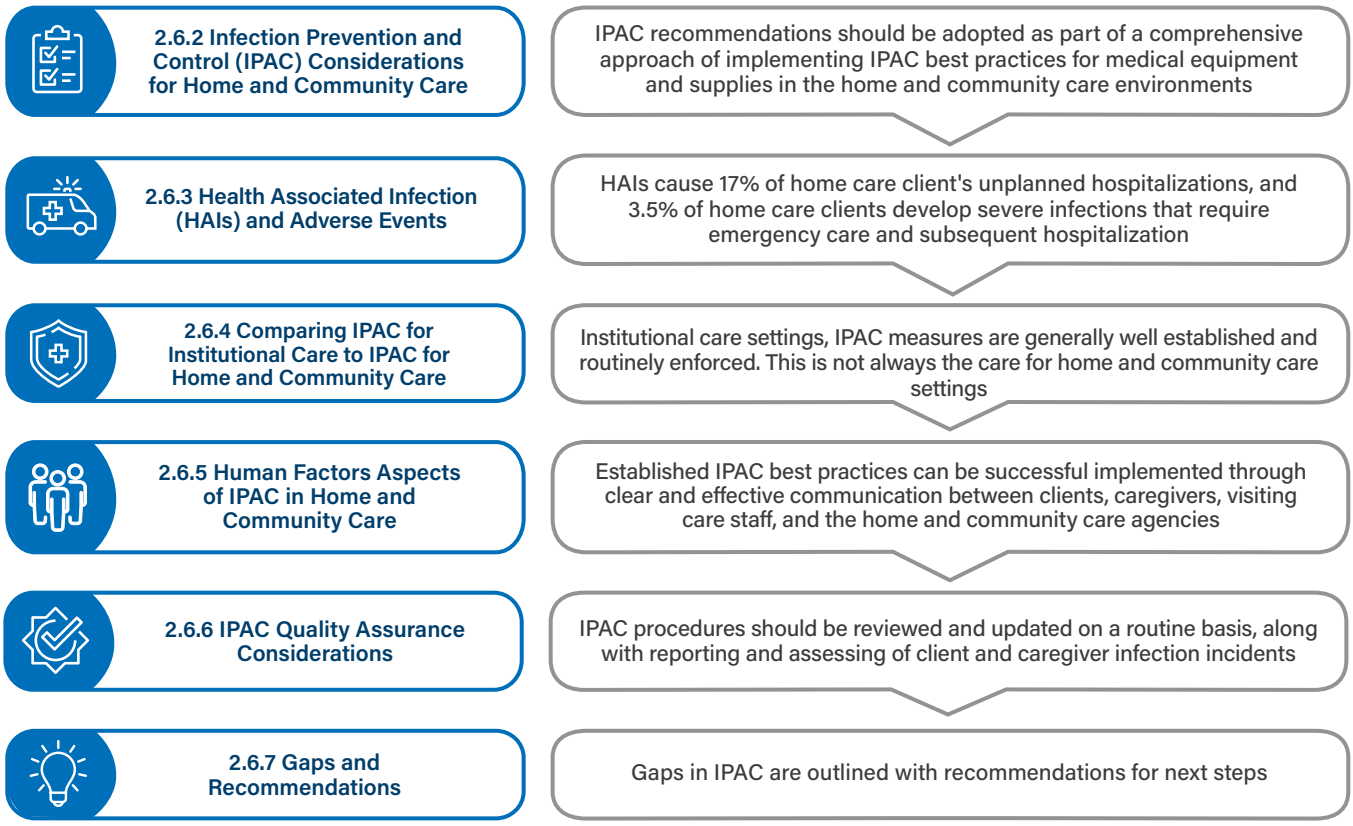
2.6.1 Overview

Case Description: Infection Prevention and Control Issues

Azul has had chronic emphysema for the past six years. About four years ago, after recovering from an acute bout of pneumonia, he was discharged with a portable ventilator. For three years, he managed well, but during the past year he has been repeatedly hospitalized with bacterial pneumonia episodes. With visual perception deteriorating and limited manual dexterity, Azul cannot keep the ventilator tubing, connectors, and humidifier clear of stagnating water. This leads to repeated aspiration pneumonia and hospitalization.

As the shift to providing higher-acuity care in home and community settings continues, more medical equipment, supplies, and medications are used outside of traditional hospital settings. Instead of licensed clinician oversight, infection prevention and control (IPAC) in the home and community relies on people who may have no clinical experience and limited medical or science literacy. The deployment of medical technologies may require direct contact with internal body tissues or mucous membranes. Equipment and supplies may include urethral catheters, suprapubic catheters, gastrostomy tubes, nasogastric tubes, central venous catheters, hemodialysis catheters, and tracheostomy tubes, and a wide variety of ingested and injected medications [104].

Figure 8: Summary of topics covered in Section 2.6



2.6.2 IPAC Considerations for Home and Community Care

In response to the COVID-19 pandemic, the Public Health Agency of Canada issued the *Infection prevention and control for COVID-19: Interim guidance for home care settings* [105]. This guidance provides detailed recommendations on IPAC best practices for home care staff and clients, including routine practices such as point-of-care risk assessments, hand hygiene, and respiratory hygiene, and the use of PPE and masking and eye protection. This document also provides detailed recommendations on the handling of client care equipment and laundry, and on environmental cleaning and disinfection.

Some of the IPAC best practices recommended by the Public Health Agency of Canada that are related to the use of medical equipment and supplies are listed below:

- Single-use equipment and disposable supplies should be used wherever possible and discarded into a plastic-lined waste receptacle after use.
- All reusable equipment and supplies should be dedicated for use by one client and should be stored at the client's home.
- Only essential equipment and devices should be brought into the home.
- After use by each client, reusable client care equipment (e.g., blood pressure monitor, stethoscopes) and devices should be cleaned first and then disinfected with a hospital-grade disinfectant (e.g., disinfectant wipes)
  - according to the manufacturer's recommended contact time and organizational protocols for cleaning and disinfection of reusable equipment, and
  - following the recommended contact time and procedures as provided in the Health Canada mandated manufacturer's instruction for use (MIFU) document of the reusable equipment [106].
- The client, household members, and home care staff (when this is part of their assigned plan of service) should be shown and explained the correct environmental cleaning and disinfection practices.
- Surfaces that are frequently touched (e.g., bedside tables, bed frames, door handles) should be cleaned and disinfected at least once daily and whenever soiled.

Other national, provincial, and US guidance documents and publications on IPAC best practices are listed in Table 4. While these guidance documents do not directly address IPAC in home and community care settings, many of their recommendations are based on good practices that are widely adopted and could be adapted as part of a comprehensive approach to implementing IPAC best practices to do with the use of medical equipment and supplies in home and community care environments.

2.6.3 Health Care-associated Infections and Adverse Events

While the increased adoption of home health technologies expands the potential for clients to receive ongoing care in the home, it also increases the risk of health care-associated infections. In 2017 the Institute for Healthcare Improvement reported that health care-associated infections caused 17% of unplanned hospitalizations among home care clients and that 3.5% of home care clients developed severe infections that required emergency care and subsequent hospitalization [115].

A study of home care clients in Manitoba, Quebec, and Nova Scotia found that 4.2% experienced an adverse event in a 12-month period after discharge. After adjustments to account for clients with lengths of stay in home care of less than one year, the adverse event incidence rate per client-year was 10.1%. Of the various adverse events reported, wound infections were the second most common after falls [26].

These data indicate that the implementation and compliance to proper IPAC measures in the home and community care settings are pressing issues.

2.6.4 Comparing IPAC for Institutional Care to IPAC for Home and Community Care

IPAC measures are generally well established and routinely enforced in hospitals, where there are IPAC teams staffed with specialists who provide guidance on

Table 4: National, provincial, and US guidance and publications on IPAC best practices for all health care settings, including home and community care

Type of guidance	Guidance documents
National guidance	▪ Ontario Agency for Health Protection and Promotion, "Routine practices and additional precautions for preventing the transmission of infection in health care" [107] ▪ IPAC Canada, "Infection Prevention and Control (IPAC) Program Standard" [108] ▪ CAN/CSA-Z314: *Canadian medical device reprocessing* [109]
Provincial and territorial guidance	▪ Ontario Agency for Health Protection and Promotion, "Routine Practices and Additional Precautions in All Health Care Settings" [110] ▪ Ontario Agency for Health Protection and Promotion, "Best Practices for Environmental Cleaning for Prevention and Control of Infections in All Health Care Settings" [111] ▪ Public Health Ontario, "Best practices for cleaning, disinfection and sterilization of medical equipment/devices in all health care settings, 3rd ed.," 2013. [81] ▪ Shared Health Manitoba, "COVID-19 Infection Prevention and Control Guidance for Personal Care Homes" [112] ▪ Nova Scotia Health, "Coronavirus disease 2019 (COVID-19): Infection prevention & control guidelines for long term care" [113] ▪ Alberta Health, "Reusable & single-use medical devices standards: Standards for the reprocessing of reusable medical devices and for the use of single-use medical devices in all health care facilities and settings" [80]
US guidance	▪ US Centres for Disease Control and Prevention, "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008" [114]

effective handwashing, handling and management of medical equipment, the correct use of PPE, the types of protective equipment to be used in specific situations, etc. Hospitals also have specialized equipment and methodologies to enforce sterile supply processing. They also conduct surveillance for outbreaks of infections such as MRSA, *Clostridioides difficile,* and multidrug-resistant Gram-negative bacteria, all of which pose significant health threats. Hospitals are also obliged to report infections to regulatory and accreditation bodies, and most hospitals employ biostatisticians to support their research and reporting obligations.

In the long-term care environment, this expertise and surveillance may vary, depending on overseeing organizations. A review of the circumstances that led to 53 deaths in Nova Scotia's largest long-term care facility during the first wave of the COVID-19 pandemic identified inconsistent cleaning, shared rooms, limited control of the temperature and humidity, and inadequate ventilation and filtering as factors contributing to the deaths. The report also identified specific needs such as increased supplies of PPE for staff and improved ventilation in bathrooms [116].

While it is possible to address IPAC issues systematically in an institutional setting with formal oversight, it becomes far more difficult in the home, where the physical environment is more varied and less consistent. Often, clients and caregivers are called on to prevent or treat infections, despite having little or no knowledge of this topic. They may not be aware of the processes to follow, may not have access to sufficient stocks of appropriate cleaning and disinfection supplies, and may lack the capacity to follow recommended IPAC procedures.

2.6.5 Human Factors Aspects of IPAC in Home and Community Care

Applying human factors methods to study and improve the levels of compliance with good IPAC practices in home and community care settings is complicated by the heterogeneous nature of the home care environment, the possible range and number of caregivers, and the diversity of medical equipment and supplies used. These challenges make it difficult to construct human factors studies that lead to clear and actionable outcomes [117, 118, 119, 120].

Studies using human factors methods have demonstrated that even in a controlled hospital environment, there were multiple issues to do with safely putting on and taking off of PPE. The design of protocols, instructional materials, and environmental factors, such as anteroom layouts, were all found to affect safety [121].

A human factors study surveyed 353 nurses across two large home care agencies to examine the relationship between IPAC and individual, home environment, and organizational factors. The surveyed nurses reported multiple barriers to proper IPAC practices in clients' homes, including cluttered and dirty environments and limited availability of IPAC supplies such as PPE. Training provided by home care agencies and decision-making resources were factors that were less significant in terms of compliance with IPAC measures compared with home environment barriers and issues with supplies [122].

2.6.6 IPAC Quality Assurance Considerations

Although quality management best practices are well documented in CAN/CSA-ISO 9001 [52], their application to IPAC quality assurance may not be obvious. At the heart of IPAC quality assurance and improvement is the challenge created by both the evolution of home health technologies and of the infection sources themselves.

Cleaning, disinfecting, and sterilizing chemicals and methods must constantly be updated as new materials and technologies are introduced to home and community care settings. The adoption of novel plastics, fabrics, composites of plastics and metal, paints, and coatings requires careful updating of all IPAC processes. Failure to update these processes hinders protection against infection and may damage or destroy the items made with these new products, for example, sensors, smartphones, tablets, and other electronic products.

At the same time, infectious bacteria, fungi, and viruses are constantly evolving to potentially resist IPAC processes. To combat the spread of dangerous infections, the chemicals and procedures used for IPAC must be modified in a timely fashion. For example, during the COVID-19 pandemic, specific disinfectant chemicals, for example, 70% alcohol, were recommended, while vinegar was found to be ineffective and diluted bleach needed to be in contact with a surface for many minutes before effective disinfection occurred [123, 124, 125].

In accordance with core CAN/CSA-ISO 9001 quality principles, IPAC procedures should be reviewed and updated on a routine basis, which may initially be on an annual cycle that is subsequently modified as appropriate. Ongoing client and caregiver infection incidents need to be reported and assessed to detect failures or breakdowns of IPAC procedures as quickly as possible.

Failure to disinfect, decontaminate, or sterilize home health technologies properly when items are transferred from client to client can create serious infection risks to all parties. If infections rates are not monitored and managed effectively by the home care agency, serious problems can arise in the communities the agency serves [126, 127, 128, 129].

2.6.7 Gaps and Recommendations

IPAC is a significant challenge in home and community settings, particularly because the entire environment cannot be rigorously maintained in a sanitary condition. In addition, home health technologies are diverse, as are the bacteria, viruses, fungi, and other threats that must be considered.

Standardization of IPAC processes in Canada for home and community care settings is scant. Developing minimum national standardized IPAC best practice recommendations or guidelines could lead to substantial risk and harm reduction. Such recommendations or guidelines could be derived

from or parallel to established Canadian, US, and international accreditation, hospital and long-term care standards, plus publications of numerous professional infection control societies in the health care industry (see Appendix D). Such baseline best practice recommendations or guidelines could evolve into a library of baseline standards that may be adopted or adapted at local and national levels.

Critical topics for a national best practice IPAC baseline include:

- Identification of responsibilities for IPAC procedures, training, and oversight, including appropriate documentation, to assure staff competency and both client and caregiver training and understanding;
- Quality management methodologies and responsibilities for reporting infections and remediation;
- Clear and consistent baseline methodologies for infection isolation and reverse-isolation, including signs and communication to ensure safe and effective compliance;
- Responsibilities for site-, client-, and technology-specific IPAC processes (including environmental and waste issues), including remediation and documentation;
- Identification of all necessary IPAC supplies, including PPE, and supply chain oversight;
- Identification and remediation of human-factors deficiencies related to all aspects of IPAC, including supplementary documentation, labelling, and training, as necessary;
- Prevention of the spread of infections and other IPAC risks between and within multiple sites when home health technologies are transferred; and
- Building a library of standardized IPAC checklists with sufficient granularity to help with compliance and problem resolution in a timely manner, and to identify ongoing issues that require specialized adaptations.

2.6.7.1 IPAC in Home and Community Care

Gap 1: There is a lack of standardized IPAC guidelines to assure product safety, quality, and efficacy in the home and community care settings.

Recommendation 1: In collaboration with the home care industry, national, provincial, and territorial (NPT) guidelines are established to provide governmental oversight for IPAC.

Gap 2: There is a lack of standardized site- and client-specific IPAC guidelines and risk assessment methods that can be put to use by home and community care agencies.

Recommendation 2: In collaboration with the home care industry, NPT public health agencies develop national guidelines for unified and standardized site- and client-specific IPAC risk assessment methods. These guidelines would be available to all home care agencies that provide services requiring site and client visitation. The RAI-HC assessment methodology [28, 95] may help inform or serve as a template for site assessments and documentations.

Gap 3: There is a lack of prioritized methods for screening and remediating IPAC risks in the relatively uncontrolled environments of home and community care settings.

Recommendation 3a: In collaboration with the home care industry and related associations, NPT and local public health agencies develop national guidelines for prioritized methods for screening and remediating IPAC risks in relatively uncontrolled home and community care environments.

Recommendation 3b: NPT and local public health agencies make such guidelines for prioritized methods for screening and remediating IPAC risks available to all home care agencies that provide services requiring site and client visitation.

Gap 4: IPAC responsibility and accountability of clients, caregivers, clinicians, home care agencies, and other issuing agencies is unclear.

Recommendation 4a: In collaboration with the home care industry, NPT public health agencies develop guidelines to clarify IPAC responsibility and accountability of home care and other issuing agencies.

Recommendation 4b: Home care and other issuing agencies provide written guidelines clarifying their IPAC responsibilities and accountability to clients, caregivers, and clinicians.

Gap 5: There is a lack of standardized IPAC surveillance techniques that are appropriate for home and community care environments.

Recommendation 5a: In collaboration with the home care industry and related associations, the NPT and local public health agencies develop unified and standardized IPAC surveillance techniques that are appropriate for the home and community environments, despite variations and inconsistencies across such care environments.

Recommendation 5b: In collaboration with the home care industry and related associations, the NPT and local public health agencies and home care agencies facilitate the implementation of and compliance with IPAC surveillance techniques in home and community care environments.

Recommendation 5c: The home care agencies are able to demonstrate the application and compliance to standardized IPAC surveillance techniques, including assessment of a home environment's suitability for providing care, ongoing monitoring, and reporting mechanisms for problems that may occur.

Gap 6: The lack of unified and standardized IPAC methodologies in the home and community care settings may interfere with use of recognized quality control and quality improvement methods.

Recommendation 6: In collaboration with the home care industry and related associations, the responsible NPT and local public health agencies develop unified and standardized IPAC measures to facilitate the use of recognized quality control and improvement methodologies.

Gap 7: Clients and caregivers may have incomplete knowledge and training in the differences in and interrelationship between cleaning, decontamination, disinfection, and sterilization.

Recommendation 7: Home care or other issuing agencies provide the client and caregivers with user-appropriate checklist-driven instructions written in plain language with pictorial diagrams in accessible formats, for cleaning, decontamination, disinfection, and sterilization of each item of equipment they provide.

Gap 8: There is limited or no control of the movement of people, pets, or any items in and out of the client care area, even when necessary to keep the area clean, decontaminated, disinfected, and sterilized.

Recommendation 8: Home care and other issuing agencies provide the client and caregivers with guidelines, written in plain language with pictorial diagrams in accessible formats, supportive training, and competency assessments, that suggest how to limit the movement of people, pets, and any items in and out of the care area.

Gap 9: There is limited involvement of individuals with specialized knowledge, credentials, and training skills in supporting IPAC implementation.

Recommendation 9: In collaboration with the home care industry and related associations, the responsible NPT and local public health agencies work with individuals with specialized knowledge, credentials, and training skills to oversee the implementation and continued support of IPAC measures carried out by home care agencies and visiting caregivers.

Gap 10: There are no standardized guidelines for isolation or reverse-isolation IPAC processes in home and community settings.

Recommendation 10a: Home care and other issuing agencies facilitate the enforcement of isolation or reverse-isolation IPAC processes when needed; provide the client and caregivers with guidelines written in plain language, supportive training, and competency assessments, in accessible formats, on how to enforce and maintain isolation or reverse-isolation conditions; and provide appropriate supplies, training, and signage that facilitate the enforcement of isolation or reverse-isolation.

Recommendation 10b: When isolation or reverse-isolation is not feasible for the home care clients who require it, clients are offered a temporary transfer to an institutional care environment to have access to proper isolation infrastructures.

Gap 11: In community care sites, numerous individuals may share common facilities, which can create novel IPAC challenges.



"In community care sites, numerous individuals may share common facilities, which can create novel IPAC challenges."

Recommendation 11: Community care agencies adapt IPAC measures used in the institutional care environments to systematically address the IPAC challenges in community care settings.

Gap 12: IPAC best practices are localized and proprietary, and implementation and compliance is neither transparent nor tracked, documented, or reported.

Recommendation 12a: In collaboration with the home care industry and related associations, the responsible NPT and local public health agencies develop unified standardized guidelines on the implementation of, compliance to, and documentation, reporting, and tracking of IPAC best practices for home care agencies.

Recommendation 12b: In collaboration with the home care industry and related associations, the responsible NPT and local public health and home care agencies facilitate the documentation of and compliance to established standardized IPAC best practices.

Recommendation 12c: Home care agencies institute processes demonstrating the adoption and enforcement of IPAC guidelines.

Gap 13: The methods and obligations for reporting adverse events are unclear, incomplete, inconsistent, and infrequently used and appear to bypass home care applications completely.

Recommendation 13a: In collaboration with the home care industry and related associations, the responsible NPT and local health agencies develop unified standardized guidelines for home care agencies on obligations and methods for reporting adverse events.

Recommendation 13b: In collaboration with the home care industry and related associations, responsible NPT and local health agencies and home care agencies facilitate the standardized reporting of adverse events in home and community care settings.

Recommendation 13c: Home care agencies institute processes demonstrating the adoption and enforcement of the standardized guidelines for reporting adverse events.

Gap 14a: Clients and family members may not be aware of IPAC best practices.

Gap 14b: Informal caregivers may not have had sufficient training in implementing established IPAC best practices.

Recommendation 14a: Home care and other issuing agencies facilitate compliance with established IPAC best practices in home and community care settings by demonstrating these best practices to clients and family members.

Recommendation 14b: Home care and other issuing agencies provide clients and family members with checklist-driven guidelines written in plain language in accessible formats, and supportive training and competency assessments in compliance with recommended IPAC best practices.

Recommendation 14c: Home care and other issuing agencies provide informal caregivers who are hired during lapses between formal home care services with written guidelines in accessible formats and supportive training to reinforce their knowledge of IPAC best practices.

Gap 15: Due to cost, supply limitations, misinformation, or other reasons, disposable or single-use medical equipment and supplies may be reused.

Recommendation 15a: Home care and other issuing agencies ensure that disposable or single-use medical equipment and supplies are used and disposed of safely.

Recommendation 15b: Home care and other issuing agencies provide clients and caregivers with user-appropriate guidelines written in plain language, with pictorial diagrams and in accessible formats, and supportive training and competency assessments on the safe use of disposable or single-use medical equipment and supplies to prevent unnecessary reuse.

Recommendation 15c: If reuse is unavoidable, the home care agencies and other issuing agencies provide clients and caregivers with user-appropriate guidelines written in plain language, with pictorial diagrams and in accessible formats, supportive training and competency assessments on how to safely reuse disposable or single-use medical equipment and supplies.

Gap 16: Because of cost and transportation logistics, home care and other issuing agencies provide medical supplies in bulk, which could make it difficult or impossible to preserve the original clean or sterile condition of individual items over longer periods.

Recommendation 16: Home care and other issuing agencies provide clients and caregivers with user-appropriate guidelines written in plain language, with pictorial diagrams and in accessible formats, and supportive training and competency assessments, on preserving the original clean or sterile condition of the bulk packaged supplies.

Gap 17: Many home and community situations may not meet minimum sanitation standards for effective implementation of IPAC best practices.

Recommendation 17a: Home care and other issuing agencies provide clients and caregivers with user-appropriate guidelines written in plain language, with pictorial diagrams and in accessible formats, and supportive training and competency assessments, on meeting minimum sanitation standards.

Recommendation 17b: Where necessary, home and community care agencies assess the site and provide site-specific guidance on how to meet minimum sanitation standards or how to remedy sanitation issues.

Recommendation 17c: If it is not possible to improve the sanitation conditions of the home environment, with client consent, the home care and other issuing agencies consider additional monitoring or arrange for transfer to a safer location.

Gap 18: Checklist libraries of standardized IPAC best practices appropriate for home and community care settings are lacking.

Recommendation 18: In collaboration with the home care industry and related associations, the responsible NPT, local public health, and home care agencies develop and establish standardized libraries of IPAC measures for home and community care settings. These libraries include user-appropriate checklists of IPAC guidelines written in plain language, with pictorial diagrams and in accessible formats to facilitate the implementation and compliance to IPAC best practices.

Gap 19: Chemicals and formulations that are safe for hospital use may not be safe for use in home and community care settings.

Recommendation 19a: Home care and other issuing agencies facilitate the safe cleaning, decontamination, disinfection, and sterilization of medical equipment and supplies in home and community care settings.

Recommendation 19b: Where possible, home care and other issuing agencies provide clients and caregivers with user-appropriate guidelines written in plain language and in accessible formats, and supportive training and competency assessments on the chemicals and formulations that are safe for cleaning, decontamination, disinfection, or sterilization of medical equipment and supplies in the home.

Recommendation 19c: If chemicals and formulations that are deemed unsafe for home use are necessary for cleaning, decontamination, disinfection, and sterilization of medical equipment and supplies, home care and other issuing agencies facilitate the cleaning, decontamination, disinfection, and sterilization of the equipment and supplies at designated health care facilities.

Gap 20: Accidental needlesticks injuries are a hazard to clients, caregivers, clinicians, and environmental waste handlers [130, 131, 132].

Recommendation 20: Each agency is responsible for seeking and implementing every reasonable opportunity to prevent and avoid needlestick injuries.

Gap 21: Reuse of needles and syringes has a high risk of infection [133].

Recommendation 21: Each agency is responsible for seeking and implementing appropriate opportunities to implement safety-engineered needles and syringes.

2.6.7.2 Human Factors Aspects of IPAC in Home and Community Care

Gap 1: There is a lack of effective, unified, and standardized communication methodologies between the home and community care agencies, caregivers, visiting home care staff, and clients, which may prevent the effective implementation of and compliance with established IPAC best practices.

Recommendation 1: In collaboration with the home care industry, NPT public health agencies adopt unified standard guidelines for effective communication requirements between home and community care clients, caregivers, the home care agencies, and other issuing agencies.

Gap 2: Environmental factors in the home and community care sites, such as clutter and dirtiness, may prevent effective implementation of established IPAC best practices.

Recommendation 2: Home care agencies regularly assess the care environment for, among other things, clutter and cleanliness, and work with clients and their families to support them in resolving or remediating any identified deficiencies or barriers. The RAI-HC assessment methodology [28, 95] may help inform or serve as a template for site assessments.

Gap 3: Clients and their family caregivers may have a variety of limitations to do with vision and visual acuity, hearing, cognition, balance, memory, strength, and physical dexterity. Any of these limitations may prevent them from effectively implementing the IPAC best practices despite the home care agency–provided guidelines.

Recommendation 3: In collaboration with the home care industry, NPT public health agencies provide publicly funded home and community care services for clients and caregivers in need, to ensure safe effective implementation of IPAC best practices.

Gap 4: The clients and family caregivers may not have access to sufficient PPE, cleaning and disinfecting/sterilizing agents, and other IPAC supplies or the financial resources to procure necessary quantities of supplies to implement IPAC best practices.

Recommendation 4a: Home care and other issuing agencies regularly check the availability of IPAC supplies and maintain and provide sufficient inventory to enable the implementation of established IPAC best practices.

Recommendation 4b: Home care and other issuing agencies create and adopt a consistent monthly supplies reconciliation program, similar to commonly accepted medication reconciliation programs, to check that the quantity of the IPAC supplies is sufficient to implement IPAC best practices.

Recommendation 4c: In collaboration with the home care industry, NPT public health agencies provide publicly funded supplies for home and community care clients and caregivers with financial limitations, to ensure they have the necessary IPAC supplies.

Gap 5: Because of pressure or stress related to caregiving, or fatigue, complacency, or misinformation, the home and community caregivers may not be able to effectively follow the guidelines on implementing IPAC best practices.Recommendation 5: In collaboration with the home care industry, NPT public health agencies

provide publicly funded home and community-based respite care services for home and community care clients where needed, to remedy caregiving-related pressure, stress, and fatigue of the caregivers.

Gap 6: Because of limitations in ancillary resources such as storage space, reusable cleaning supplies, or specialized waste disposal systems, clients and caregivers may not be able to follow the guidelines for implementing IPAC best practices provided by home care agency.

Recommendation 6: In collaboration with the home care industry, NPT public health agencies provide publicly funded assistance to home and community care clients and caregivers with limited resources to ensure they can effectively implement IPAC best practices.

Gap 7: The labelling for home health technologies, such as status of sterility, for internal or external use, etc., may be inconsistent and may not match human factors best practices for home and community care clients and caregivers.

Recommendation 7: Home care agencies, medical equipment and supplies manufacturers, and issuing agencies ensure that labelling of home health technologies consistently matches human factors best practices for home and community care clients and caregivers.

Gap 8a: There is a lack of standardized and consistent cleaning, disinfection, and sterilization requirements for medical equipment and supplies used in the home and community care settings.

Gap 8b: Cleaning, disinfection, and sterilization of medical equipment and supplies used in the home may be complex and may not match human factors best practices for home and community care clients and caregivers.

Recommendation 8: Home care agencies, medical equipment and supplies manufacturers, and device-issuing agencies ensure that cleaning, disinfection, and sterilization requirements are easy to follow, appropriate to the care environment, and match human factors best practices for home and community care clients, caregivers, and field service technicians.

2.7 Medication Management for Safe Home and Community Care

2.7.1 Overview

Case Description: Medication Management Issues

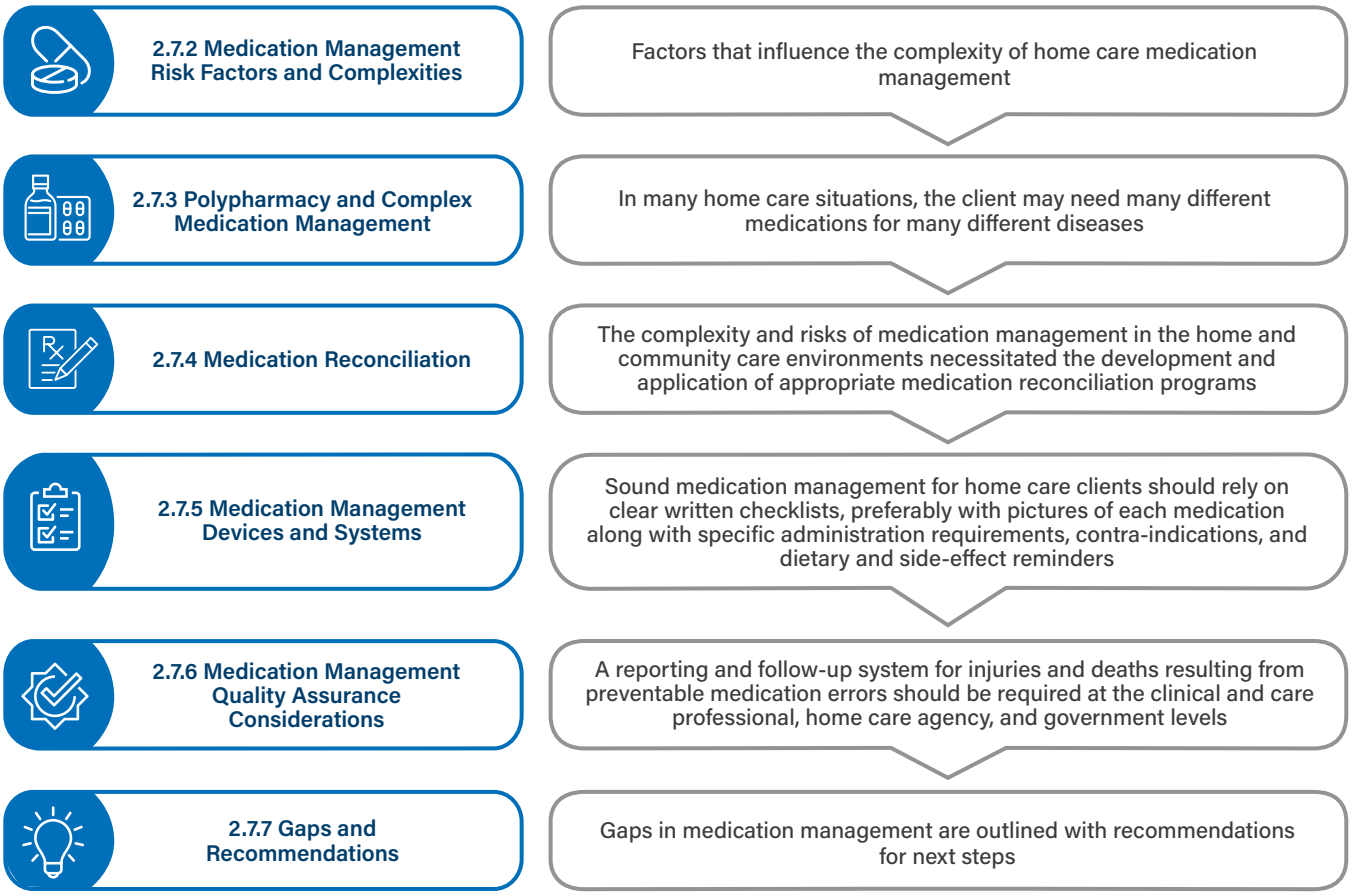
Cameron has congestive heart failure and atrial fibrillation episodes that are not well controlled by the Metoprolol prescribed for this condition. He has also had some recent minor strokes, and has been prescribed Coumadin. Cameron has to undergo bi-weekly home blood clotting testing and has periodic dose changes as a part of his anticoagulate treatment.

He also undergoes a medication reconciliation process each month. However in the past four months, Cameron's drug counts have not matched the prescribed doses for Metoprolol or Coumadin. He reports that he sometimes forgets to take his medication, and has skipped doses because of side effects.

Medications are a common and important aspect of health care, providing life-saving, life-improving, and life-sustaining benefits. Nevertheless, medication errors have been cited as one of the most significant causes of serious patient injury and deaths, in the Institute of Medicine report To Err is Human in 2020 [59, 134, 135, 136]. A considerable body of Canadian and international research shows these problems persist in home and community care settings. Given the large volume of medications used in home care, even a small fraction of preventable serious injuries and deaths creates significant personal and economic losses.

The home care setting is not inherently more dangerous, but certain aspects of use and management of medications in the home add complexity. Although research has focused on hospital-based medication errors, problems to do with home-based medication management have received more attention as home care has expanded [24, 26, 137, 138, 139].

Figure 9: Summary of topics covered in Section 2.7



2.7.2 Medication Management Risk Factors and Complexities

As described in Section 2.4.2, medications can vary widely, especially as generic substitutes have become common. Tablets, capsules, or liquid formulations supplied by different manufacturers may only be required to demonstrate chemical equivalence of the active ingredient. There may be few controls on the non-medicinal ingredients used to make each version. Medication packaging can also vary, with different containers, caps, security seals, dose administration, and labelling for each manufacturer's generic variant.

The risk factors that home medication management should address, as identified by research cited in Section 2.7.1, include, but are not limited to, the following:

- Polypharmacy, where a person takes five or more medications concurrently for a single condition [140], and increasing comorbidities, resulting in taking many different medications each day.
- Many medications have similar looking and sounding names that are difficult to pronounce or distinguish from each other [141].
- Some medications have many brand names in addition to a generic name.
- The same medication may be manufactured by different firms in different colours, shapes, sizes, or markings.
- Some medications are prescribed for "off label" uses, preventing people from finding information about safe medical use.

- Medications are sometimes combined and given new names, masking overdose risks that result from taking multiple forms of the same medication.
- Medications often have specific and dissimilar schedules for each dose or have to be combined with foods or other drugs or avoided when eating or taking other medications; this can be difficult to manage and confusing.
- Making up missed doses (because of travel, forgetfulness, or medication loss or shortage) varies by medication, illness, and other circumstances, and errors can lead to over- or underdose complications, especially when taking multiple medications.
- Some medications cause cognitive dissonance and confusion, further complicating selection, identification, and administration.
- Some medications are only taken as needed, creating opportunities for misinterpretation or forgetting safe-use rules.
- Medications may be prescribed by multiple physicians or hospitals, and the prescriptions filled by multiple pharmacists, preventing cohesive oversight of risks, redundancies, or gaps.
- Inappropriate diet, fluid intake, or other chemical interactions may disturb medication regimens, reducing safety and effectiveness.
- Some medications have strict expiration dates, sometimes printed in very small font sizes, that people continue taking with unknown consequences.
- Most Canadian health care providers rely on paper records or electronic records that are only visible to a small number of allied hospitals, physicians, pharmacists, and other allied health professionals, which means that not everyone who may need to know has access to these records.
- Many people use over-the-counter medications, homeopathic, herbal, or nutraceutical supplements, many of which interact with prescription medications in detrimental or unpredictable ways.
- Certain medications are considered "high alert", either because of significant side effects, extremely harmful over- or underdose risks, or very rigid timing and administration requirements.
- Many chemotherapy medications can be toxic to recipients, caregivers, or bystanders if spilled or administered incorrectly.
- Some custom-blended medications and non-parenteral feeding solutions are not sterile, and may spoil if not stored and handled correctly.
- Some medications can be damaged by storage in the wrong conditions, be it at room temperature or in a refrigerator or freezer or in excessive heat or direct light.

Safe management of medications is further complicated by the needs of a widely divergent population of home care services clients. The use cases for medication are extensive, as shown in the following non-exclusive list [29, 33, 34, 71, 135, 136, 137, 138, 139, 142, 143, 144, 145, 146, 147, 148]:

- Newborns, who have novel health profiles, challenges, and risks compared to adults;
- People with short-term disabilities or recovering after, for example, a fall;
- People with long-term disabilities who need lifelong medication management to sustain activities of daily living (ADLs) and independence;
- People with chronic diseases with stable or slowly declining health, who can be maintained with relatively routine medication regimens;
- People with multimorbidities who may need many medications, with dosages adjusted as needed;
- Rehabilitation patients, post-hospitalization, who need combinations of medications, physical therapy, occupational therapy, and nursing care;
- Individuals undergoing prehabilitation prior to hospitalization, to improve vital signs for better surgical outcomes;
- People post surgery or recovering from decubitus ulcers or trauma injuries who require wound care;
- People receiving chemotherapy, who may have some or all their care at home;
- People with a contagious disease who require caregiver isolation;
- People with suppressed immune systems who require special protection from infections;

- People with mild cognitive disabilities with few significant illnesses;
- People receiving home hemodialysis;
- People receiving hospice and palliative care;
- Hospital-at-Home and Acute-Care-at-Home patients receiving clinical care from hospital staff in a remote setting.

Home care situations may be a blend of the list of factors for concern, and the list of use cases. Some clients may fall into several categories, for example, pediatric clients with long-term disabilities, or older adults with weakness, mild dementia, and co-existing chronic diseases such as obesity, osteoarthritis, diabetes, chronic obstructive pulmonary disease, congestive heart failure, and sleep apnea. Medication regimens for these situations may be complex, combining numerous parenteral and non-parenteral medications, medical devices, and special dietary constraints.

2.7.3 Polypharmacy and Complex Medication Management

In some situations, a client may need many different medications ("polypharmacy") for many different diseases or conditions ("multimorbidity") [140, 149]. Those medications may be prescribed by numerous specialists and dispensed by multiple pharmacists. The medications may also be supplied by many different manufacturers who use different colours, shapes, sizes, and markings for the pills.

These complexities create the need to manage many different medications. Another complexity that compounds polypharmacy is the common need for periodic changes to adjust for side effects, new symptoms, new diseases, or other causes. Changes can be complicated, for example, cutting and taking half-pill doses, skipping days, or only taking some medications (labelled PRN, standing for pro re nata, Latin for "when necessary") as needed, when symptoms surge or ebb.

Risks increase when the medications involved have high potential for serious harm if not used exactly as prescribed. Such errors may directly cause injury or death due to overdose or failure to maintain critical metabolic functions. In addition, medication errors are known to cause or contribute to secondary injuries or death, such as falls, inadvertent severe dehydration or weight loss, or neuropathy of the hands or feet, which can lead to untreated wounds, infection, and gangrene. In one study of 1,200 home care adverse events, medications contributed to 21.5% of the serious events including falls and other harms [24,26].

2.7.4 Medication Reconciliation

Medication reconciliation is the process of creating the most accurate list possible of all medications a client is taking – including drug name, dosage, frequency, and route – and comparing that list against clinician admission, transfer, and discharge orders [150]. The concept of medication reconciliation has been adapted from hospital procedures and developed for the home and community care settings. Medication reconciliation is intended to be a regular and routine task for both clinical and non-clinical caregivers.

Many published, open-source procedures and forms are available as guides for implementing medication reconciliation. The basic process begins with client verification and includes:

- Review of formal current and discontinued prescriptions;
- Review of medications (including non-prescription medications, homeopathic or herbal medications, and nutraceuticals) in the home;
- Review of current regimen;
- Identification of potential conflicts or errors; and
- Reconciliation of all gaps to restore proper medication activities.

In a hospital setting, all medications, supplements, and dietary matters are generally managed by a central pharmacy and dietary service, ensuring consistent enforcement. Further, nurses are trained to follow a strict regimen for medication dispensing, variously described as the five, seven, or eight rights of medication management [146, 147, 148]. In the home setting, such strict controls may be impossible. Also, geographic distances and costs may prevent continuous medication management by a caregiver, leaving a significant amount of daily medication management to the client's judgment and control.

2.7.5 Medication Management Devices and Systems

An emerging middle-ground for medication management in home and community care settings involve use of Automated Medication Dispensing Systems (AMDS). AMDS can be programmed to dispense pills and capsules on a scheduled basis, but parenteral medications, which are typically administered by injection into muscle or venous sites, and ointments, sprays, and dermal patches still need to be managed separately.

Where AMDS are unavailable or not applicable, simpler non-automated pill planning devices are commonly used in home and community care settings. These typically have individual storage cells for morning, noon, and nighttime medications for daily, weekly, or bi-weekly medication plans.

In these cases, unless there is no polypharmacy, sound medication management for home care clients should rely on checklists, preferably with pictures of each medication, along with specific administration requirements, contraindications, and dietary and side-effect reminders, in accessible formats. Creating such checklists is often the final step of a medication reconciliation process.

2.7.6 Medication Management Quality Assurance Considerations

A CQI strategy for medication management is appropriate as there is no framework in which a fractional percent of preventable deaths can be endorsed or tolerated.

As applied to medication management, injuries and deaths as a result of preventable medication errors require a reporting and follow-up system at the clinical and care professional, home care agency, and governmental level. Actual incidents and near misses must be resolved in a timely way at the client/caregiver level. All such incidents should be reported to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) [33]. National agencies must be notified so that effective remediation actions are taken (e.g., recalls, black box warning labels, and/or physician/client documentation revision). In addition, an affirmative local resolution process is needed to protect people from a repeat incident.

Failure of home or community care recipients or providers to actively report medication incidents to CMIRPS deprives the nation of documentation and data that could save lives. For example, on 19 February 2021, Health Canada published a public advisory about accidental acetaminophen overdoses among young children [151]. This 2021 notification expands upon an earlier pediatric overdose notice posted in 2017 [152].

2.7.7 Gaps and Recommendations

Because medication management is well-documented as a way of preventing injury and death, a Canadian best practices guideline or standard that focuses explicitly on home and community care across Canada would serve all stakeholders.

Components of such a national guideline or standard should include:

- Medication-specific quality assurance guidelines that are based on CAN/CSA-ISO 9001, with specific clarity about the responsibility of senior management, documented and validated staff training and competence, and CQI processes;
- Assertion of governmental and institutional communication and action mechanisms to ensure that information about medication recalls and hazards extends all the way through the distribution chain to medication recipients, with documentation showing that appropriate remediation has been completed;
- Integration of localized/regionalized medication error and incident reporting to help assure:
  - Timely remediation of identified patient risks; and
  - Timely notification of the Health Canada / ISMP Canada medication error/incident reporting system including near misses, e.g., a non-fatal accidental medication overdose caused by erroneous, misleading, or confusing medication labelling, packaging, or handling;
- Consistent national paper or online medication reconciliation procedures and documentation that:
  - Spans local, provincial, and national regulatory bodies,
  - Includes all recommended and required schedule and application constraints needed for safe and effective medication use,

  - Identifies and reconciles duplicate or conflicting prescriptions from prior illnesses or multiple specialists' unsynchronized treatments, and
  - Helps ensure identification and safe, legal disposal of out-of-date, surplus, or discontinued medications.
- A policy and framework to empower consistent and documented informed consent for home and community care clients who elect to avoid, ignore, override, interfere, or invalidate physician prescriptions and guidance.

All these components should clearly indicate that the responsibility of medication reconciliation must extend beyond prescription medications because polypharmacy risks include over-the-counter medications and homeopathic and nutraceutical substances and may also include specific dietary and activity constraints or considerations.

2.7.7.1 Medication Management Risk Factors and Complexities

Gap: Home and community care clients typically have multimorbidity as well as mobility limitations and possibly cognitive limitations, and may require numerous medications, medical equipment and supplies, and special diets. A wide range of conditions may contribute to a complex medication regimen that is difficult to manage.

Recommendation: Where possible and where medication histories are available, the medication-issuing agency ensures the necessary medications do not require complex management and do not add to the complexities in the existing medication regimen. The RAI-HC assessment methodology [28, 95] may help inform or serve as a template for assessing and documenting the clients' ability to safely manage their medications.

2.7.7.2 Polypharmacy and Complex Medication Management

Gap 1: Home and community care clients may need many different medications prescribed by multiple specialists and provided by different pharmacies. The medication may be manufactured with non-standardized colours, shapes, sizes, and markings, which does not facilitate medication management.

Recommendation 1: The medication manufacturers adopt standardized colours, shapes, sizes, and markings for equivalent medications.

Gap 2: The medications prescribed to home and community care clients may have overlapping side effects and complicated schedules of administration and dosage. The mismanagement of medication, especially in people with multimorbidity that requires polypharmacy, may lead to increased risk of secondary injuries or death.

Recommendation 2: The home care agency and medication-issuing agency facilitate the development and implementation of a medication reconciliation program appropriate for home and community care as well as compliance with this program.

2.7.7.3 Medication Reconciliation

Gap 1: The complexity and risks of medication management in the home and community care environments necessitates the development and application of appropriate medication reconciliation programs.

Recommendation 1: The home and community care agencies, medication-issuing agencies (e.g., specialists and pharmacists) and other issuing agencies facilitate the development of, implementation of, and compliance to medication reconciliation program appropriate for the home and community care environments.

Gap 2: Because strict control of prescribed medication is largely impossible in home care settings and due to other barriers such as cost and geographic distances, continuous medication management by professional and caregivers may not be feasible in some home and community care settings, leaving clients to self-manage their medications.

Recommendation 2a: Where possible, the home and community care agencies, medication-issuing agencies (e.g., specialists and pharmacists) and other issuing agencies help the client manage their medication, for example, through daily or periodic inspection or through check-up by visiting caregivers.

Recommendation 2b: Where self-management of medication by the client is unavoidable, the home and community care agencies, medication-issuing agencies (e.g., specialists and pharmacists) and other issuing agencies provide home and community care clients with guidelines written in plain language and in accessible formats on safe and effective medication management.

2.7.7.4 Medication Management Devices and Systems

Gap 1: Medications not in pill or capsule form may not be manageable using AMDS and require separate management by clients and caregivers. Simple non-automated pill planning devices may have limited flexibility in terms of storage and schedule of administration and may be confusing to the client if not designed and labelled with them in mind.

Recommendation 1: In addition to the use of AMDS and other non-automated pill planning devices, the home and community care agencies, medication-issuing agencies (e.g., specialists and pharmacists) and other issuing agencies provide home and community care clients with guidelines written in plain language and accessible formats, such as checklists with pictures of each medication along with specific administration requirements, contraindications, and dietary and side-effect reminders.

Gap 2: It can be confusing when medications that are dispensed in unit doses and blister packaging are discontinued, changed, or only intended for as-needed dosing [145].

Recommendation 2: Whenever unit-dose or blister packaging is used, the home care agency provides complete documentation and training to manage exceptions safely and include them in their medication reconciliation program.

3 Conclusion

This report has examined many challenges related to safely providing equipment, supplies, and medications to individuals receiving health care at home and in the community. The report identifies gaps and provides recommendations to address those gaps. A list of best practices and recommendations that offer suggestions are provided for new guidance and standards to be developed that may help to improve the safe provision of equipment supplies and medications for home care.

The development of consistent national standards and guidelines that address the many existing gaps and shortcomings in home and community health care will positively affect Canadians. The demand for care in the home is increasing steadily, and health technologies are making many additional types of care possible. These, in turn, bring challenges in terms of safe and effective implementation. The overarching theme of this report is to identify these challenges and propose effective approaches for addressing them. Home care is here to stay. It is vitally important to take steps to ensure that home care meets the needs of the individuals who receive it.

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Appendix A – Standards Roadmaps

Table 5: Summary of Standards Recommendations from Section 2.0 and Subsections

2.2 Environmental Considerations
Opportunities exist to develop standards and guidelines for the home health care environment based on work done in other countries that has not yet been recognized in Canada. The fact that Canada's national residential building code applies to new construction presents such an opportunity. For example, US *National Healthy Housing Standard,* issued in 2014 by the National Center for Healthy Housing and the American Public Health Association has health-based provisions to fill gaps where no property maintenance policy exists [54]. The standard acts as a complement to policies already in use by local and state governments and federal agencies for the upkeep of existing homes. The *National Healthy Housing Standard* covers the following topics on the use of home health technologies: ▪ Duties of owners and occupants; ▪ Structures, facilities, plumbing, and space requirements; ▪ Safety and personal security; ▪ Lighting and electrical systems; ▪ Thermal comfort, ventilation, and energy efficiency; ▪ Moisture control, solid waste, and pest management; and ▪ Chemical and radiological agents. A similar standard developed for Canada should provide details on these topics to ensure the safety and suitability of the home care and community care environment. A uniform approach is required for the safe handling and disposal of hazardous biomedical, biological, and infectious waste produced in home and community care settings across Canada and even within provinces and territories. While most of CSA Z317.10 [55] addresses the handling of health care waste materials in health care facilities, the standard includes a section on the home environment. This section outlines the duties of the home care provider and the client. It also includes a sample checklist for home care services in an appendix. There is a need for more extensive guidelines, checklists, and oversight programs that focus specifically on home care. These could be adopted by municipal waste collection agencies and disseminated to home care users and caregivers. A unified national guideline could be developed for the safe disposal of medications and other biomedical waste in the home that is based on CSA Z317.10 [55].

2.3 Managing Human Factors

The rapid increase in the use of health care technologies in Canadian homes helps to support a much wider range of care than previously possible. The factors driving this change point to this trend growing with hospitals seeking to discharge those who can manage at home and people exerting their preference to receive treatment in their home.

Medical devices and supplies find their way into the home from hospitals, assistive devices programs, medical device vendors, and leasing programs. Some are purchased by the user. Many are designed primarily for use in health care institutions.

Challenges in home and community care settings include the design of medical devices and technologies and suitable training for lay operators, the lack of on-site and on-demand technical support, the variations in home settings, the hazards that can be present in the home, and effective cleaning and sterilization of devices and supplies in the home.

Chapter 25 of ANSI/AAMI HE75) [63] focuses specifically on issues that should be addressed when designing medical devices and supplies for use in the home. While ANSI/AAMI HE75 focuses on device design, CSA C22.2 No. 60601-1-11 [67] is broader in scope and refers to many of the issues raised in this report, with Annex A of CSA C22.2 No. 60601-1-11 providing a rationale that addresses these points. While both standards focus on designing medical devices for the home and provide significant insight into the issues that should be considered during the design process, they contain limited guidance on the selection process and the training needed by intended users.

There is a significant opportunity to develop standards that address the criteria used when selecting health technologies for the home. The target audience for these standards should be the health care professionals who either issue medical devices or provide guidance to clients on their selection and purchase. The standards should explain the issues in the home environment to try to make sure that the selected technology can be safely used in this specific case, taking into account the lay operator's skills and abilities and the level of support available to them.

Health technology selection will always be limited to the items that are currently available in the location of care. It would therefore be useful to have additional standards guidance on preparing suitable training materials and delivering suitable hands-on training for each client and their caregivers. As with selecting health technologies, the focus of the standard should be on the health care provider team supporting the care of the client in the home.

In some circumstances, a client acquires health technologies for use in the home without the support of a health care team. The recommended standards should include guidance on direct purchases, for health care team members who visit the home, so that they can assess whether a directly acquired technology poses a significant risk to a client in a given situation and how to mitigate that risk.

To summarize, in the context of the human factors issues, practical implementation guidance would help improve the safety and efficacy of health care technology use in the home care environment, at selection (as discussed in Section 2.2) and during ongoing management (as discussed in Section 2.3):

- Designing technologies that are suited to lay operators – home care clients and caregivers – in the home.
- Selecting technologies appropriate for the challenges lay operators face in the home.
- Assessing the technologies that clients directly acquire for their safety in the home.
- Designing and supplying appropriate training and training materials on using health care technologies in the home.

To be effective, guidance on these points needs to be framed in a manner that addresses the practicalities of implementation, providing clear direction on what steps need to be taken to address each issue.

2.4 Health Technology Assessment

The process, practice, and discipline of HTA is a primary foundation for assuring safe, efficient, and cost-effective medical care. Skipped, incomplete, or inappropriate HTA inevitably leads to problems. Nevertheless, established HTA methods have largely focused on hospital applications, where the environment is relatively controlled (as described in Section 2.2) and access to trained technical staff is regulated.

Home and community care relies on safe, effective, reliable, and reasonably affordable technologies in locations that can be quite remote and inhospitable compared to hospital settings. Because home and community health care are growing segments of Canadian medicine, there exists an opportunity to develop best practice guidelines or standards for HTA to assure optimum health technology selection for home and community care settings.

Components of such a national HTA guideline or standard should include:

- A consistent core description of HTA processes as applied to home and community care settings, placing special emphasis on internal and external environmental limitations and challenges, and the human factors needs of care recipients and caregivers without clinical or technical experience;
- A clear focus on the life cycle costs and labour for supporting technologies outside of the traditional hospital setting, including relevant aspects of supplies, accessories, medications, installation, training, troubleshooting, maintenance, and repair;
- An enduring and consistent process to ensure that manufacturers are obligated to provide necessary repair and operational parts, user and service documentation, and warranty fulfillment resources for safe, affordable, and clinically effective use;
- A sensitivity to and incorporation of likely site-specific modifications that a particular health technology may require in the home or community care setting, such as special electrical or water provisions, waste management, and supply chain support for all consumable items, routine maintenance, and repairs;
- Consistent documentation of HTA process, including appropriate senior management oversight, review, and intervention;
- Consistent and continuous HTA process improvement, based on CAN/CSA-ISO 9001 [52] quality management methods, which ensure that changes in device specifications, changes in home and community care applications, and ongoing maintenance and failure histories are all used to routinely improve each product's HTA methods to maximise safety, reliability, and clinical efficacy; and
- Frequent, regular, and consistent reviews of appropriate Canadian, FDA/MAUDE and ECRI databases to avoid acquiring products with pre-existing recalls or other deficits, and a periodic review of those sources on a timely basis.

Although it may not be feasible to initially create a single national guideline or standard, it may be an opportunity to bring stakeholders together to begin harmonizing provincial HTA regulations, standards, and practices toward the goal of establishing national best practices for HTA for home and community health care.

2.5 Health Technology Management

Home and community care requires an HTM best practices guideline or standard that focuses explicitly on their needs. The following are useful sources:

- *Clinical Engineering Standards of Practice – 2014 [86];*
- *Guide 4: How to Operate your Healthcare Technology Effectively and Safely [93];*
- *Guide 5: How to Organize the Maintenance of your Healthcare Technology [94];*
- *Home Care Services, Ver. 14 [49];*
- *Clinical Engineering Handbook, 2nd ed. [88];*
- *Managing Medical Devices: Guidance for health and social care organisations [90].*

The two Ziken guides, Guide 4 [93] and Guide 5 [94] and the guidance from the United Kingdom [90] have common public domain uses, and may be easier to adapt. Older US Army and US Air Force manuals that cover similar topics may also have public use status.

Management of certain home health technologies in community care settings may differ from that in an individual home setting, so HTM best practice guidance or standards may need to accommodate both situations. In community care settings, for example, it may be necessary to address novel infection prevention and control, default start-up settings, and post-use cleaning and configuration differently from home care settings. This applies to devices, such as infusion pumps, blood pressure monitors, and medication nebulizers; to reusable and disposable supplies, such as ventilator humidifiers, oxygen nasal cannula; and to PPE, such as masks and face shields. It may also apply to certain bulk medications and dispensers for drugs in pill, powder, or liquid form.

To support such an effort, development and adoption of a Canadian HTM nomenclature would be extremely helpful. The COVID-19 pandemic highlighted the lack of a robust way to describe and identify products. Too many similar products have been assigned conflicting names, making identification, prescription, acquisition, recalls, management and, ultimately proper disposal difficult or impossible. For example, ventilators are sometimes mistakenly called respirators or resuscitators or even reanimators. A consistent, hierarchical nomenclature system would solve such problems, such as, "Ventilator, Emergency", "Ventilator, Pediatric", "Ventilator, Neonatal", "Ventilator, ICU", "Ventilator, Portable", "Ventilator, Non-Invasive, Positive Airway Pressure", etc. WHO has a high-priority project that might help Canada fill this void [95]. The two existing systems, the Universal Medical Device Nomenclature System (UMDNS) and the Global Medical Device Nomenclature (GMDN), are incomplete and incompatible, and both have copyright constraints.

Another need for guidelines or standards would be "clinical use cases". Specific clinical home care applications can be grouped together with focused best practices. For example, home care oxygen concentrator management involves filter replacement, humidification, and oxygen concentration and flow rate verification, and periodic major product refurbishment. Home chemotherapy infusion, home pain management infusion, home COVID-19 pulse oximeter, and ventilator care are other examples of well-known non-treatment-specific applications that could benefit from best practices. Such guidelines or standards need not be overly brand-, model-, or situation-specific, but can set minimum recommended best practices based on representative clinical use cases. *Clinical Procedures for Safer Patient Care* [103], which is a recognized and respected open-source Canadian clinical care book, could be used for many of these use cases and could also serve as a template to develop HTM guidance for other common clinical use cases. Rather than attempting to write manuals for all possible scenarios and technologies, the home care industry, together with appropriate government bodies, should collaborate to identify high-risk, high-cost, and high-benefit home care use cases for such an effort.

2.6 Infection Prevention and Control

IPAC is a significant challenge in home and community settings, particularly because the entire environment cannot be rigorously maintained in a sanitary condition. In addition, home health technologies are diverse, as are the bacteria, viruses, fungi, and other threats that must be considered.

Standardization of IPAC processes in Canada for home and community care settings is scant. Developing minimum national standardized IPAC best practice recommendations or guidelines could lead to substantial risk and harm reduction. Such recommendations or guidelines could be derived from or parallel to established Canadian, US, and international accreditation, hospital and long-term care standards, plus publications of numerous professional infection control societies in the health care industry (see Appendix D). Such baseline best practice recommendations or guidelines could evolve into a library of baseline standards that may be adopted or adapted at local and national levels.

Critical topics for a national IPAC baseline include:

- Identification of responsibilities for IPAC procedures, training, and oversight, including appropriate documentation, to assure staff competency and both client and caregiver training and understanding;
- Quality management methodologies and responsibilities for reporting infections and remediation;
- Clear and consistent baseline methodologies for infection isolation and reverse-isolation, including signs and communication to ensure safe and effective compliance;
- Responsibilities for site-, client-, and technology-specific IPAC processes (including environmental and waste issues), including remediation and documentation;
- Identification of all necessary IPAC supplies, including PPE, and supply chain oversight;
- Identification and remediation of human-factors deficiencies related to all aspects of IPAC, including supplementary documentation, labelling, and training, as necessary;
- Prevention of the spread of infections and other IPAC risks between and within multiple sites when home health technologies are transferred; and
- Building a library of standardized IPAC checklists with sufficient granularity to help with compliance and problem resolution in a timely manner, and to identify ongoing issues that require specialized adaptations.

Medication Management

Because medication management is well-documented as a way of preventing injury and death, a Canadian best practices guideline or standard that focuses explicitly on home and community care across Canada would serve all stakeholders.

Components of such a national guideline or standard should include:

- Medication-specific quality assurance guidelines that are based on CAN/CSA-ISO 9001 [52], with specific clarity about the responsibility of senior management, documented and validated staff training and competence, and CQI processes;
- Assertion of governmental and institutional communication and action mechanisms to ensure that information about medication recalls and hazards extends all the way through the distribution chain to medication recipients, with documentation showing that appropriate remediation has been completed;
- Integration of localized/regionalized medication error and incident reporting to assure:
  - Timely remediation of identified patient risks; and
  - Timely notification of the Health Canada / ISMP Canada medication error/incident reporting system including near misses, e.g., a non-fatal accidental medication overdose caused by erroneous, misleading, or confusing medication labelling, packaging, or handling;
- Consistent national paper or online medication reconciliation procedures and documentation that:
  - Spans local, provincial, and national regulatory bodies,
  - Includes all recommended and required schedule and application constraints needed for safe and effective medication use,
  - Identifies and reconciles duplicate or conflicting prescriptions from prior illnesses or multiple specialists' unsynchronized treatments, and
  - Helps ensure identification and safe, legal disposal of out-of-date, surplus, or discontinued medications.
- A policy and framework to empower consistent and documented informed consent for home and community care clients who elect to avoid, ignore, override, interfere, or invalidate physician prescriptions and guidance.

All these components should clearly indicate that the responsibility of medication reconciliation must extend beyond prescription medications because polypharmacy risks include over-the-counter medications and homeopathic and nutraceutical substances and may also include specific dietary and activity constraints or considerations.

Appendix B – Best Practices

Section 2.1.2: Provincial and territorial legislation of home care programs and services

There exists a set of national benchmarks that establish baseline quality, safety, equity, and efficacy levels with the goal of optimizing patient- and family-centric satisfaction. This benefits all Canadian home care providers, recipients, families, clinicians, and stakeholders.

Section 2.1.3: Provincial and territorial HTA processes

1. There exist well-organized regional HTA guidelines and recommendations that provide a clear mandate and method to help ensure that Canadians have access to the safest, most effective, appropriate, and cost-effective home care devices, supplies, and medications.
2. There exists a cohesive program and process whereby new devices, supplies, or medications for home care can be identified and scheduled for HTA review and recommendation, and the same pathway could be used to apply for HTA of a novel application of an existing product for home care use.

Section 2.1.5: Funding policies

The provincial and territorial eligibility, coverage, co-payment, and funding policies for home health technologies are consistent, to help ensure all Canadians have equitable access, supply chain sufficiency, and costs.

Section 2.2.2: Internal environmental hazards

A minimum unified set of baseline environmental guidelines for safe use of home health technologies, developed with home care industry stakeholders, is available for all individuals and agencies. These guidelines are developed with an awareness and recognition of cultural differences in Canada's multicultural population. The guidelines have corresponding checklists to help guide safety assessments.

Section 2.2.3: Falls risks

Comprehensive guidelines for falls prevention programs that incorporate the safe use of home health technologies are developed and made available for home care clients, families, and caregivers. Based on these programs, and potentially using checklist-driven guides, home care staff can routinely assess, identify, and where possible, make recommendations to remediate any hazards in the home and community care environment including when home health technologies are present.

Section 2.2.4: Bathroom hazards

Minimum national guidelines and standards are developed, in collaboration with industry stakeholders and government agencies, to mitigate risks in the bathroom. Realistic home bathroom constraints minimizing hazards are designed, or adapted, and made available as essential home health technologies.

Section 2.2.5: Safety lessons from home hemodialysis

There is a uniform and consistent guideline, with related procedures and checklists, with respect to the intended home health technology to allow home care providers to identify deficiencies in each home environment, along with a baseline recommendation for safety remediation steps. These guidelines can be similar to what currently exists for home hemodialysis [23].

Section 2.2.6: Reporting internal environment adverse events in home care

All home care stakeholders – caregivers, home care clients and their families – have a clear incident-reporting system for all home health technologies. This system parallels the medication incident-reporting program and Vanessa's Law so that government and public oversight is available.

Section 2.2.7: Home care waste management

Expired, surplus, or undesired medications, intravenous (IV) chemotherapy waste, and infectious or biological waste are properly managed and disposed of safely. Guidelines for disposal of medical waste mimic the relevant provincial occupational health and safety (OHS) guidelines while taking into account home care circumstances. The disposal is directed by consistent national medications disposal guidelines and checklist-driven protocols to avoid environmental contamination and unsafe resale or mislabelling and relabelling and to minimize risk to those who must handle these wastes.

Section 2.2.8: Home care hazard accreditation standards

Hazard-free home care and freedom from environmental risks and damage are maximized as far as possible using national, standardized baseline approaches and checklist-driven methodologies to document and manage home care and home health technology hazards for the occupants.

Sections 2.3.2 and 2.3.3: Managing home care clients' and caregivers' human factors limitations

1. Home health technologies are designed with intrinsic features, labelling, and documentation to reduce or eliminate confusion and errors. This reduces mistakes that can cause injuries or serious harm to the user. Home health technologies intended for use in home or community care settings come with training and checklist-driven documentation, in accessible formats, specifically designed for people without clinical or technical experience.
2. Where appropriate, home care recipients and caregivers receive user-appropriate hands-on training and checklist-driven documentation, in plain language and in accessible formats, on safely and effectively operating technologies in the home or community care setting.
3. Clinical caregivers and teams who issue or manage home health technologies support caregivers without clinical experience, so that they can safely and effectively operate and use the home health technologies. Clinical caregivers routinely assess whether the non-clinical caregivers have received and retained adequate training and have the support they need to competently fulfill this function.

Section 2.3.4: Clinical caregivers' awareness of human factors

Clinical caregivers ensure that medical devices and supplies selected for home or community care use are appropriate:

- by reviewing the selection processes for these technologies;
- by reviewing the available training materials and training methods; and
- by assessing clients' and caregivers' abilities to use the technologies safely and effectively in real world settings.

Section 2.3.5.1: Managing home health technologies: medical devices and supplies

Manufacturers, home care agencies, and issuing agencies fully comply with the requirements of:

- ANSI/AAMI HE75 with an emphasis on Chapter 25, "Home health care" [63], and
- CSA C22.2 No. 60601-1-11 [67].

Section 2.3.5.2: Managing home health technologies: medications

Medications are provided to clients in home and community care settings in a coordinated and unambiguous manner. Clinical care providers ensure that clients and caregivers understand the complete range of medications issued and how to take them appropriately and safely.

Section 2.4.3: Matching devices, supplies, and medications to the environment

1. Health technologies are matched to ensure acceptable and safe performance in the actual home and community care environment, taking into account room features and risks.
2. The roles and responsibilities for identifying, selecting, procuring, and deploying safe and effective home health technologies are clearly identified so that responsibility and accountability are never in doubt.
3. All technology assessment processes cover each individual health care technology and all related supplies, accessories, medications, and any other items necessary for safe and effective use for the intended setting, and the storage capacity, ability to provide refrigeration, etc.
4. Minimum standards, guidelines, or recommendations are established for electricity, water, sewage and waste disposal, storage, security, access, communication services, and safety.

Section 2.4.4: HTA of human factors

Health technologies are matched to the home and community care client and caregivers, taking into account their physical and cognitive abilities (ease of use, ease of troubleshooting, ease of cleaning, control/display visibility, dexterity, height, weight, balance, mobility).

Section 2.4.5: HTA process for management of dangerous or recalled products

Home and community care device-issuing agencies manage recalls and hazard reports to make sure clients and their families and caregivers are not adversely affected.

Section 2.4.6: HTA of manufacturer documentation

Manufacturer documentation, specifications, website, warranty, or marketing materials that may identify constraints, requirements, or prohibitions (e.g., requiring sole use of proprietary supplies or accessories, or sole use of manufacturer-certified technicians) that could limit or waive liability and displace liability onto the home and community care agencies, clients, or caregivers are clearly identified.

Section 2.4.7: HTA for developing pre-purchase safety and quality assurance processes

Quality and safety cannot be "tested into" products. Proven quality assurance methods that inform pre-purchase product evaluation and planning have become standard for health care applications. Customer and staff complaints, product failures, and unanticipated wear or degradation of product or its subcomponents are analyzed for early indication of quality/risk exposures.

Section 2.4.8: Developing initial safety and quality assurance processes

Because health technologies and products can develop defects caused by shipping, storage, handling, etc., clear acceptance criteria, methods, and documentation exist to prevent payment or deployment to home and community care clients when defects are identified.

Section 2.4.9: Master records for each product

A print or electronic master record is created and maintained for each product to support problem identification and resolution with the vendor or manufacturer in the future.

Section 2.4.10: HTA procedures and documentation quality assurance

Device-issuing agencies periodically update the HTA documentation and procedures to reflect the current product and application circumstances.

Section 2.5.2: Inspections of all devices, accessories, supplies, and medications

1. All purchased products are thoroughly inspected in case they are substandard or do not meet contractual obligations.
2. Health care technologies are inspected before they are delivered and installed to be sure that they are safe, reliable, and effective for the clinical application(s) and home.

Section 2.5.3: Addressing safety of returned products

All products that clients return, such as beds, monitors, infusion devices, and respiratory therapy devices, are tested to ensure they are complete, safe, and suitable for continued use, and this testing is documented.

Section 2.5.4: Site assessment for safety and risk

Home and community care site inspections are conducted to help assure that the care environment and client capabilities are appropriate and adequate for safe, reliable, and effective home care.

Section 2.5.5: Completion of scheduled maintenance

Scheduled maintenance is performed after a specific number of weeks, months, or hours of use, as appropriate for the particular device and the conditions of use.

Section 2.5.6: Preventive maintenance processes

Preventive maintenance is performed after a specific number of weeks, months, or hours of use, as appropriate for the particular device and the conditions of use.

Section 2.5.7: HTM quality assurance considerations

The HTM documentation and procedures are periodically updated to reflect current product and application circumstances.

Section 2.6.4: IPAC for home care and community care

1. IPAC practices for home and community care follow unified national guidelines to assure product safety, quality, and efficacy.
2. Standardized guidelines for site- and client-specific IPAC risk assessments exist and are available to home and community care agencies.
3. Standardized guidelines for prioritizing methods for screening and remediating IPAC risks in home and community care settings are available to home and community care agencies.
4. The IPAC responsibilities and accountabilities of all relevant parties in home and community care are clearly delineated.
5. Effective and site-appropriate IPAC surveillance techniques exist for home and community care.
6. Quality control and improvement methodologies for quality of care exist for home and community care.
7. The differences and interrelationship between cleaning, decontamination, disinfection, and sterilization is clearly delineated for home and community care clients and caregivers.
8. Where strictly necessary, movement of people, pets, and any items in and out of the client care area in the home is appropriately controlled, as is common in institutional care settings.
9. Individuals with appropriate knowledge and specialized training oversee the implementation and continued support of IPAC in home and community care settings.
10. Standardized guidelines for effective and site-appropriate isolation or reverse-isolation IPAC processes exist for home and community care settings.
11. For community care settings, IPAC guidelines exist to assure that common shared facilities and areas of facilities are safe.
12. Home and community care agencies track, clearly document, and report the implementation of and compliance with established IPAC practices.
13. Home and community care agencies report adverse events clearly, consistently, and regularly by way of standardized reporting channels.
14. Home and community care agencies demonstrate established IPAC best practices to clients and family members, and provide appropriate training to informal caregivers who are hired if formal caregivers are unavailable or during lapses between professional home care services so that they can implement the IPAC best practices at the care sites.
15. Disposable or single-use medical equipment and supplies are not reused.
16. The clean and sterile condition of medical supplies is always preserved.
17. Each home and community site meets minimum sanitation standards for effective implementation of IPAC best practices.
18. Checklists of IPAC best practices for home and community care are easily and readily available in plain language and accessible formats for use by home and community care agencies, other issuing agencies, clients, and caregivers.
19. Medical equipment and supplies used in home and community care are safely cleaned, decontaminated, disinfected, and sterilized.
20. Where feasible, appropriate, affordable, needlestick injury prevention technologies are used.
21. Where feasible, appropriate, affordable, safety-engineered needles and syringes that prevent reuse are implemented.

Section 2.6.5: Human factors aspects of IPAC in home and community care

1. The effective implementation of established IPAC best practices is achieved through clear communication between home and community care agencies, caregivers, visiting care staff, and clients.
2. Environmental factors in home and community care sites allow for the effective implementation of IPAC best practices.
3. Home and community care clients and caregivers have access to sufficient support to implement IPAC best practices in their care environments, irrespective of any limitations they may have in terms of vision and visual acuity, hearing, cognition, balance, memory, strength, and physical dexterity.
4. Home and community care clients and caregivers have access to sufficient PPE, cleaning and disinfection supplies, and other IPAC supplies to implement and follow established IPAC best practices.
5. Home and community caregivers have access to sufficient support in caregiving to implement IPAC best practices in their care environments.
6. Home and community care clients and caregivers have access to sufficient ancillary resources such as storage space, reusable cleaning supplies, or specialized waste disposal systems to implement IPAC best practices.
7. Medical equipment and supplies used in home and community care are labelled in ways that are consistently clear, easy to follow, and appropriate to the care environment and home and community care clients and caregivers.
8. Cleaning, disinfection, and sterilization of medical equipment and supplies is sufficiently simple for home and community care clients and caregivers in their homes and community care settings.

Section 2.7.2 Medication Management Risk Factors and Complexities

1. The medication regimen of home and community care clients is sufficiently simple and straightforward for self-management or for management by caregivers.

Section 2.7.3 Polypharmacy and Complex Medication Management

1. The design of the medication used in home and community care is standardized to facilitate medication management.
2. Where complex management is needed due to polypharmacy, the home care agency and medication-issuing agency facilitate medication management.

Section 2.7.4 Medication Reconciliation

1. Medication reconciliation programs exist for home and community care settings for safe and effective medication management.
2. If and when the client can be supported to safely manage their own medications, the home care agency provides a viable written medication management plan and coordinates adequate training of the client and caregiver.

Section 2.7.5 Medication Management Devices and Systems

1. The home and community care agency and the medication-issuing agency facilitate effective medication management in the home and community, even when AMDS or other pill planning devices are used.
2. When unit-dose or blister-packaged medications are used, the client and caregiver receive procedures written in plain language and in accessible formats to help them deal with any medication exceptions and changes.

Appendix C – Provincial and Territorial Legislation, Standards and Policies for Home Care Services

Sources mainly based on a 1999 publication by Dumont-Lemasson et al [7], a 2018 publication by Peckham et al. [14], and a non-exhaustive legislation search. The search of the legislation was carried out using a common search engine (Google), based on keywords identified from current provincial/territorial home care guidelines, standards of care, and policies that are listed on relevant provincial and territorial government and ministries of health websites.

Table 6: Provincial and territorial legislation, standards and policies for home care services.

Provinces/ Territories	Legislation	Notes
Alberta	▪ *Public Health Act,* RSA 2000, c P-37 ▪ *Regional Health Authorities Act,* RSA 2000, c R-10 ▪ *Co-ordinated Home Care Program Regulation, Public Health Act,* Alberta Regulation 296/2003, 2018 ▪ *Continuing Care Health Service Standards* [139] ▪ *Alberta Aids to Daily Living and Extended Health Benefits Regulation,* Alberta Regulation 236/1985	
British Columbia	▪ *Continuing Care Act,* RSBC 1996, c 70 ▪ *Hospital Act,* RSBC 1996, c 200 ▪ *Community Care and Assisted Living Act,* SBC 2002, c 75 ▪ *Continuing Care Fees Regulation, Continuing Care Act, Continuing Care Act,* BC Reg 330/97 ▪ *Continuing Care Programs Regulation, Continuing Care Act,* BC Reg 146/95, amended Apr 2019 ▪ *Assisted Living Regulation, Community Care and Assisted Living Act,* BC Reg 189/2019, Amended Dec 2020 ▪ *Model Standards for Continuing Care and Extended Care Services,* Ministry of Health and Ministry Responsible for Seniors, April 1999 ▪ Home and Community Care – Policy Manual ▪ *Employment and Assistance for Persons with Disabilities Act,* SBC 2002, c 41 ▪ *Employment and Assistance for Persons with Disabilities Regulation, Employment and Assistance for Persons with Disabilities Act,* BC Reg 265/2002 ▪ *Employment and Assistance Act,* SBC 2002, c 40 ▪ *Employment and Assistance Regulation, Employment and Assistance Act,* BC Reg 263/2002	

Provinces/ Territories	Legislation	Notes
Manitoba	▪ *Public Health Act,* C.C.S.M. c. P210 ▪ *The Health Services Insurance Act,* CCSM c H35 ▪ *Prosthetic, Orthotic and other Medical Devices Insurance Regulation, The Health Services Insurance Act,* Man Reg 53/93 ▪ *Excluded Services Regulation, The Health Services Insurance Act,* Man Reg 46/93	▪ Home care program established through order-in-council [7]
New Brunswick	▪ *Bill 85, An Act to Amend the Hospital Act, Hospital Act,* SNB 1992, c H-6.1 ▪ *Family Services Act,* SNB 1980, c F-2.2 ▪ *Home Support Services Standards,* 2011 ▪ *Health Services Act,* SNB 2014, c 112 ▪ *General Regulation, Health Services Act,* NB Reg 84-115 ▪ *Family Income Security Act,* SNB 1994, c F-2.01 ▪ *General Regulation, Family Income Security Act,* NB Reg 95-61	▪ Extra-Mural Program (NB home care program) falls under Bill 85, An Act to Amend the Public Hospitals Act (1996) [7]
Newfoundland and Labrador	▪ *Health and Community Services Act,* SNL1995 c P-37.1 ▪ *Self-Managed Home Support Service Act,* SNL 1998 c S-13.1 ▪ *Provincial Home Support Program Operation Standards,* Department of Health and Community Services, 2005 ▪ *Income and Employment Support Act,* SNL 2002, c I-0.1 ▪ *Income and Employment Support Regulation, Income and Employment Support Act,* NLR 144/04	
Northwest Territories	▪ *Hospital Insurance and Health and Social Services Administration Act,* R.S.N.W.T. (Nu) 1998, C T-3 ▪ *Public Health Act,* SNWT 2007, c 17 ▪ *Northwest Territories Continuing Care Standards, Health and Social Services,* 2015 ▪ NWT Community Health Core Services Standards and Protocols	
Nova Scotia	▪ *Homemaker Services Act,* R.S., c 201, s 1 ▪ *Co-ordinated Home Care Act,* 1990, c 6, s 1 ▪ *Health Authorities Act,* SNS 2014 c 32 ▪ *Social Assistance Act,* RSNS 1989, c 432 ▪ *Municipal Assistance Regulations, Social Assistance Act,* NS Reg 76/81 ▪ *Home Care Policy Manual,* Nova Scotia Department of Health and Wellness, 2011	
Nunavut	▪ Not found	
Ontario	▪ *Health Insurance Act,* R.S.O. 1990, c H.6 ▪ *Homemakers and Nursing Services Act,* R.S.O. 1990, c H.10 ▪ Bill 175, *An Act to amend and repeal various Acts respecting home care and community services,* 2020 ▪ *Connecting Care Act,* 2019, S.O. 2019, c. 5, Sched. 1 ▪ *Home Care and Community Services Act,* 1994, S.O. 1994, c. 26 ▪ *Ministry of Health and Long-Term Care Act,* R.S.O. 1990, c. M.26 ▪ *Ontario Disability Support Program Act,* 1997, SO 1997, c 25, Sched. B, General, O Reg 222/98 ▪ *Employment Supports, Ontario Disability Support Program Act, O Reg 223/98* ▪ *Administration and Cost Sharing Regulation, Ontario Disability Support Program Act,* S.O. 1997, c. 25, Sched. B, O Reg 225/98 ▪ *Prescribed Policy Statements Regulation, Ontario Disability Support Program Act,* S.O. 1997, c. 25, Sched. B, O Reg 562/05	▪ Standards available for long-term care homes and nursing homes, but no specific standards for home care

Provinces/ Territories	Legislation	Notes
Prince Edward Island	▪ *Community Care Facilities and Nursing Homes Act,* R.S.P.E.I. 1988, c C-13 ▪ *Operational and Care Service Standards for Community Care Facilities,* Department of Health, 2009, Revised 2016. ▪ *Rehabilitation of Disabled Persons Act,* RSPEI 1988, c R-12 ▪ *Social Assistance Act,* RSPEI 1988, c S-4.3 ▪ *Social Assistance Act Regulations, Social Assistance Act,* PEI Reg EC396/03, (Social Assistance Act)	▪ Homecare support program implemented through – Order-in-Executive Council [7]
Quebec	▪ *Act Respecting Health Services and Social Services,* CQLR c S-4.2 ▪ *Act Respecting Health Services and Social Services for Cree Native Persons,* CQLR c S-5 ▪ *Règlement d'application de la Loi sur les services de santé et les services sociaux pour les autochtones cris,* R.R.Q., c. S-5, r.1 ▪ *Individual and Family Assistance Act,* CQLR c A-13.1.1 ▪ *Individual and Family Assistance Regulation, Individual and Family Assistance Act,* CQLR c A-13.1.1, r.1	▪ Two official documents by MSSS and the Act Respecting Health and Social Services (S.80) gives mission and requirements at CLSCs (local community services centres) that are responsible for home care [7] ▪ No specific home care services legislation [7]
Saskatchewan	▪ *The Provincial Health Authority Act,* SS 2017, c P-30.3 ▪ *Saskatchewan Home Care Policy Manual,* 2021 ▪ *The Saskatchewan Aids to Independent Living Regulations, The Health Administration Act,* 1976, Sask Reg 292/76 ▪ *The Saskatchewan Assistance Plan Supplementary Health Benefits Regulations, The Health Administration Act,* Sask Reg 65/66 ▪ *The Rehabilitation Act,* RSS 1978, c R-17 ▪ *The Rehabilitation Regulations, The Rehabilitation Act,* Sask Reg 265/72 ▪ *The Saskatchewan Assistance Act,* RSS 1978, c S-8 ▪ *The Saskatchewan Assured Income for Disability Regulations, The Saskatchewan Assistance Act,* 2012, RRS c S-8 Reg 11 ▪ *The Saskatchewan Assistance Regulations, Saskatchewan Assistance Act,* 2014, RRS c S-8 Reg 12 ▪ *The Public Health Act,* 1994, SS 1994, c P-37.1 ▪ *Paraplegia under The Health Services Act,* Sask Reg 786/68	
Yukon	▪ *Health Care Insurance Plan Act,* RSY 2002, c 107 ▪ *Social Assistance Regulation, Social Assistance Act,* YOIC 2012/83 ▪ *Health Act,* RSY 2002, c 106 ▪ *Chronic Disease and Disability Benefits Regulation, Health Act and Health Care Insurance Plan,* YOIC 1994/16822	▪ No legislation on the delivery of home care services, but the legislative authority for home care program and services derived from the Yukon Health Act [7]

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Appendix D – Supplementary Resources

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