

Public Inquiry into the Safety and Security of Residents in the Long-Term Care Homes System

REPORT

The Honourable Eileen E. Gillese Commissioner

Volume 1 – Executive Summary and Consolidated Recommendations

Volume 2 – A Systemic Inquiry into the Offences

Volume 3 – A Strategy for Safety

Volume 4 – The Inquiry Process



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This Report consists of four volumes:

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ISBN 978-1-4868-3586-7 (PDF) ISBN 978-1-4868-3582-9 (Print)

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Disponible en français

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Volume 3 of the Report is dedicated to the many nurses and other caregivers who perform their jobs in the long-term care system with great kindness and skill. Our Strategy for Safety cannot succeed without their continued dedication to those in their care. In opening our eyes to the one nurse who harmed, we must not forget the work of the many who are a credit to their professions.

Acronyms and Abbreviations

ADC	automated dispensing cabinets
ADR	alternative dispute resolution
APR	automated provider reports
ВСМА	barcode-assisted medication administration
ВРМН	best possible medication history
DEIVILI	best possible medication history
CAMH	Centre for Addiction and Mental Health
CCAC	Community Care Access Centre
CCF	complaint, critical incident and follow-up
CFS	Centre of Forensic Sciences
CIAF	Canadian Incident Analysis Framework
CIATT	Centralized Intake, Assessment and Triage Team
CIHI	Canadian Institute for Health Information
CIS	Critical Incident System
CLRIs	Centres for Learning, Research and Innovation
cMAR	computer-generated medication administration record
CMI	Case Mix Index
CNO	College of Nurses of Ontario
COPD	chronic obstructive pulmonary disease
CVA	cardiovas cular accident
CVH	cardiovascular heart disease
DIOC	Death Investigation Oversight Council
DNR	do not resuscitate
DOC	director of care
DON	director of nursing
	-
EDB	emergency drug box
eMAR	electronic medication administration record
FSPΔ	External Service Provider Agencies Policy

ETMS events tracking management system

FPU	Forensic Pathology Unit
FTE	full-time-equivalent (employee)
HCCSA	Home Care and Community Services Act, 1994
HCSK	healthcare serial killer
HESP	Health, Education and Social Policy (Committee of Cabinet)
HNHB	Haldimand Niagara Haldimand Brant
HQO	Health Quality Ontario
HSARB	Health Services Appeal and Review Board
HSIM	Health System Information Management (Division)
HSMR	hospital standardized mortality ratio
HSP	health service provider
HSSP	Health and Social Services Policy (Committee of Cabinet)
IALP	Inter-Agency Leadership Partnership
I/CAD	Intergraph Computer Aided Dispatch
ICRC	Inquiry, Complaints and Reports Committee
IPDR	Institutional Patient Death Record
IQS	Inspector's Quality Solution
ISMP	Institute for Safe Medication Practices
LHIN	Local Health Integration Network
LHSIA	Local Health System Integration Act, 2006
LQIP	Long-Term Care Home Quality Inspection Program
LRPA	Long-Term Care Home Quality Inspection Program Risk Performance Assessment
LSAA	Long-Term Care Home Service Accountability Agreement
LTC	long-term care
LTCH	Long-Term Care Home (Division)
LTCHA	Long-Term Care Homes Act, 2007
LTCI	Long-Term Care Homes Public Inquiry
MAPLe	Method for Assigning Priority Levels
MAR	medication administration record
MAR/TAR	medication administration record / treatment administration record

MDS Minimum Data Set MOU memorandum of understanding MPP Member of Provincial Parliament NHA **Nursing Homes Act** NHP Nurses' Health Program NP nurse practitioner NPC nursing and personal care OARC Ontario Association of Residents' Councils OCC Office of the Chief Coroner OCD obsessive compulsive disorder OFPS Ontario Forensic Pathology Service Ontario Health Insurance Plan OHIP OIC Order in Council OLTCA Ontario Long Term Care Association ONA Ontario Nurses' Association OPA Ontario Pharmacists Association PAC **Professional Advisory Committee** PFPU Provincial Forensic Pathology Unit PIA Public Inquiries Act, 2009 PICB Performance Improvement and Compliance Branch PICC peripherally inserted central catheter PLP Preceptee Learning / Developmental Plan PME Post Mortem Examination POM provider operations meeting PRN pro re nata ("as needed") PSW personal support worker RAI Resident Assessment Instrument RAI-CA Resident Assessment Instrument – Contact Assessment RAI-HC Resident Assessment Instrument – Home Care RAI-MDS Resident Assessment Instrument–Minimum Data Set RCPSC Royal College of Physicians and Surgeons of Canada

SW LHIN

RHPA Regulated Health Professions Act, 1991 RL6 system electronic complaint / incident reporting system (Saint Elizabeth Health Care) RN registered nurse RPN registered practical nurse RPNAO Registered Practical Nurses Association of Ontario RQI resident quality inspection RSC regional supervising coroner SAO Service Area Office SCAN Suspected Child Abuse and Neglect (Program) SDM substitute decision-maker **Special Investigations Unit** SIU SW CCAC South West Community Care Access Centre

TAR treatment administration record

WHMIS Workplace Hazardous Materials Information System

South West Local Health Integration Network

WSIB Workplace Safety and Insurance Board

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I. Introduction

Based on the evidence I heard in the public hearings, it is my view that systemic failings in the long-term care (LTC) system – not individual ones – created the circumstances that allowed Wettlaufer to commit the Offences. In this volume of the Report, I describe the systemic vulnerabilities identified through the Inquiry processes and propose systemic responses that must be taken if we are to avoid similar tragedies in the future. These responses are designed to prevent, deter, and detect wrongdoing of the sort that Wettlaufer, a healthcare serial killer (HCSK), committed. This chapter is devoted to strategies whose goal is prevention. Later chapters in this volume are directed at the strategies for deterrence and detection.

I begin this chapter by considering why systemic issues demand a systemic response. In the next section, I explain that although the LTC system is grappling with serious challenges, it is far from broken. In the section that follows, I call for the Ministry of Health and Long-Term Care (Ministry) to play an expanded leadership role. In fulfilling this expanded role, the Ministry will strengthen the LTC home system through capacity building and the sharing of excellence. I call for a new unit in the Long-Term Care Homes Division to support LTC homes in achieving regulatory compliance and to spread best practices throughout the sector. I also recommend that the Ministry provide funding for bridging and laddering programs in LTC homes and that it play an enhanced role in encouraging innovation and the use of new technologies in the LTC system. Strengthening the LTC system is the best form of prevention.

In Chapter 16, I set out the results of the Inquiry's expert evidence and research on the HCSK phenomenon. Although rare, the HCSK phenomenon is long-standing and global in its reach. As I explain, the essential first step in combatting HCSKs is to build awareness, throughout the healthcare system, of the possibility that healthcare providers may intentionally harm those in their care. The recommendations in Chapter 16 set out a plan on how to build, develop, and maintain that awareness.

Wettlaufer committed the Offences using insulin that she had diverted in the places in which she worked. The focus of Chapter 17 is on the medication management system in LTC homes and how to limit diversion. I call for a three-pronged approach to deterrence: strengthen the medication management system in LTC homes; improve homes' medication incident analysis; and increase the number of registered staff in the homes.

In Chapter 18, I consider Ontario's death investigation system and its current shortcomings in respect to deaths of residents in LTC homes. I propose two key strategies to remedy this situation: a redesigned Institutional Patient Death Record, and the use of data analytics, including through the Ministry's project to detect elevated death rates in LTC homes.

Finally, in Chapter 19, I discuss suggestions the Inquiry received on how to prevent similar tragedies but which did not ultimately become recommendations. I explain why these suggestions – many of which initially appear compelling – fell outside the scope of the Inquiry mandate, were unworkable in practice, or simply attracted too high a cost to be implemented. I hasten to add that cost was calculated with due consideration for the rights of residents and others, and not merely as a matter of dollars and cents. As I note in Chapter 19, the suggestions were useful, however, because exploring them helped to guide this Report and the recommendations in it.

II. Systemic Issues Demand a Systemic Response

Systemic issues tend to be complex, multifaceted, and/or polycentric in nature; they go beyond who did what to whom and require us to look at the operation of the system as a whole. In Canada, public inquiries are often established to address tragedies that arise from systemic issues. As Ronda Bessner recently wrote:

The issues in inquiries are larger than "who did what to whom." Unlike civil and criminal trials, which focus on narrow issues between the parties, and determining whether the evidence supports a particular finding, public inquiries are concerned with broader systemic and institutional issues.¹

Systemic issues require a systemic response. Systemic responses are not about finger-pointing, assigning blame, or looking for scapegoats. As Justice Archie Campbell explained in the context of the Bernardo Investigation Review, individual mistakes did not cause the tragedy or overall disaster: "Although the Bernardo case, like every similar investigation, had its share of human error, the overall story is a story of great dedication and investigative skill defeated by systemic failure." Since individual mistakes do not cause the tragedy, assigning blame to individuals will not remedy the problem or

Ronda Bessner, "Introduction to Public Inquiries in Canada" in Ronda Bessner and Susan Lightstone (eds), Public Inquiries in Canada: Law and Practice (Toronto: Thomson Reuters, 2017), 8.

² Justice Archie Campbell, "The Bernardo Investigation Review," in Allan Manson and David Mullan (eds), Commissions of Inquiry: Praise or Reappraise? (Toronto: Irwin Law, 2003), 398.

guard against future similar tragedies. As Justice Campbell put it, "[U]nless the underlying problem is addressed, the same mistakes or wrongdoing will likely occur again if the system that permitted them is not fixed."³

Effective systemic responses require those in the system – both individuals and organizations – to work together to address the systemic failings that have been identified. Even those recommendations targeted at specific actors in the system must be approached collaboratively. For example, I recommend that the Office of the Chief Coroner / Ontario Forensic Pathology Service (OCC/OFPS) revise the Institutional Patient Death Record (IPDR) and make it evidence-based. In this way, the OCC/OFPS should get better information on which to make the crucial decision of whether to investigate a resident's death. But the value of this recommendation depends not only on the OCC/OFPS redesigning the IPDR but also on the LTC homes making sure that those in the home who will be responsible for completing the revised IPDR have the opportunity for training on how to properly complete it. It also depends on the home's staff and family members sharing information about the manner of the resident's death; individual coroners taking new training on performing death investigations in LTC homes; and the professionals who receive copies of the redesigned IPDRs taking the time to review them and consider whether they have additional information or concerns that should be raised with the OCC/OFPS.

Given the need for those throughout a system to work collaboratively in resolving systemic issues, assigning blame to individuals or different organizations in the system is counterproductive. Systemic issues are "best dealt with by encouraging people to go down a path where they can change the things that went wrong." In the Report of the Arbour Inquiry into the Events at the Prison for Women in Kingston, Justice Louise Arbour was reluctant to attribute responsibility to any one individual for this reason. As she explained:

Attribution of personal blame would suggest personal rather than systemic shortcomings and justifiably demoralize the staff, while offering neither redress nor hope for a better system.⁵

³ Campbell, "Bernardo Investigation Review," 399.

⁴ Campbell, "Bernardo Investigation Review," 400.

⁵ Arbour Inquiry into the Events at the Prison for Women in Kingston, referenced in Campbell, "Bernardo Investigation Review," 400.

The LTC system is a complex and polycentric system, with multiple institutions and organizations all playing roles in the provision of care to those within it. The issues that must be addressed to guard against HCSKs are systemic in nature. Addressing them requires the participation, buy-in, and support of all those within the LTC system. Based on the evidence at the public hearings, the Participants' closing submissions, and the willing and active engagement of the Participants and other stakeholders during the consultations in part 2 of the Inquiry process, I am confident that those who work in the LTC system are ready and willing to do exactly that. What is needed, however, is leadership – a body that is capable of pulling together the stakeholders and providing a structure within which the necessary collaboration and co-operation can be nourished and sustained. Fortunately, as I explain below, the Ministry is ideally positioned to expand its existing leadership role to embrace this challenge.

III. The Current System – A Solid Foundation on Which to Build

The evidence at the hearings painted a comprehensive picture of the LTC system and how it operates. It also made clear that the LTC system – and those who work in it – are under pressure. LTC homes are the most regulated area of healthcare in the province. Despite limited resources, the staff in LTC homes must meet the regulatory dictates and provide care for residents with ever-increasing acuity. (See Chapter 1 for a discussion of the increasing acuity of both residents and those aging at home.)

Although the LTC system is strained, it is not broken. The regulatory regime that governs the LTC system, together with those who work in it, provides a solid foundation on which to address the systemic issues identified in this Inquiry.

A. The LTCHA and Regulation

The Long-Term Care Homes Act, 2007 (LTCHA),⁶ and its regulations⁷ (Regulation) create a solid regulatory framework for resident-centred care. The resident focus is evident throughout the LTCHA, beginning with the preamble and followed by the statement of its fundamental principle in section 1:

[A] long-term care home is primarily the home of its residents and is to be operated so that it is a place where they may live with dignity and in security, safety and comfort and have their physical, psychological, social, spiritual and cultural needs adequately met.

The LTCHA and Regulation impose clear standards for LTC homes and a rigorous inspection regime to enforce those standards. The regulatory regime plays an important role by establishing minimum standards of care for residents on a broad range of matters, including residents' rights, care, and services; reporting requirements; medication management; infection control; food safety and quality; and staffing in the home. It places obligations on all licensees of LTC homes that are detailed, comprehensive, and prescriptive. By setting the foundation for good resident care in Ontario's LTC homes, this regulatory regime is designed to ensure that residents are safe and secure, and are treated with dignity and respect.

Unlike under the previous regulatory regime, however, under the LTCHA regime Ministry inspectors cannot advise homes on how to comply with the regulatory requirements: they must issue a notice of non-compliance if they find that a licensee has failed to comply with the LTCHA or Regulation. Although the Ministry provided training for licensees and LTC home staff before the LTCHA regime was rolled out, it is now expected that licensees and those who work in LTC homes understand the regulatory requirements. They cannot turn to inspectors for advice.

In both the public hearings and the consultations, I heard from LTC homes about the challenges posed by having to comply with the more than 1,000 requirements imposed by the LTCHA and Regulation. Some homes struggle in trying to make sense of these requirements. Others are frustrated by the elimination of the compliance advisor role because they find it difficult to meet Ministry expectations without advice or guidance.

⁶ SO 2007, c 8.

⁷ O Reg 79/10.

I also heard that homes find the inspection processes under the LTCHA regime increasingly onerous, taking staff and management away from resident care and producing stress among staff. Some expressed concern that this regulatory regime – and the inspection process – have led to a "check-box" mentality in which it is more important to show compliance with specific provisions than to demonstrate that the care provided in the home is leading to improved quality of life for residents.

Perhaps as a result of these concerns, a somewhat adversarial relationship appears to have developed between staff in LTC homes and those in the Ministry. Instead of working together to seek excellence in the provision of care in LTC homes, the focus appears to be on ensuring that the minimum standards established by the regulatory regime are met.

It is important to note that meeting the regulatory standards and striving for the highest possible quality of resident care are not mutually exclusive: there can be no excellence in care without first meeting the regulatory standards. The standards established by the LTCHA and Regulation are important, and Ministry inspectors play an important role in this regulatory regime by ensuring that homes comply with its dictates. However, this Inquiry has identified systemic shortcomings that must be addressed if we are to avoid tragedies similar to the Offences in the future. Avoiding similar tragedies can best be achieved through prevention, deterrence, and detection of healthcare workers who seek to intentionally harm those for whom they care. As I explain below, the Ministry must play a key role in prevention, building on the LTC sector's strong foundation and leading it into one that is more consistently characterized by excellence.

B. The People and Organizations in the LTC System

I have seen first-hand, through this Inquiry, that the vast majority of those who work in long-term care are dedicated both to the ideals of resident-focused care and to the people for whom they provide care.

Witnesses in the public hearings came from all parts of the LTC system, including those who work in LTC homes, those who inspect the homes, and those responsible for ensuring the safe delivery of publicly funded home care. The pain they felt as a result of the Offences was evident. What was also evident was their passion for the work they do and their commitment to the residents and clients in the LTC system.

In the part 2 consultations, I met directly with many stakeholders, including residents, frontline staff, those in management positions in LTC homes, individuals engaged in policy development and oversight at the Ministry, professional regulatory bodies, and professional advocacy bodies. All who came to the consultations did so willingly, eagerly, and fully prepared. They offered thoughtful and constructive comments, observations, and ideas for further consideration. Afterward, many provided additional information relating to issues that had been raised in the consultations. Like those who gave evidence at the public hearings, I found the people who attended the consultations to be hard-working individuals who care deeply about long-term care. Many in both groups said the same thing: their work in long-term care is a vocation, not just a job.

As the saying goes, "Actions speak louder than words." I set out below two types of stakeholder initiatives that, in my view, are incontestable evidence of the dedication and commitment to care of the individuals who work in the LTC system.

1. Pro-active Stakeholder Initiatives

The initiatives listed below are but a sample of those that stakeholders undertook in response to issues that the Commission and I identified in the public hearings and the consultations. These stakeholders did not wait until this Report was released before acting. When they learned of something that could be done to improve the LTC system, if the matter was within their control, they acted immediately.

a) Working Group on Improving the Safety and Security in the LTC Medication Management Systems

Earlier this year, the Ministry established a time-limited working group composed of sector partners to seek ideas and best practices to increase the safety of the medication management system in LTC homes. The list of stakeholders includes:

- The Institute for Safe Medication Practices Canada;
- · Ontario Long Term Care Clinicians;
- Registered Nurses' Association of Ontario;
- Registered Practical Nurses Association of Ontario;
- · pharmacy service providers; and
- LTC home licensees.

In establishing this working group, the Ministry stated:

Given the nature of the [Offences], changes to the medication management system may help to reduce the likelihood of these events occurring in the future. The ministry is committed to considering the recommendations coming out of the Public Inquiry and will incorporate them into a medication management strategy as appropriate.⁸

b) Amendments to the Coroners Act

Following the public hearings and consultations, Dr. Dirk Huyer, Ontario's chief coroner, took steps to have changes made to the *Coroners Act* that would enhance coroners' powers in the death investigation process. The *Comprehensive Ontario Police Services Act*, 2019,⁹ which came into force in March 2019, amended the *Coroners Act* so that:

- coroners now have earlier access to records relating to a deceased (including residents), which will give them more information when deciding whether to conduct a death investigation;¹⁰ and
- it is clear that the chief coroner has the power to conduct historical death reviews.¹¹

c) Redesign of the Institutional Patient Death Record

The Office of the Chief Coroner / Ontario Forensic Pathology Service has already begun the necessary work to redesign the Institutional Patient Death Record (IPDR), a task called for by recommendations in this Report and which were discussed in its consultation process. Chapters 14 and 18 include a discussion of the goals to be achieved through the redesigned IPDR.

d) A Retrospective Forensic Pathology Review of Concealed Homicides

The Offences are concealed homicides: had Wettlaufer not confessed, they would not have been discovered. (See Chapter 1 for a full discussion of this point.) This knowledge was a factor in Dr. Michael Pollanen, Ontario's

Ministry of Health and Long-Term Care, Working Group on Improving Safety and Security in LTC Medication Management Systems, Terms of Reference, p 2.

⁹ SO 2019, c 1.

¹⁰ *Coroners Act*, RSO 1990 c C37, s 15(1.1).

¹¹ Coroners Act. RSO 1990 c C37, s 25.1.

chief forensic pathologist, conducting a retrospective review of concealed homicides. His conclusions include the following:

- the involvement of forensic pathologists in death investigations is an important tool to detect homicides that would have otherwise remained hidden; and
- a multidisciplinary approach using both medical and investigative methods is essential to seek the truth of such homicides.

e) Raising Awareness of the Healthcare Serial Killer Phenomenon

Anne Coghlan, the executive director and chief executive officer of the College of Nurses of Ontario (College), together with other College staff members, published an article on regulatory responses to the healthcare serial killer phenomenon. ¹² In it, they make recommendations on how to raise awareness of the phenomenon. As they knew from the Inquiry's public hearings and consultations, the need for increased awareness is critical if we are to avoid similar tragedies in the future. The article also describes the need for regulators to have systems, at a national level, that facilitate information sharing.

f) Nurses' Employment History on the College Register

In the public hearings and consultations, concerns were expressed about the adequacy of information on nurses' employment history that is available on the College Register. The College addressed this matter recently through an amendment to its by-laws:

44.1.06 ... the following additional information shall be kept in the register of the College:

- 1. Any change to each member's name which has been made in the register of the College since he or she first became registered with the College.
- 2. Where a member is or has been engaged in nursing practice during the previous three calendar years, the name and address of all persons and businesses for whom or through which the member engages or engaged in nursing practice during those years, whether in Ontario or any other jurisdiction, including the year on which the member commenced practice and the year on which the member ceased practice, if applicable, for each of those persons or businesses.

Erin Tilley et al. "A Regulatory Response to Healthcare Serial Killing," (2019) 10(1) Journal of Nursing Regulation.

g) Employer Reference Group

The College also established an employer reference group to identify and collaborate on areas of concern and ensure better understanding of the respective roles of both the College and employers in protection of the public. The need for more communication between the College and employer and facility operators in the LTC system had been identified in both the Inquiry's public hearings and its consultations.

h) Training on Reporting

During the public hearings, it became apparent that there was a general lack of understanding about the reporting requirements of those in the LTC system. Within weeks of the conclusion of the public hearings, AdvantAge Ontario delivered a workshop entitled "Essential Reporting Requirements for Long Term Care Homes." ¹³

2. Ongoing Stakeholder-Led Innovation

During the Inquiry, I learned of various ongoing stakeholder-led programs to improve the lives of residents and those who work with them. These programs show that there is strong leadership in the LTC sector, a willingness to collaborate, and a commitment to innovation. In some cases, the programs pre-existed the Inquiry; in all cases, they will carry on long after its conclusion. These innovative programs also show that big steps forward in long-term care cannot be undertaken by a single organization. To make lasting improvements to the quality of resident care requires a systemic response. Below, I describe only a few of these stakeholder-led innovations.

a) Medication Safety Pilot Project

In 2017, PeopleCare Inc. and Hogan Pharmacy Partners received a grant of \$476,348 from the provincial government's Health Technologies Fund to develop a communication and documentation process to improve medication safety in LTC homes, including for patients transitioning from hospital to long-term care. The process includes a pharmacist-led medication reconciliation, an important task that is usually conducted by nurses in LTC homes.

¹³ https://www.advantageontario.ca/AAO/Learning/2018MR.aspx

The process was piloted in four LTC homes and recently evaluated by a team of researchers at the World Health Innovation Network in the Odette School of Business at the University of Windsor, Ontario. They concluded that pharmacist-led medication reconciliations are more efficient and have the potential to prevent more adverse drug events than those conducted by nurses. The researchers also found that each pharmacist-led medication reconciliation saved three hours of a nurse's time, which could then be used for direct resident care.¹⁴

b) Clinical Support Tools

Using funding provided by the Ministry, the Ontario Long Term Care Association (OLTCA), AdvantAge Ontario, and Think Research (a medical technology company specializing in tools to improve the organization of health information) developed a series of clinical support tools. These tools bring evidence-based clinical knowledge on health conditions to the "point of care" (the time when the caregiver actually delivers care) to achieve standardization and improve clinical decision-making in LTC homes. The clinical support tools include:

- · behavioural and psychological symptoms of dementia;
- palliative and end-of-life care;
- continence, constipation, and urinary tract infection;
- wound assessment;
- stable chronic obstructive pulmonary disease; and
- hypoglycemia.¹⁵

The clinical support tools were implemented in waves, starting with 46 LTC homes in 2017. Each wave was divided into structured phases to ensure that the homes were guided through initiation and implementation. The fifth and final wave is to finish this year (2019), at which point the program will be in place in all 626 LTC homes in the province.

Anne Snowdon and Ryan DeForge, Examining the Impact of Pharmacist-led Medication Reconciliation in Long-term Care, Final Report World Health Innovation Network, Odette School of Business, University of Windsor.

¹⁵ https://www.thinkresearch.com/ca/programs/onltc/

c) Qindex

Qindex is a collaboration between OLTCA and the University of Toronto, with funds from the federal government's Health System Impact Fellowship. Its goal is to create an overall quality index that reflects performance on the nine publicly reported quality indicators from the Canadian Institute for Health Information and Health Quality Ontario. 16 Qindex will describe trends in quality performance in LTC homes over the previous five years and determine if organizational and/or regional factors have an impact on quality.

OLTCA plans to use Qindex to enhance decision support tools and showcase the quality of care and quality improvement efforts across the LTC sector. OLTCA has a related initiative in which it provides member homes with "dashboards" that show, among other things, Qindex information (some of which is comparative) for the homes.

d) Nurses' Health Program

The College of Nurses of Ontario, together with the Registered Practical Nurses Association of Ontario, the Registered Nurses' Association of Ontario, and the Ontario Nurses' Association, developed a nurses' health program that came into existence in early 2019. This voluntary program encourages nurses to seek treatment for substance use and/or mental health disorders. It is modelled on similar programs used by other regulated healthcare professions in Ontario.¹⁷

IV. Building Capacity and Promoting Excellence in the LTC System

A. Prevention – the Impetus for Change

Although the LTC system has a solid foundation, the fact remains that over a period of nine years, Wettlaufer harmed or killed 14 people within that system, without detection or even suspicion. (See Chapter 1 for an explanation of how and why Wettlaufer's crimes would not have been discovered had she not confessed to them and turned herself in.) As I explain above, we must take a systemic approach to safeguard residents in future.

These indicators are: experience pain; experience worsened pain; falls in the last 30 days; improved physical functioning; potentially inappropriate use of antipsychotics; restraint use; worsened depressive mood; worsened physical functioning; and worsened pressure ulcer.

¹⁷ http://www.cno.org/en/news/2019/january-2019/new-nurses-health-program-launched/

In Chapters 16, 17, and 18, I make systemic recommendations to address the deterrence and detection of intentional wrongdoing in the LTC system. In this chapter, I call on the Ministry – working collaboratively and in partnerships with key stakeholders – to take an expanded leadership role in preventing future tragedies of this sort.

B. An Expanded Ministry Role

The Ministry plays a major leadership role in the LTC sector. This is not surprising, given its resources, its responsibility for oversight of long-term care, and the powers conferred on it by the LTCHA and Regulation. Add to these factors the Ministry's control over the funding for LTC homes and its vast knowledge base of the LTC homes and their residents – one that is greater than any other stakeholder in the system – and it is self-evident that the Ministry holds a dominant position in the LTC sector.

The Ministry has used its leadership position strategically, targeting the areas of greatest need in the sector, as the Behavioural Supports Ontario (BSO) program demonstrates. The BSO initiative was launched in 2010, following a consultation led by the Alzheimer Knowledge Exchange with key stakeholders that work with persons with dementia.

Initially, the Ministry invested \$40 million toward developing "an evidence and experience-based framework to enhance the availability of supports and services to persons living with responsive behaviours." In 2011, the BSO initiative was piloted at four LHIN sites. By the end of 2012, the BSO program was rolled out to the remaining 10 LHINs. 19 This program was created by leveraging existing resources and enhancing system coordination across the continuum of care. It provides support across Ontario, including to LTC homes, through:

- mobile interdisciplinary behavioural support outreach teams that provide support to professional care providers and informal family caregivers;
- case management and transitional supports to ensure care continuity and integration across sectors, as well as dementia day programs and respite care; and
- specialized short- and long-stay residential care for those with particularly complex and challenging health issues.

¹⁸ http://behaviouralsupportsontario.ca/29/Background/

¹⁹ http://behaviouralsupportsontario.ca/29/Background/

The BSO initiative continues to make a critical difference in the lives of both residents and those who care for them in LTC homes. With enhanced support and training, staff are better equipped to care for the ever-increasing number of residents with dementia. And the benefits extend beyond the home because better management of the complex challenges arising from dementia leads to reduced demands on hospital and psychiatric facility services.

BSO is widely regarded as a successful innovation. In an article examining the factors leading to its success, the authors note:

The development of and adherence to a pan-provincial change strategy framework was fundamental to the success of the project. This framework galvanized values, philosophies and cultures within and between healthcare sectors. The principle-based, evidence-informed framework was developed with input from both formal and informal care providers and respected lived experiences, as well as practice-based evidence and research. Structures brought together people from multiple sectors and provided oversight, clinical resources, and advice.²⁰

The Ministry also works collaboratively in the exercise of its leadership function, an approach that assists in maximizing the use of its resources. Its success can be seen in the stakeholder-led initiatives directed at improved resident outcomes discussed above, such as the Medication Safety Pilot project and the Clinical Support Tools initiative.

In my view, the Ministry is to be applauded for its leadership; for the commitment and hard work of its staff, who strive to uphold the resident-focused goals of the LTCHA; and for its willingness to collaborate to achieve real and lasting improvements to the LTC system. To prevent tragedies such as the Offences from occurring again, I recommend that the Ministry expand its leadership role to include:

- actively supporting and assisting LTC homes that are struggling to meet the existing regulatory standards;
- spreading best practices across the LTC system;
- providing LTC homes with bridging and laddering programs; and
- encouraging innovation and the use of new technologies in the LTC homes sector.

²⁰ Iris Gutmanis et al., "Health Care Redesign for Responsive Behaviours – The Behavioural Supports Ontario Experience: Lessons Learned and Keys to Success" (2015) 34(1) Canadian Journal of Community Mental Health, 56.

1. Support for LTC Homes in Achieving Regulatory Compliance

By supporting LTC homes in achieving regulatory compliance, the Ministry will fulfill a role called for in *Commitment to Care*, ²¹ Monique Smith's 2004 report that led to the enactment of the LTCHA and Regulation. In *Commitment to Care*, Ms. Smith was emphatic that the Ministry's inspection role had to be separate from an advisory role. However, her vision for a renewed LTC sector did not encompass eliminating the advisory role that the Ministry then provided to homes. Rather, she expressly called for the Ministry to continue performing an educational function, by assisting homes with compliance and becoming a bigger presence in those homes failing to meet regulatory standards. ²² The LTC homes' experience over the past decade, under the LTCHA regime, shows that there would be much benefit to reinstituting the Ministry's education and support function for them.

I acknowledge the legitimate concerns that mandate a separation between those who inspect homes for compliance and those who advise homes on compliance issues. It makes sense that those who help homes struggling to comply are not also tasked with inspecting to determine whether compliance had been achieved. For this reason, I recommend that the Ministry establish a dedicated unit in the Long-Term Care Homes (LTCH) Division to fulfill a number of functions, beginning with providing support to homes struggling with compliance. I recommend that the dedicated unit be a part of the LTCH Division because those in the new unit must work closely with Ministry inspectors to ensure they have a shared understanding of the Ministry's regulatory expectations: the information and support provided to homes by the new unit cannot be inconsistent with inspectors' expectations.

In fulfilling its role, the new unit should work collaboratively with stakeholders throughout the LTC sector, drawing on existing Ministry partnerships and forging new ones. I recommend that it establish a broadly representative advisory board that includes representatives from the different types of LTC homes (municipal homes, not-for-profit homes, and for-profit homes) to assist with its work. By engaging the sector in this way, the new unit will increase its understanding of the challenges LTC homes face and align stakeholders in addressing them.

²¹ Ontario, Ministry of Health and Long-Term Care, Commitment to Care (2004).

²² Commitment to Care, 19.

2. Spreading Best Practices Across the LTC System

In *Commitment to Care*, Monique Smith also envisioned the Ministry playing a role in building excellence in the LTC sector. She wrote:

The Ministry should consider how to develop better expertise in the long-term care sector including professional development, development of protocols and standards of care, and the dissemination of knowledge and best practices to front line staff. Several suggestions were made to us in this regard including establishing Centres of Excellence and pilot projects that linked an academic research centre to an LTC facility.²³

The Ministry acted on Ms. Smith's suggestion to establish Centres of Excellence; however, it did not take up her broader call to bring best practices to frontline staff in the LTC sector. In 2011, the Ministry launched the Ontario Centres for Learning, Research and Innovation in Long-Term Care (CLRIs). The CLRIs are situated in three locations: Baycrest Health Sciences in Toronto; Bruyère Research Institute in Ottawa; and Schlegel-UW Research Institute for Aging in Waterloo. Each CLRI is affiliated with an LTC home. Although the three centres initially operated independently, they now work together as an integrated program to create, present, and assess education programs and resources for the long-term care workforce.

When the Ministry established the CLRIs, it provided them with funding through to March 31, 2016. In August 2017, the Ministry injected additional base funding. When this additional funding was announced, the executive director at Schlegel-UW Research Institute for Aging said that research and innovation would be "accelerated and shared to benefit long-term care homes across the province." In my consultations, I learned that LTC homes welcomed the promise of an increased scope in the CLRIs' work, noting that their impact has been largely concentrated on the homes and communities in which the three centres were located.

It has been nearly a decade since the LTCHA and Regulation came into effect. It is time to implement Ms. Smith's suggestion that the Ministry develop better expertise in the LTC sector and disseminate knowledge and best practices to frontline staff. Much has been learned about which policies, practices, and tools work best in different LTC homes. Extensive data are available about the

²³ Commitment to Care, 24.

health of residents and their quality of life. There are many excellent practices in the LTC system, and they should be widely shared. The current inspection program must identify successful programs and practices in the homes and share that information with the new unit. The Ministry, through the new unit in the LTCH Division, is uniquely positioned to spread these best practices across the province.

3. Funding Bridging and Laddering Programs in LTC Homes

I recommend that the Ministry fund bridging and laddering programs in LTC homes. This recommendation is designed to work in conjunction with the recommendation made in Chapter 9 that the Ministry create a new, permanent funding envelope for LTC Homes to fund education, training, and professional development for all LTC home staff.

While both this recommendation and that in Chapter 9 are aimed at providing LTC home staff with education and training, the overall goals of the two recommendations are different. The goal of the Chapter 9 recommendation is to ensure that all those who work in LTC homes have the necessary training and knowledge to provide high-quality resident care. The goal of bridging and laddering programs is to build human resource capacity in the LTC sector by enabling homes to retain and develop their most promising and dedicated staff members.

Bridging and laddering programs offer staff already working in LTC homes with training and education opportunities to advance their career progression. For example, through bridging and laddering programs, RPNs have acquired the necessary qualifications to become RNs, and registered staff have acquired the necessary qualifications and training to advance to positions such as the administrator or the director of nursing.

As discussed in Chapter 4, LTC homes face challenges in recruiting and retaining staff, particularly registered staff. The advancement opportunities generated by bridging and laddering programs will make it more likely that LTC homes will retain their most promising and motivated staff. In my consultations with stakeholders, I learned that the Ministry has supported bridging and laddering programs in the past to the benefit of both the homes and the staff. The Ministry should reintroduce this proven strategy for increasing the existing human resource capacity in LTC homes.

4. Encouraging Innovation and the Use of New Technologies

In 2017, OLTCA convened a Strategic Innovation Council to accelerate innovation in the LTC system. It described the LTC system as a "diverse set of stakeholders, each of which plays a crucial role in enabling innovation to flourish." ²⁴ The Report of the Strategic Innovation Council recognizes that because of the highly regulated nature of the LTC system, the government plays a crucial role: "In a publicly funded and regulated system, governments are essential in laying the foundation for innovation to flourish." ²⁵ This point is echoed in an article written on the broader topic of the role of government in innovation:

Governments aren't generally known as innovative environments. But although innovation may not always come naturally to these institutions, scale certainly does. So when they do find ways to incubate and support promising social innovations, especially in partnership, the impact can be tremendous.²⁶

As I discuss earlier in this chapter, many stakeholders in the LTC system have been actively pursuing innovations and new technologies to support excellence in the delivery of resident care. This is important because innovation and technology have the potential to save time and costs, reduce human error, lead to improved resident outcomes, and provide oversight.

However, LTC homes do not have the resources to stay abreast of new developments. Continued Ministry leadership offers a coordinated approach to encouraging innovation, the use of technologies, and assisting in their implementation, including through the provision of necessary funding. Many other stakeholders in the LTC system have expertise that can be drawn upon to support innovation. I recommend that the Ministry expand its leadership role in this area by harnessing that expertise, encouraging new innovations, and supporting the introduction and better use of new technologies in LTC homes.

Ontario Long Term Care Association Strategic Innovation Council, Accelerating Our Innovation Potential: Actions to Advance Innovation in Ontario's Long-Term Care Ecosystem (Toronto: Ontario Long Term Care Association, 2018), 2, https://www.oltca.com/OLTCA/Documents/Reports/ SICReport_AcceleratingInnovationPotential_Nov2018.pdf.

²⁵ Ontario Long Term Care Association Strategic Innovation Council, Accelerating Our Innovation Potential, 4.

Rahul Nayar, Asif Saleh, Anna Minj, "Scaling Up Innovations with Government" (2016) 14(2) Stanford Social Innovation Review, https://ssir.org/articles/entry/scaling_up_innovations_with_government.

V. Conclusion

In this chapter, I call on the Ministry to play an expanded leadership role. My recommendations have the goal of preventing future tragedies of the sort that Wettlaufer inflicted. The best way to prevent tragedies like the Offences from occurring again is to strengthen the capacity of those who work in LTC homes and encourage excellence in resident care. The recommendations in this chapter are strategies to do precisely that: to strengthen the LTC home system through capacity building and the sharing of excellence. The beauty of this expanded Ministry role is that it fits entirely with the fundamental principle in section 1 of the LTCHA: to make long-term care homes into real homes for the residents – places in which they live with dignity, and in security, safety, and comfort.

RECOMMENDATIONS

Recommendation 62: The Ministry of Health and Long-Term Care (Ministry) must play an expanded leadership role in the long-term care system by:

- establishing a dedicated unit within the Long-Term Care Homes
 Division to:
 - support long-term care (LTC) homes in achieving regulatory compliance; and
 - identify, recognize, and share best practices leading to excellence in the provision of care in LTC homes;
- · providing bridging and laddering programs in LTC homes; and
- encouraging innovation and the use of new technologies in the long-term care system.

Both the Ministry and the dedicated unit should work collaboratively with stakeholders throughout the LTC sector, drawing on existing partnerships and forging new ones.

Details

- The dedicated unit should act in collaboration with a broadly representative advisory board that includes representatives from the different types of long-term care (LTC) homes (not-for-profit, for-profit, and municipal homes), residents' councils, family councils, and the various LTC associations.
- The dedicated unit should:
 - identify the most significant areas of non-compliance across the province and provide homes with positive strategies for coming into compliance on those areas;
 - provide homes with advance notice of new areas on which it will inspect, clear explanations of the Ministry of Health and Long-Term Care's (Ministry) expectations in those areas, and information and support to meet those expectations;
 - take immediate steps to help homes that are struggling to come into compliance;
 - identify best practices, policies, and procedures, and share them with all LTC homes:

- identify areas of excellence in LTC homes that can be expanded throughout the system; and
- share information and resources in a variety of readily accessible electronic formats, moving beyond the existing Itchomes.net forum, which is difficult to navigate.
- The dedicated unit should draw on and expand existing collaborations, such as with the Centres for Learning, Research and Innovation. It should continue to partner with existing organizations in the sector, such as the Ontario Association of Residents' Councils, AdvantAge Ontario, and the Ontario Long Term Care Association, when providing information and training for LTC homes.
- The dedicated unit must work separately from inspectors to avoid the
 contradictory roles of providing advice and inspecting for compliance –
 but it must work sufficiently closely with those conducting inspections to
 ensure they do not work at cross-purposes.
- The Ministry should establish a stakeholder working group to learn about and evaluate new technology and innovations relevant to the LTC sector; identify areas where technology and innovation are needed; and engage with the broader community of innovators in the healthcare system to encourage the development of new technologies to address those areas.

Rationale for Recommendation 62

- The best way to prevent tragedies like the Offences from occurring again is to strengthen LTC homes and encourage excellence in resident care. Excellence in long-term care is more than keeping residents safe and secure; it is giving residents the highest possible quality of life.
- The Long-Term Care Homes Act, 2007, and its regulations have been in
 effect for almost a decade. This regulatory regime creates a clear set of
 requirements that licensees and LTC homes must meet to ensure that
 residents are safe and secure. Under this regime, the quality of care in
 LTC homes has demonstrably improved in recent years.
- Although compliance with the regulatory regime is necessary, moving
 to consistent excellence in the provision of resident care will take the
 co-operation, collaboration, and commitment of all elements of the
 LTC system. The Ministry must provide the necessary leadership for this
 movement to become a reality.

- · Ministry leadership will be seen:
 - through its support for struggling homes so they achieve compliance;
 - through its identification and recognition of the many existing areas of excellence in the LTC sector and spreading that excellence across homes through training, education, and support;
 - through increasing the capacity of LTC homes staff, who are under ever-increasing demands because of the increased acuity of residents; and
 - by continuing to foster the development of innovations and encouraging their use in the provision of long-term care.
- By partnering with stakeholders, the dedicated unit will work
 collaboratively to develop a shared understanding of the challenges
 facing long-term care and a shared vision of how these challenges can
 be addressed. It will also shift the relationship between the Ministry and
 LTC homes which many perceive as adversarial to one of co-operation,
 with a shared commitment to excellence in resident care.

Recommendation 63: The Long-Term Care Homes Division within the Ministry of Health and Long-Term Care must communicate and collaborate with the Home and Community Care Branch and the Local Health Integration Networks (or successor organization) in providing healthcare services to older Ontarians.

Rationale for Recommendation 63

- Although the long-term care homes sector and the home care sector operate in different contexts and under different regulatory regimes, both are part of the continuum in which healthcare services are provided to older Ontarians. Wettlaufer committed Offences in both the long-term care and the home care sectors. Thus, both sectors need to take steps to prevent, deter, and detect similar wrongdoing so that these tragedies are not repeated. Each sector will be strengthened by the sharing of knowledge and initiatives, particularly in responding to common challenges, which include:
 - rising acuity in those for whom both sectors provide care, including increased levels of dementia;
 - recruiting and retaining nurses and personal care staff; and
 - easing the transition of those who move from living in the community to living in long-term care homes.

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RECO	MMENDATIONS

I. Introduction

The murders Elizabeth Wettlaufer committed while working as a nurse are shocking and tragic. However, they are not unprecedented. A growing body of research and literature shows that healthcare serial killing is a phenomenon which, while rare, is long-standing and universal in its reach, with documented cases dating back to the 1800s. Expert evidence presented in this Inquiry shows that since 1970, 90 healthcare serial killers (HCSKs) have been convicted throughout the world, including in Canada, the United States, and Western Europe.¹

Healthcare serial killers (HCSKs) are "employees in the healthcare system who use their position to murder at least two patients in two separate incidents, with the psychological capacity for more killing." They take advantage of the trust placed in healthcare workers to exploit gaps in the healthcare system, kill vulnerable patients, and devastate families, healthcare workers, communities, and the public at large. Healthcare serial killings are not to be confused with "euthanasia, assisted suicide, the mass murder or assault of patients for political reasons, or the episodic murder of a patient as a crime of passion or in the course of carrying out another crime."

Wettlaufer killed eight residents in long-term care (LTC) homes and harmed or attempted to kill a further six people under her care. She confessed to the wrongdoing and pled guilty to, and was convicted of, eight counts of first-degree murder, two counts of aggravated assault, and four counts of attempted murder (the Offences). She is clearly a healthcare serial killer.

Wettlaufer shares a number of common features with other HCSKs. She was a registered nurse and committed the Offences in the course of providing nursing services. She had no particular motive for the Offences she committed. She chose as victims those in her care whom she saw as particularly vulnerable. She committed the Offences while working the evening or night shift. And, like many other HCSKs, Wettlaufer committed the Offences by injecting her victims with large amounts of insulin.

¹ Expert Report of Professor Beatrice Crofts Yorker Schumacher, May 27, 2018, p 3.

² Katherine Ramsland, *Inside the Minds of Healthcare Serial Killers: Why They Kill* (Westport, Conn.: Praeger, 2007), xi–xii.

³ See Chapter 1 for a description of the scope of the harm caused by healthcare serial killers.

⁴ Kenneth W. Kizer and Beatrice C. Yorker, "Health Care Serial Murder: A Patient Safety Orphan" (2010) 36(4) Joint Commission Journal on Quality and Patient Safety 186 at 186.

Although many HCSKs have operated in hospitals, Wettlaufer committed all but one of the Offences while working as a nurse in various LTC homes. She committed the last Offence while providing publicly funded nursing care to a person in her private home.

Wettlaufer is unlike other HCSKs in one important regard: her wrongdoing came to light only because she voluntarily turned herself in to the authorities and confessed. Other HCSKs have also confessed, but those confessions were made after their crimes had been discovered and they had been arrested or convicted.⁵ In Wettlaufer's case, however, the Offences would never have been discovered had she not confessed. Even after the police investigations, it was clear that, without the detailed content of her confession, the Offences would have remained undetected.⁶

This Inquiry has exposed systemic vulnerabilities throughout the LTC system, including delayed recognition and inadequate investigation of suspicious incidents; ineffective surveillance, monitoring, and evaluation of adverse care-related events; gaps in the medication management systems in LTC homes; and difficulties in sharing information about potentially problematic healthcare workers. The Offences spanned nine years, three LTC homes, and one private home. As explained above, had Wettlaufer not confessed, the Offences would never have been discovered. Without a concerted systemic response involving all stakeholders in Ontario's healthcare system, we remain vulnerable to HCSKs. Ontario's aging population, in particular, will remain exposed to the possibility of intentional harm by HCSKs.

Fortunately, several systemic measures can be taken to deter and detect HCSKs. These measures include strengthening the medication management

⁵ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 14.

As discussed in Chapter 1, before Wettlaufer came forward to confess, there had been no suggestion – or even suspicion – that she had intentionally harmed those under her care. None of the colleagues who worked alongside her had any idea that she was intentionally injecting residents with insulin to kill them. No concerns had been identified – or suspicions raised – following the deaths of the eight residents she murdered. No autopsies were conducted on any of those residents. However, even if they had been, given the difficulties in detecting insulin post mortem, it is very unlikely that the autopsies would have detected that the victims died from an intentional insulin overdose, with the possible exception of Maureen Pickering (see Affidavit of Dr. Michael Pollanen, paras 103–11; Testimony of Dr. Michael Pollanen, Transcript, July 23, 2018, pp 5070–74, 5106–10, 5117–19). Although the police investigation uncovered some circumstantial evidence that corroborated Wettlaufer's account of her crimes, such as medical records showing that residents had some hypoglycemic symptoms, there was no conclusive evidence that tied her to the Offences. As Justice Thomas said when sentencing Wettlaufer, "Without her confessions, I am convinced this offender would never have been brought to justice": *R v Wettlaufer*, 2017 ONSC 4347 at 10.

system in LTC homes, improving medication incident analysis, and reforming the death investigation process in LTC homes. These measures are the focus of Chapters 17 and 18.

As a critical first step, however, an increased awareness of the HCSK phenomenon must be developed throughout the healthcare system. Without awareness that a healthcare provider could intentionally harm those in his or her care, it is not possible to detect – or deter – such behaviour. As discussed below, previous investigations and public inquiries into HCSKs have confirmed that a lack of awareness of the HCSK phenomenon enables such wrongdoing to continue undetected for long periods.

Professor Beatrice Crofts Yorker gave expert evidence on the HCSK phenomenon in this Inquiry.⁷ In the report she prepared for the Inquiry and in her testimony, Professor Crofts Yorker⁸ explains that increased awareness of the potential for healthcare workers to intentionally harm, combined with improved medication management systems and tracking of adverse incidents and unexpected events, can help both to deter HCSKs and lead to their early detection:

[T]here is evidence to indicate that overall improvements in patient safety, including support for nursing vigilance regarding the potential for intentional acts, medication dispensing systems, as well as routine tracking of adverse events and unexpected deterioration of patients' condition, are all recommended measures that can contribute to the deterrence, reduction, and early detection of [HCSKs].⁹

In this chapter, I begin by reviewing the existing literature and research on the HCSK phenomenon and the toll exacted by healthcare serial killings. Next, I describe the features common to HCSKs and the ways in which they operate. Last, I explain why building an awareness of the HCSK phenomenon among all stakeholders in the healthcare system is the first step in combatting the HCSK phenomenon, and why the Office of the Chief Coroner and the Ontario Forensic Pathology Service (OCC/OFPS) should be made responsible for building that awareness.

She was qualified as an expert witness in the areas of "studies of healthcare serial killing" and "nursing education." Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, Sept. 12, 2018, p 7967.

Professor Crofts Yorker Schumacher generally does not use "Schumacher" when giving her name. For this reason, she is referred to as Professor Crofts Yorker throughout the text in this Report; in citations to her expert report and her testimony, her full name is used.

⁹ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 22.

II. HCSKs: A Widespread and Long-standing Phenomenon

A. Documenting HCSK Cases

HCSKs cases began to be documented in the 1850s – at the same time that advances in medical technology, such as improvements to the syringe and the refinement of opium into morphine, made it easier for healthcare workers to kill patients surreptitiously. Although the available drugs and tools were not as sophisticated as they are today, they were effective. Early examples of HCSKs include:

- in the 1850s and 1860s, British nurse Catherine Wilson was convicted
 of murdering a patient by poisoning her with colchicum, but she was
 believed to have murdered six or seven others in the same manner and
 had previously been prosecuted for attempting to murder another patient
 with sulphuric acid;¹²
- in the late 1800s and early 1900s, American nurse Jane Toppan killed several people in Massachusetts – including patients in her care – by drugging them with atropine and morphine; she confessed to 31 murders but admitted there had been more, possibly over one hundred;¹³
- in the 1880s and 1890s, Dr. Henry Howard Holmes confessed to murdering 27 victims in the United States and Canada through asphyxiation or incineration, before selling their bleached skeletons to medical schools;¹⁴
- between 1924 and 1926, French nurse Antoinette Scieri poisoned and killed a number of elderly individuals to whom she was providing private nursing care;¹⁵ and

Robert M. Kaplan, Medical Murder: Disturbing Cases of Doctors Who Kill (Sydney, NSW: Allen & Unwin, 2009), 11.

¹¹ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, Sept. 12, 2018, p 7972.

Montagu Stephen Williams, Leaves of a Life: Being the Reminiscences of Montagu Williams, Q.C. (London: Macmillan, 1893), 44–47; "The Gallows," Harper's Weekly, Nov. 22, 1862, 743, http://www.sonofthesouth.net/leefoundation/civil-war/1862/november/execution-catharine-wilson.htm [accessed April 10, 2019].

¹³ Ramsland, *Inside the Minds of Healthcare Serial Killers*, 23–26.

Ramsland, Inside the Minds of Healthcare Serial Killers, 14–16; Encyclopaedia Britannica, "H.H. Holmes," https://www.britannica.com/biography/H-H-Holmes [accessed March 14, 2019].

There was significant discrepancy in the number of victims attributed to Dr. Holmes. Although he initially confessed to 27 murders, he later increased that number to 130, and some accounts reported that he had killed as many as 200 people. However, only nine deaths could plausibly be confirmed as caused by him. Several of the people he claimed to have killed were still alive. See Adam Selzer, H.H. Holmes: The True History of the White City Devil (New York: Skyhorse Publishing, 2017).

¹⁵ Ramsland, Inside the Minds of Healthcare Serial Killers, 26–27.

• in the early 1900s, Amelia Sach and Annie Walters, who presented themselves as a "type of nurse," ran a business in the United Kingdom purporting to find adoptions for the babies of unhappily pregnant women. Instead, they smothered or poisoned the babies, with the total number of victims thought to be in the dozens. 16

B. HCSK Cases Since 1970

Before 1970, there were few reported HCSK cases; it was only then that such cases began to be more systematically uncovered and documented. By that point, healthcare surveillance had improved, and the US Centers for Disease Control frequently became involved in tracking suspicious death patterns.¹⁷

Documented cases since then show that the HCSK phenomenon goes beyond a few shocking, isolated incidents.¹⁸ In preparing her report for the Inquiry, Professor Crofts Yorker reviewed the cases of 131 healthcare providers who, between 1970 and May 2018, had been prosecuted for serial murders and/ or assaults of patients in their care. These cases took place in 25 countries, primarily in Western Europe and the United States.¹⁹ Of the 131 healthcare providers who were prosecuted, 90 were convicted. Professor Crofts Yorker compiled Table 16.1, setting out the prosecutions and convictions of HCSKs, by country, between 1970 and May 2018.²⁰

¹⁶ Ramsland, *Inside the Minds of Healthcare Serial Killers*, 27. While Ramsland notes that Sach and Walters were "not strictly healthcare workers," they "purported to be a type of nurse."

Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, pp 7971–72. For a discussion of the involvement of the Centers for Disease Control in tracking suspicious deaths, see Jeoffrey K. Stross, D. Michael Shasby, and William R. Harlan, "An Epidemic of Mysterious Cardiopulmonary Arrests" (1976) 295(20) New England Journal of Medicine 1107 at 1108.

¹⁸ Beatrice Crofts Yorker et al., "Serial Murder by Healthcare Professionals" (Nov. 2006) 51(6) Journal of Forensic Sciences 1362.

¹⁹ Michael Swango, MD, was investigated, prosecuted, and served time in the United States before moving to Zimbabwe, where he was again investigated for poisoning and killing patients. He was ultimately apprehended and convicted in the United States with the assistance of the Zimbabwe government. See Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 5.

Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 5. In her report, Professor Crofts Yorker outlines her methodology in compiling these cases, pp 2–4. The initial research conducted by Professor Crofts Yorker and her colleagues revealed 90 HCSK prosecutions between 1970 and 2006. Their results were published in 2006 in the *Journal of Forensic Sciences*: Crofts Yorker et al., "Serial Murder by Healthcare Professionals." In her report for the Inquiry, Professor Crofts Yorker updated her research, finding an additional 41 HCSK prosecutions between 2006 and May 2018. Occasionally, throughout this chapter, I will use Professor Crofts Yorker's report to distinguish data between 1970 and 2006 from data between 2006 and May 2018.

Table 16.1: Prosecutions and Convictions of HCSKs by Country, 1970 to May 2018

COUNTRY	PROSECUTIONS	CONVICTIONS
Australia	3	3
Austria	4	4
Belgium	7	5
Brazil	3	2
Canada	2	1
Czech Republic	2	1
Egypt	1	1
England	12	9
Finland	2	2
France	2	1
Germany	20	15
Hungary	1	1
Ireland	2	1
Italy	6	4
Japan	3	2
Netherlands	4	2
Norway	1	1
Poland	4	4
Russia	5	1
Scotland	1	0
Spain	1	1
Switzerland	1	1
United States	40	28
Uruguay	2	0
Wales	2	0
Totals: 25	131	90

Source: Compiled by Professor Crofts Yorker at the request of the Commission.

Note: Data are based on cases that were reported in LexisNexis, Westlaw, and searchable internet outlets or that otherwise came to Professor Crofts Yorker's attention.

During the course of this Inquiry, the media reported the arrests of two more alleged HCSKs. In July 2018, a British healthcare worker was arrested on the suspicion that she had murdered eight babies and tried to kill six others while she worked at the Countess of Chester Hospital in northwestern England.²¹ Days later, there were reports that a Japanese nurse had been arrested on the suspicion that she injected disinfectant into intravenous bags, killing approximately 20 elderly patients in her care at a Yokohama hospital.²²

C. Numbers of Patients Murdered by HCSKs

Professor Crofts Yorker acknowledges that the number of HCSKs is quite small, as is the number of serial killers generally. She also acknowledges that "[t]he chances of being killed by a healthcare serial killer are extremely low."²³ However, while the known number of HCSKs is small, the number of victims is not. Professor Crofts Yorker emphasizes that the phenomenon should cause concern because HCSKs cause a "significant number" of patient deaths.²⁴ The 90 HCSKs convicted since 1970 have been found guilty of murdering at least 450 patients. They have also been convicted of assault or grave bodily injury involving at least 150 other patients.²⁵

These are significant numbers: 90 healthcare providers killed 450 patients and assaulted a further 150. But, according to Professor Crofts Yorker's report, those figures significantly understate the actual number of victims: the total number of suspicious deaths attributed to the 90 convicted HCSKs exceeds 2,600.²⁶ Professor Crofts Yorker explained that prosecutors did not pursue prosecutions of all suspected deaths because proving guilt beyond a reasonable doubt on all suspicious deaths is not cost-effective.²⁷ For example, American nurse Genene Jones was linked to 27 suspicious deaths, but

^{21 &}quot;U.K. police arrest health care worker on suspicion of baby murders," Associated Press, July 3, 2018, https://www.ctvnews.ca/world/u-k-police-arrest-health-care-worker-on-suspicionof-baby-murders-1.3997617 [accessed March 14, 2019].

Julian Ryall, "Japanese nurse investigated over 20 killings at end of shifts to avoid 'nuisance' of telling families of deaths," *The Telegraph*, July 10, 2018, https://www.telegraph.co.uk/news/2018/07/10/japanese-nurse-investigated-20-killings-end-shifts-avoid-nuisance/ [accessed March 14, 2019].

²³ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 7.

²⁴ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, pp 7972–73; Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 6.

²⁵ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 6.

²⁶ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 6.

²⁷ Crofts Yorker et al., "Serial Murder by Healthcare Professionals," 1365–66.

prosecuted for, and convicted of, only one murder.²⁸ The Bexar County district attorney responsible for that prosecution stated that "[n]o useful purpose would be served" by seeking additional indictments against her because she was already likely to "spend the rest of her life in jail."²⁹

Furthermore, after the prosecution of an HCSK is complete, it is not unusual for the number of deaths linked to a particular HCSK to be revised upwards. For example, German nurse Niels Högel was sentenced in 2008 for attempted murder. In 2015, he was sentenced to life for two murders and for several attempted murders. In August 2017, the police concluded there was evidence that Högel was responsible for the deaths of at least 90 patients. In November 2017, the total number of victims attributed to Högel was revised to 106, with further suspicious deaths still under investigation. In January 2018, German prosecutors charged Högel with the murder of 97 additional patients. Högel subsequently admitted to killing these patients. In Investigators and prosecutors ultimately indicated he may have killed more than 200 people.

In this Inquiry, questions also arose, after Wettlaufer was convicted, as to whether she had committed additional crimes. While in prison for the Offences, Wettlaufer told prison staff that she had harmed two other residents

Expert Report of Professor Beatrice Crofts Yorker Schumacher, Tab F. In her list of HCSKs, Professor Crofts Yorker includes healthcare workers such as Jones who, while charged with only one murder in a healthcare setting, were also linked to other suspicious deaths. Professor Crofts Yorker noted that Jones "was associated with a cluster of deaths in a pediatric intensive care unit, and later in a pediatrician's outpatient clinic": Crofts Yorker et al., "Serial Murder by Healthcare Professionals," 1364–65. The data in this article were used in Professor Crofts Yorker Schumacher's Expert Report for the Inquiry, pp 2–3.

²⁹ James M. Thunder, "Quiet Killings in Medical Facilities: Detection & Prevention" (2003) 18(3) Issues in Law & Medicine 211 at 228, quoting News Services, "No More Indictments," Washington Post, Oct. 26, 1984, A10.

^{30 &}quot;German nurse suspected of murdering at least 90 patients," Guardian, Aug. 28, 2017, https://www.theguardian.com/world/2017/aug/28/german-nurse-niels-hoegel-suspected-murdering-90-patients [accessed March 14, 2019].

^{31 &}quot;Un infirmier allemand soupçonné d'une centaine de meurtres," Le Monde, Nov. 9, 2017, https://www.lemonde.fr/europe/article/2017/11/09/un-infirmier-allemand-soupconne-d-une-centaine-de-meurtres_5212789_3214.html [accessed March 14, 2019].

^{32 &}quot;Jailed German serial killer charged with 97 new counts of murder," USA Today, Jan. 23, 2018, https://www.usatoday.com/story/news/world/2018/01/23/jailed-german-serial-killer-charged-97-new-counts-murder/1056823001/ [accessed March 14, 2019].

[&]quot;German nurse admits to killing 100 patients as trial opens: Niels Hoegel, already serving 15 years, has been accused of deliberately overdosing victims," *The Guardian*, Oct. 30, 2018, https://www.theguardian.com/world/2018/oct/30/german-nurse-serial-killer-niels-hoegel-on-trial-100-patients-deaths [accessed March 13, 2019].

³⁴ "German nurse admits to killing 100 patients as trial opens."

in LTC homes. Police investigated the two other disclosed incidents, but no charges were laid in relation to them.

According to Professor Crofts Yorker, the following HCSKs are also linked to many more suspicious deaths than the deaths for which they have been convicted:

- Dutch nurse Frans Hooijmaijers was sentenced in December 1976 to 13 years in prison for murdering five elderly patients with overdoses of insulin, although he was linked to 259 suspicious deaths.³⁵
- British physician Dr. Harold Shipman was convicted of murdering 15 patients in 2000.³⁶ A public inquiry concluded that he had in fact killed 215 of his patients over the course of his career, starting in 1975, most frequently through the injection of a lethal dose of an opiate such as diamorphine (heroin).³⁷ A further 45 deaths associated with Dr. Shipman were identified as suspicious.³⁸
- American nurse Orville Lynn Majors was convicted of six murders in 1999 for injecting patients in a rural Indiana hospital with epinephrine and potassium chloride. He is linked to 124 suspicious deaths.³⁹ A review of the hospital medical records revealed that there were between 24 and 31 deaths each year from 1990 to 1993. However, in 1994, the year after Majors was hired, 101 patients died, even though the number of patient admissions had not increased. While Majors was on duty, deaths occurred

³⁵ Expert Report of Professor Beatrice Crofts Yorker Schumacher, Tab F; "Dutch jail nurse in 5 deaths," New York Times, Dec. 8, 1976, https://www.nytimes.com/1976/12/08/archives/dutch-jail-nurse-in-5-deaths.html [accessed April 10, 2019].

³⁶ Great Britain, Shipman Inquiry, *The Shipman Inquiry: First Report* (Manchester: Shipman Inquiry, [2002]), p 16, para 1.48 (Dame Janet Smith, chair).

³⁷ Shipman Inquiry: First Report, p 2, para 15, pp 297–316.

Shipman Inquiry: First Report, p 3, para 22. See also The Shipman Inquiry: First Report, p 198, paras 14.6–14.7, discussing a statistical review of Shipman's clinical practice, published by Professor Richard Baker in 2001. The large number of suspicious deaths is supported by the conclusions of Professor Baker, who compared the death rates among Dr. Shipman's patients with those of other comparable general practitioners. Professor Baker estimated that the number of excess deaths "about which there should be concern" was likely 236, which is very close to the 215 killings found by the inquiry, particularly if some of the 45 additional "suspicious" deaths were in fact killings.

³⁹ Expert Report of Professor Beatrice Crofts Yorker Schumacher, Tab F; Bill Dedman, "Nurse guilty of killing six of his patients," New York Times, Oct. 18, 1999, https://www.nytimes.com/1999/10/18/us/nurse-guilty-of-killing-six-of-his-patients.html [accessed April 10, 2019]; Ramsland, Inside the Minds of Healthcare Serial Killers, 64–65.

every 23 hours, on average. When he was not, they occurred every 552 hours.⁴⁰ Nurses would place bets on which patients would die when Majors was on duty.⁴¹

- American nurse Charles Cullen was convicted of 29 murders in several prosecutions in the early 2000s⁴² but confessed to killing more than 40 patients by injecting them with various medications such as insulin, digoxin, and epinephrine.⁴³ According to experts (and to Cullen himself), even this number is low. Cullen may be responsible for approximately 400 murders in hospitals.⁴⁴
- American nurse Kristen Gilbert was convicted of four murders and two attempted murders in 2001.⁴⁵ She was suspected of killing as many as 50 patients by spiking their IV bags with epinephrine.⁴⁶

Professor Crofts Yorker's estimate of 2,600 deaths relates to the deaths thought to be attributable to the 90 convicted HCSKs.⁴⁷ The true number of victims of HCSKs, however, is simply unknown.

In some cases, intentional killings go undetected, so the HCSK is never apprehended. This possibility is demonstrated by the Wettlaufer case, where everyone believed the victims had died of natural causes until she came forward and confessed.

In other cases, even where there is good reason to believe that deaths in a healthcare setting were the result of intentional killing, it may not be possible to identify the perpetrator. This may have happened in Ontario following the

⁴⁰ Bill Dedman, "Trial opens for ex-nurse charged in Indiana deaths," New York Times, Aug. 31, 1999, https://www.nytimes.com/1999/08/31/us/trial-opens-for-ex-nurse-charged-in-indiana-deaths. html [accessed April 10, 2019].

⁴¹ Dedman, "Nurse guilty of killing six of his patients."

Janon Fisher, "Former nurse pleads guilty in killings of another 3," New York Times, May 20, 2004, https://www.nytimes.com/2004/05/20/nyregion/former-nurse-pleads-guilty-in-killings-of-another-3.html [accessed April 2, 2019]; "Nurse who killed 29 sentenced to 11 life terms," NBC News, March 2, 2006, http://www.nbcnews.com/id/11636992/ns/us_news-crime_and_courts/t/nurse-who-killed-sentenced-life-terms/#.XKO8dGY1t9A [accessed April 2, 2019].

⁴³ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 11; Kizer and Yorker, "Health Care Serial Murder," 187; Charles Graeber, *The Good Nurse* (New York: Twelve, 2013), 22, 90–91, 112–13, 255–56.

⁴⁴ Graeber, The Good Nurse, 255.

⁴⁵ Elizabeth Mehren, "Ex-VA nurse is spared death penalty," Los Angeles Times, March 27, 2001, https://www.latimes.com/archives/la-xpm-2001-mar-27-mn-43272-story.html [accessed April 2, 2019].

⁴⁶ Kizer and Yorker, "Health Care Serial Murder," 187; Mehren, "Ex-VA nurse is spared death penalty."

⁴⁷ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 6.

suspicious deaths of 33 babies and three older children at the Hospital for Sick Children in Toronto (SickKids) between June 30, 1980, and March 22, 1981. After the suspicious deaths were detected, nurse Susan Nelles was arrested and charged with four counts of first-degree murder. The charges against her were ultimately stayed, following a preliminary inquiry before Justice Vanek of the Ontario Provincial Court. Significantly, although Justice Vanek found there was sufficient evidence to go to a jury that the deaths were caused by deliberately administered overdoses of digoxin (a drug used to treat congestive heart failure), the evidence was not sufficient to connect Ms. Nelles to those wrongful acts. As such, "no sufficient case was made out to put the accused on trial on any of the four charges."

Many people still believe that the deaths at SickKids were caused by an HCSK whose identity was never established. Commissioner Samuel Grange, who chaired the public inquiry tasked with examining the victims' cause of death and the police investigation into Ms. Nelles, determined that: "On the evidence I cannot find that any one of the deaths that I conclude or believe or suspect were caused by digoxin toxicity was the result of accident or medication error." A subsequent epidemiological study by the Centers for Disease Control found the presence of a nurse (other than Nelles) was "very strongly associated with infant cardiac arrests." Since no one was ever charged – and thus no one was ever convicted – these 36 deaths are not included among the suspicious deaths attributed to convicted HCSKs.

Other authors maintain there are cases where employers or investigators have evidence that deaths may have been intentionally caused but lack sufficient evidence to identify the perpetrators or to pursue a criminal prosecution.⁵¹

⁴⁸ R v Nelles (1982), 16 CCC (3d) 97 at 110, 140; Ontario, Royal Commission of Inquiry into Certain Deaths at the Hospital for Sick Children and Related Matters, Report (Toronto: Ministry of the Attorney General, 1984), 1 (Commissioner S.G.M. Grange) (Grange Inquiry).

⁴⁹ Grange Inquiry, *Report*, 172. However, Gavin Hamilton has expressed doubt as to whether the deaths were intentionally caused. He suggests that a chemical compound found in the rubber seals in the children's IV lines and disposable syringes had leached into the contents of those devices, unintentionally poisoning them. He also suggests that the post mortem tests used in the SickKids cases were unreliable and may have given a false reading of how much digoxin was present. See Gavin Hamilton, *The Nurses Are Innocent: The Digoxin Poisoning Fallacy* (Toronto: Dundurn, 2011).

⁵⁰ Beatrice Crofts Yorker, "An Analysis of Murder Charges Against Nurses" (1994) 1(3) Journal of Nursing Law 35 at 35–46, 39; James W. Buehler et al., "Unexplained Deaths in a Children's Hospital: An Epidemiologic Assessment" (1985) 313 New England Journal of Medicine 211 at 215.

⁵¹ See, for example, Thunder, "Quiet Killings in Medical Facilities," 218; Kelly M. Pyrek, Healthcare Crime: Investigating Abuse, Fraud, and Homicide by Caregivers (Boca Raton, Fla: CRC Press, 2011), 148. See also Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 7992.

For example, James Thunder argues that a 1999 *Washington Post* investigative report provides a concrete example of suspicious deaths where no charges have been laid or prosecutions pursued, likely because the identity of the killer remained unknown.⁵² According to that report, between 1993 and 1999, 116 residents with mental disabilities died while living in group homes run by the District of Columbia. Of these residents, 30 had no identified cause of death, and the cause of death for another 34 was delayed treatment or neglect. Thunder maintains that the failure to give the cause of death of 30 residents is suspicious.⁵³ Some of the records relating to the deaths of these residents were also falsified. As late as 2006, a court monitor found that death reports relating to residents in these group homes continued to be altered.⁵⁴

The Gosport War Memorial Hospital in the United Kingdom has also been the setting of a large number of seemingly suspicious deaths, none of which have resulted in charges being laid or prosecuted. An independent inquiry, the Gosport Panel, found that 456 patients died at the hospital between 1989 and 2000 after being prescribed and administered opioids without appropriate clinical justification, and that there may have been an additional 200 deaths. Many of these patients had been admitted for rehabilitation or respite care, but were effectively placed on a terminal care pathway.

⁵² Thunder, "Quiet Killings in Medical Facilities," 218.

⁵³ Thunder, "Quiet Killings in Medical Facilities," 218.

⁵⁴ Spencer S. Hsu, "After 40 years, U.S. court ends supervision of D.C.'s care for mentally disabled citizens," Washington Post, Jan. 11, 2017, https://www.washingtonpost.com/local/public-safety/after-40-years-us-court-ends-supervision-of-dcs-care-for-mentally-disabled-citizens/2017/01/10/b006c52a-d681-11e6-9f9f-5cdb4b7f8dd7_story.html?utm_term=. ed6c0a66c18d [accessed March 14, 2019].

Several other studies have called attention to oversight weaknesses in long-term care and nursing homes which allow the abuse and neglect of residents to go undetected. Some of this abuse and neglect may be sufficiently serious to cause the deaths of residents. See, for example, *Nursing Home Deaths: Arkansas Coroner Referrals Confirm Weaknesses in State and Federal Oversight of Quality of Care*, Report to Confessional Requesters (Washington, DC: US Government Accountability Office, 2004), digital.library.unt.edu/ark:/67531/metadc298866/m1/2/ [accessed Jan. 17, 2019]. For a discussion on the available evidence about the nature, scope, and causes of abuse and neglect in long-term care and nursing homes, see Catherine Hawes, "Elder Abuse in Residential Long-Term Care Settings: What Is Known and What Information Is Needed?" in Richard J. Bonnie and Robert B. Wallace (eds.), *Elder Mistreatment: Abuse, Neglect, and Exploitation in an Aging America* (Washington, DC: National Academies Press, 2003).

⁵⁵ Great Britain, Gosport Independent Panel, Gosport War Memorial Hospital. Report of the Gosport Independent Panel (London: Crown Copyright, 2018) [Gosport Report], pp 37–38, 316–17.

⁵⁶ Gosport Report, viii.

The Gosport Panel found that staff had poor record-keeping practices and did not comply with the analgesic ladder, which "encourages the use of opioids in severe pain but in a logical, stepped process of escalating use of analgesics in response to patients' symptoms." A 2010 General Medical Council investigation found the physician who was responsible for the practice of prescribing that prevailed on the wards "guilty of serious professional misconduct" and concluded that she had put her patients at risk. It did not, however, suspend her medical licence. To date, no charges have been laid in respect of the Gosport deaths, although police are reviewing the evidence to determine whether to open another investigation.

D. The Toll Exacted by HCSKs

The harm caused by HCSKs radiates beyond the immediate victims. HCSK murders devastate the victims' families and their loved ones, healthcare workers, and the communities in which the offences are committed. As well, as we have seen through this Inquiry, they erode public trust in the healthcare system and in authority in general. The suffering caused by the Offences is described in Chapter 1 of the Report.

In addition to the immeasurable human cost of HCSKs, considerable tangible costs result from their investigation and prosecution. In several cases, moreover, public inquiries and review processes have been launched to determine how the crimes were committed and what steps must be taken to avoid similar tragedies.

Investigations into offences committed by HCSKs are costly, particularly where multiple murders are involved. For example, the investigation of respiratory therapist Efren Saldivar, who pled guilty to six murders and was linked to 165 suspicious deaths, cost \$1.2 million and spanned nearly three years.⁶¹

⁵⁷ Gosport Report, pp 20, 27, 34, 76–77.

⁵⁸ Gosport Report, pp 77, 204–11.

⁵⁹ Gosport Report, pp 209–11.

^{60 &}quot;Gosport hospital deaths: Evidence 'strong enough to bring charges," BBC News, Jan. 20, 2019, https://www.bbc.com/news/uk-england-hampshire-46924754 [accessed March 13, 2019].

Expert Report of Professor Beatrice Crofts Yorker Schumacher, Tab F; Jeff Adler, "Is California worker 'angel of death'?" Washington Post, Feb. 4, 2001, https://www.washingtonpost.com/archive/politics/2001/02/04/is-california-hospital-worker-angel-of-death/976245f2-7e03-4ff1-89f2-0104e99df2f9/?noredirect=on&utm_term=.d8a90f1ecf89 [accessed April 11, 2019]; "California's 'angel of death' pleads guilty to 6 deaths, gets life," CNN, March 12, 2002, http://www.cnn.com/2002/LAW/03/12/angel.death/index.html [accessed April 11, 2019].

The investigation of Orville Lynn Majors – who was convicted of six murders and linked to 124 suspicious deaths – cost \$1.5 million.⁶² These figures do not include the costs of the subsequent prosecutions.

The actions of HCSKs and suspicious deaths in the healthcare context have triggered public inquiries, investigations, and reviews, all of which are expensive endeavours, and some of which recommend costly changes to prevent future intentional wrongdoing by healthcare workers. For example:

- The suspicious deaths at SickKids in the early 1980s, discussed above, led to two investigations. The first, a Review Committee chaired by Justice Charles Dubin, examined the patient care practices and procedures in place in the Departments of Cardiology and Neonatology at SickKids to determine whether they sufficiently protected patient safety and security.⁶³ The Dubin Report, released on January 19, 1983, made 98 recommendations to SickKids, targeting various areas including the board of trustees, the administration, the medical staff and nursing staff, various divisions and departments of the hospital, communications, and the patient care safety system.
- The second SickKids investigation was a public Inquiry chaired by Justice Samuel Grange. This public inquiry lasted 20 months, with 191 days of hearings.⁶⁴ It examined the cause of death for all 36 victims and the police investigation into nurse Nelles.⁶⁵ The inquiry report, submitted on December 28, 1984, recommended that Ms. Nelles be compensated for the legal costs she incurred between the time of her arrest and the conclusion of the preliminary inquiry.⁶⁶ Ultimately, Nelles settled with the police for \$190,000 and with the Ontario government for \$60,000.⁶⁷

⁶² Judy Pasternak, "Deaths at hospital roil rural county," Los Angeles Times, Dec. 31, 1997, https://www.latimes.com/archives/la-xpm-1997-dec-31-mn-3820-story.html [accessed Apr 11, 2019].

⁶³ Ontario, Hospital for Sick Children, *Report of the Hospital for Sick Children Review Committee* (Toronto: The Committee, 1983), xiv–xv (Charles L. Dubin, chair) (Dubin Report).

⁶⁴ Grange Inquiry, Report; Roy McMurtry, Memoirs and Reflections (Toronto: Osgoode Society for Canadian Legal History, 2013), 283.

⁶⁵ Grange Inquiry, *Report*, 1–2.

⁶⁶ Grange Inquiry, Report, 222.

⁶⁷ Peter Bowal and Kelsey Horvat, "Whatever Happened to ... The Prosecution of Susan Nelles" (Sept./Oct. 2011) LawNow 55 at 58.

- In the United Kingdom, the Allitt Inquiry was established following the conviction of nurse Beverley Allitt for the murder of four children and the attempted murder of three others, and for causing grievous bodily harm to a further six on the children's ward of Grantham and Kesteven General Hospital. The inquiry sought to "enquire into the circumstances leading to the deaths of four children and injuries to nine others." Its recommendations, which were endorsed by the UK government, included increasing awareness of the possibility of intentional harm by healthcare providers and addressing limitations in the screening of nurses, the coroner's post mortem reports, and the role of pediatric pathology services.
- A second inquiry into the same events the Regional Fact Finding Inquiry into Paediatric Services at Grantham and Kesteven General Hospital – issued 51 recommendations targeting the management of pediatric and neonatal services at the hospital, including an increase in medical and nurse staffing levels and better record-keeping with respect to the qualification and registration status of nurses. Many of the recommendations were subsequently implemented.⁷¹
- The Shipman Inquiry was launched shortly after Dr. Harold Shipman was convicted of 15 murders in the United Kingdom in January 2000. The Shipman Inquiry spanned four years and cost £21 million.⁷² The Inquiry took approximately 2,500 witness statements, analyzed approximately 270,000 pages of evidence, and released six reports.⁷³ It issued almost 200 recommendations on broad systemic matters such as the safeguarding and management of controlled drugs, the monitoring of patient mortality rates, the general availability of information about

⁶⁸ Sir Cecil Clothier, The Allitt Inquiry: Independent Inquiry Relating to Deaths and Injuries on the Children's Ward at Grantham and Kesteven General Hospital During the Period February to April 1991 (London: HMSO, 1994), para 1.7.

⁶⁹ Anne MacDonald, "Responding to the Results of the Beverly Allitt Inquiry" (Jan. 10, 1996) 92(2) Nursing Times 22.

⁷⁰ Clothier, *The Allitt Inquiry*, para 7.8.

⁷¹ Clothier, *The Allitt Inquiry*, paras 6.3, 6.5, 6.6.

⁷² Clare Dyer, "What Have We Learnt from Shipman?" (Oct. 23, 2010) 341 *British Medical Journal* 341 at 341.

^{73 &}quot;The Shipman Inquiry: Questions and Answers," https://webarchive.nationalarchives. gov.uk/20090808155104/http://www.the-shipman-inquiry.org.uk/qanda.asp [accessed April 11, 2019]; "The Shipman Inquiry: Reports," https://webarchive.nationalarchives.gov. uk/20090808155110/http://www.the-shipman-inquiry.org.uk/reports.asp [accessed April 11, 2019].

- doctors, the identification and investigation of complaints related to patient safety in the medical system, and the process of death certification. The government provided a detailed response to the recommendations and implemented numerous changes.⁷⁴
- Following the May 2006 conviction of nurse Benjamin Geen for murdering two patients and causing grievous bodily harm to 15 others at the Horton General Hospital in the United Kingdom, the Thames Valley Strategic Health Authority commissioned an independent review (Geen Review) to determine how Geen had been able to commit the offences and how similar wrongdoing could be prevented in the future. The report made numerous systemic recommendations related to clinical governance, risk management, the medication management system, employee recruiting procedures, assessment of staff, the hospital's audit system, and data analytics.
- Following the 2006 arrest and subsequent confession of Czech nurse Petr Zelenka to seven murders and 10 attempted murders, the minister of health struck an expert commission to inquire into the events. By January 2007, it had connected five additional deaths to Zelenka.⁷⁷

⁷⁴ See Learning from Tragedy, Keeping Patients Safe: Overview of the Government's Action Programme in Response to the Recommendations of the Shipman Inquiry, Presented to Parliament by the Home Secretary and the Secretary of State for Health by Command of Her Majesty, CM 7014 (London: The Stationery Office, 2007); Safer Management of Controlled Drugs: The Government Response to the Fourth Report of the Shipman Inquiry, Presented to Parliament by the Home Secretary and the Secretary of State for Health by Command of Her Majesty, CM 6434 (Norwich: Crown Copyright, 2004); Safer Management of Controlled Drugs: Private CD Prescriptions and Other Changes to the Prescribing and Dispensing of CDs: Guidance for Implementation (Leeds: Department of Health, June 2006); Department of Health and Social Care, Safeguarding Patients: Government's Response to the Recommendations of the Shipman Inquiries, Presented to Parliament by the Secretary of State for Health by Command of Her Majesty, CM 7015 (London: The Stationery Office, 2007). Independent Review into the Horton General Hospital Accident & Emergency Department, Horton General Hospital Emergency Department Review: Final Report, August 2006 (Geen Review), pp 4, 7.

⁷⁵ Independent Review into the Horton General Hospital Accident & Emergency Department, Horton General Hospital Emergency Department Review: Final Report, August 2006 (Geen Review), pp 4, 7.

⁷⁶ Geen Review, pp 27–28, 30–32, 39, 59–60.

Ramsland, Inside the Minds of Healthcare Serial Killers, xiii–xiv. Unlike Wettlaufer, Zelenka did not turn himself in: he confessed only after he was arrested.

A number of healthcare institutions have faced civil lawsuits following the convictions of HCSKs. These, too, attract significant expense, both in terms of defending the lawsuits and payment of damage awards or the costs of settling the action out of court. Professor Crofts Yorker testified that "[t]he cost of wrongful deaths as a result of hiring a person who's been associated with adverse patient incidents is in the millions." The families of nurse Cullen's victims and potential victims sued the hospitals where he had worked – and eventually settled out of court for an undisclosed amount. The families of respiratory therapist Saldivar's victims sued the hospital where he worked; some families settled with the hospital out of court.

Even when suspected HCSKs are acquitted or never prosecuted, the victims (if still living) or their loved ones have sometimes launched successful lawsuits for damages against public institutions. In the United States, Michael Beckelic was suspected of injecting several newborns with a toxic dose of lidocaine, killing some and permanently injuring others, while working in the nursery of the Maxwell Air Force Base hospital. He was never charged criminally, but the families of the newborns successfully sued the hospital and were awarded \$27 million in damages.⁸¹ Other claims involving suspected HCSKs have led to civil damages awards against hospitals of \$450,000 and approximately \$8 million.⁸²

⁷⁸ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 8085.

⁷⁹ Graeber, *The Good Nurse*, 271.

Mmber Willard, "One civil case remains against accused mass killer," Glendale News-Press, Oct. 30, 2001, http://articles.glendalenewspress.com/2001-10-30/news/export33781_1_ respiratory-therapist-terry-goldberg-efren-saldivar [accessed Jan. 17, 2019].

Expert Report of Professor Beatrice Crofts Yorker Schumacher, Tab F; Associated Press, "Case of newborns drugged at Air Force nursery settled," April 4, 1998, in Los Angeles Times, http://articles.latimes.com/1998/apr/04/news/mn-35913 [accessed Sept. 18, 2018].

⁸² For example, Richard Williams, who had been charged with 10 murders at a Veterans Affairs hospital for administering lethal injections of succinylcholine, had those charges dropped after medical tests did not necessarily point to murder. However, in 1998, the widow of one of the individuals who died in the hospital won a \$450,000 civil negligence suit against the hospital. On a preponderance of the evidence, the presiding judge found that Williams was responsible for the death and that the hospital had reason to believe Williams was a danger to his patients but did nothing to stop him. Expert Report of Professor Beatrice Crofts Yorker Schumacher, Tab F; Eric Slater, "Former nurse charged with killing 10 veterans is set free," Los Angeles Times, Aug. 7, 2003, http://articles.latimes.com/2003/aug/07/nation/na-nurse7, [accessed Sept. 18, 2018]; Pyrek, Healthcare Crime, 147. Another suspected HCSK, Jane Bolding, was suspected for 17 murders and 23 attempted murders. She was prosecuted for some of these suspected crimes but was ultimately acquitted. Nonetheless, approximately \$8 million in damages was paid to settle various wrongful death suits against her: see Crofts Yorker et al., "Serial Murder by Healthcare Professionals," 1367; Beatrice Crofts Yorker, "An Analysis of Murder Charges Against Nurses" (1994) 1(3) Journal of Nursing Law 35 at 41; Expert Report of Professor Beatrice Crofts Yorker Schumacher, Tab F.

Similarly, the deaths (and abuse) of persons with mental disabilities living in group homes run by the District of Columbia, discussed above, resulted in decades of class-action litigation and court supervision. This litigation ultimately led to more than \$2.3 billion in federal aid to address systemic shortcomings and completely overhaul a "broken" system.⁸³

III. Common Features of HCSKs

A. Who They Are

1. Most HCSKs Are Nurses

According to Professor Crofts Yorker's research, of the 131 HCSKs who have been prosecuted since 1970, 80 were registered nurses (RNs), eight were practical nurses, and 23 were nurses' aides. In other words, as Figure 16.1 sets out, 85% of prosecuted HCSKs were nursing staff. In addition, 15 physicians have been prosecuted, and five others were staff such as paramedics.⁸⁴

Relative to their numbers in the nursing profession, the number of male nurses prosecuted for murder is disproportionately high. An American survey found that only 6% of RNs are male, but 44% of the RNs prosecuted for murder between 1971 and 2006 were male.⁸⁵ More generally, the HCSK population is made up of roughly equal proportions of men and women.⁸⁶ Figure 16.1 shows the professional backgrounds of HCSKs prosecuted between 1970 and May 2018.

⁸³ Hsu, "After 40 years, U.S. court ends supervision of D.C.'s care for mentally disabled citizens."

⁸⁴ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 6, Tab F.

⁸⁵ Crofts Yorker et al., "Serial Murder by Healthcare Professionals," 1365.

⁸⁶ Crofts Yorker et al., "Serial Murder by Healthcare Professionals," 1365.

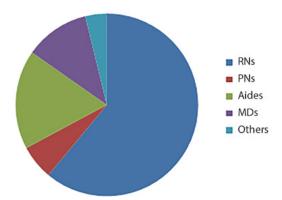


Figure 16.1: Professions of 131 Prosecuted HCSKs Between 1970 and May 2018

Source: Expert Report of Professor Beatrice Crofts Yorker Schumacher, Exhibit 163, Figure 1.

Notes: Data are based on cases reported in LexisNexis, Westlaw, and searchable internet outlets or that otherwise came to Professor Crofts Yorker's attention. Figures 16.1–16.5 are unchanged from Professor Beatrice Crofts Yorker Schumacher's Expert Report. The Commission has spelled out some abbreviations.

Professors Kizer and Crofts Yorker opine that healthcare workers are overrepresented among known serial killers.⁸⁷ Many female serial killers commit their offences in the healthcare context: the author of one study observed that 20% of known female serial killers in the United States were nurses charged with causing cardiopulmonary arrest among their patients,⁸⁸ while another author found that the typical female serial killer is either in a health-related role (such as nursing) or in a caretaker role.⁸⁹

2. HCSKs Have No Consistent Motives

HCSKs have no consistent motives for their murders. Some disproportionately kill patients they believe to be "whiny" or "demanding" (e.g., Orville Lynn Majors), 90 others kill out of laziness or to ease their workload

⁸⁷ Kizer and Yorker, "Health Care Serial Murder," 186.

⁸⁸ Beatrice Crofts Yorker, "Hospital Epidemics of Factitious Disorder by Proxy," in Marc D. Feldman and Stuart J. Eisendrath (eds.), *The Spectrum of Factitious Disorders* (Washington, DC: American Psychiatric Press, 1996), 160, citing R.M. Holmes and S.T. Holmes, *Murder in America* (Thousand Oaks, Calif.: Sage, 1993).

Marissa A. Harrison et al., "Female Serial Killers in the United States: Means, Motives, and Makings" (February 2015) Journal of Forensic Psychiatry & Psychology 1 at 8.

⁹⁰ Crofts Yorker et al., "Serial Murder by Healthcare Professionals," 1367.

(e.g., Efren Saldivar);⁹¹ and yet others kill for "the excitement of trying to revive" a patient, to "test" the doctors' skills, or from a desire for the respect they get from colleagues for performing well in responding to a code (e.g., Benjamin Geen, Richard Angelo, Petr Zelenka).⁹² At least one HCSK killed for attention from her lover. Kristen Gilbert, an RN convicted of four murders but linked to 50 suspicious deaths, overdosed patients with adrenaline to attract the attention of her boyfriend, who also worked in the hospital, by showing him how she could handle an emergency. The epidemiological data revealed that suspicious codes occurred only when both she and her boyfriend were on duty.⁹³

What is clear is that HCSKs are not committing "mercy killings." As Professor Crofts Yorker testified:

My research is pretty clear that in the rare cases of a nurse who, when confronted with evidence admits to anything, they will sometimes say things like, I was only trying to help the patients; or, It was their time to die; or, I hated to see them suffer.

What the actual medical record review revealed, though, is that that was a very self-serving statement on the part of the nurse, that some of the patients they said they were trying to help were not terminally ill and were expected to recover. So, right, this is not mercy killing.⁹⁴

Psychologist Katherine Ramsland echoes Professor Crofts Yorker's findings, noting that HCSKs "are quick to claim when apprehended that their motives were mercy or compassion. In most cases, evidence undermines this claim." ⁹⁵

The only consistent motive among HCSKs is the desire to kill, which is the same motive that drives other serial killers. As Professor Crofts Yorker explains:

Contrary to the vast majority of homicides and assaults, which are acts of violence directed toward specific individuals, the victims of serial murder are generally simply in the wrong place at the wrong time. Serial murder has an underlying compulsive psychological drive, whereas other forms of murder are usually motivated by anger, revenge, money, or jealousy.⁹⁶

⁹¹ Ramsland, *Inside the Minds of Healthcare Serial Killers*, 119.

⁹² Ramsland, *Inside the Minds of Healthcare Serial Killers*, xiii–xiv, 114; Crofts Yorker et al., "Serial Murder by Healthcare Professionals," 1367.

⁹³ Crofts Yorker et al., "Serial Murder by Healthcare Professionals," 1367; Kizer and Yorker, "Health Care Serial Murder," 187; Thunder, "Quiet Killings in Medical Facilities," 214.

⁹⁴ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 8109.

⁹⁵ Ramsland, Inside the Minds of Healthcare Serial Killers, 114.

⁹⁶ Crofts Yorker, "Hospital Epidemics of Factitious Disorder by Proxy," 164.

3. HCSKs Have No Clear Psychological Profiles

There is no useful way to categorize the psychological profiles of HCSKs. At a general level, most experts agree that they are often psychopaths. As one scholar explained, "Serial killing is the hallmark of the psychopath, a character incapable of remorse, lacking empathy for other people's feelings and driven solely by the desire to reward his or her own needs." Psychopaths have less empathy, remorse, or guilt; they also tend to need stimulation. But the value of this categorization is limited because there are "varying degrees of psychopathy." For example, men with psychopathic traits comprise approximately 1% of non-institutionalized adult men in the United States, to yet psychopathy does not automatically lead to murder.

In her testimony, Professor Crofts Yorker noted that several HCSKs have exhibited many of the same features as patients diagnosed with Munchausen syndrome or Munchausen syndrome by proxy.¹⁰¹ Professor Crofts Yorker explained that Munchausen syndrome is "a psychological condition where you make yourself ill for the purpose of getting medical attention ... Munchausen by proxy is making a dependent in your care ill."¹⁰²

Beverley Allitt, for example, who killed several children in a British hospital with insulin overdoses and another with a large air bubble, exhibited symptoms of both Munchausen syndrome and Munchausen syndrome by proxy. As Professor Crofts Yorker explained:

[D] uring nursing school, she had 146 visits to the student infirmary. She often had her arm in a sling. She was crisscrossed with incisions on her abdomen. She had urinary retention. She went so far as to inject ... her own breasts with normal saline to give herself breast lumps. And then when she got a job in a pediatric hospital area she became miraculously well, and the children started having critical incidents. ¹⁰³

Other HCSKs have exhibited similar symptoms. 104

⁹⁷ Kaplan, Medical Murder, 24. See also Pyrek, Healthcare Crime, 161.

⁹⁸ Kent A. Kiehl and Morris B. Hoffman, "The Criminal Psychopath: History, Neuroscience, Treatment, and Economics" (2011) 51 Jurimetrics 355.

⁹⁹ Kaplan, Medical Murder, 24.

¹⁰⁰ Kiehl and Hoffman, "The Criminal Psychopath," 355–97.

¹⁰¹ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 7983

¹⁰² Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 7984.

¹⁰³ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 7984.

¹⁰⁴ Crofts Yorker, "Hospital Epidemics of Factitious Disorder by Proxy," 165–66, 169.

Most instances of Munchausen by proxy involve mothers inducing or simulating disease states in their children, sometimes killing them in the act. ¹⁰⁵ It is not clear whether nurses, physicians, and nurses' aides who harm patients are compelled by the same dynamics "or whether they are simply serial murderers who perpetrated in the course of employment." ¹⁰⁶ Professor Crofts Yorker writes that the behaviours of HCSKs and of mothers suffering from Munchausen by proxy are the same: attention-seeking and erratic behaviour, as well as an emphatic denial of their murders even while in jail. ¹⁰⁷

Practically speaking, because no specific psychological profiles are associated with HCSKs, there is little value in profiling employment candidates in the healthcare sector or suspects in HCSK prosecutions. Professor Crofts Yorker has not seen any effective profiling throughout her years of research in the field. Although some individual nurses have character disorders or mental health issues, no screening exists for "predictive traits" that would establish whether these nurses are more likely than others to harm or kill patients. In fact, as Professor Crofts Yorker testified at the hearings, nurses who successfully manage their mental health issues are "some of the best nurses." Professor Crofts Yorker confirmed that she herself has never engaged "in any profiling activity" in the course of her consultancy work on HCSKs. As she explained, "I felt that convictions should not rest on a profile."

¹⁰⁵ Charles V. Ford, "Ethical and Legal Issues in Factitious Disorders: An Overview," in Feldman and Eisendrath (eds.), *The Spectrum of Factitious Disorders* 51 at 57–58; Barbara M. Osterfeld and Marc D. Feldman, "Factitious Disorder by Proxy: Clinical Features, Detection, and Management," in Feldman and Eisendrath (eds.), *The Spectrum of Factitious Disorders* 83 at 84.

¹⁰⁶ Crofts Yorker, "Hospital Epidemics of Factitious Disorder by Proxy," 163.

¹⁰⁷ Crofts Yorker, "Hospital Epidemics of Factitious Disorder by Proxy," 169–71.

¹⁰⁸ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, pp 7983–84, 8021–23; Karl H. Beine, "Homicides of Patients in Hospitals and Nursing Homes: A Comparative Analysis of Case Series" (2003) 26 *International Journal of Law and Psychiatry* 373 at 376–77; John Field and Alan Pearson, "Caring to Death: The Murder of Patients by Nurses" (2010) 16 *International Journal of Nursing Practice* 301 at 303.

Although Yardley and Wilson identify "some common criminological and socio-demographic characteristics in cases of healthcare serial murder" and consider these traits to be useful in investigating potential HCSKs, they do not suggest that individuals with these characteristics should be excluded from employment in the healthcare professions: Elizabeth Yardley and David Wilson, "In Search of the 'Angels of Death': Conceptualizing the Contemporary Nurse Healthcare Serial Killer" (2016) 13 *Journal of Investigative Psychology and Offender Profiling* 39 at 52–53.

¹⁰⁹ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, pp 7983–84.

¹¹⁰ Ramsland, *Inside the Minds of Healthcare Serial Killers*, 129 (interview with Beatrice Crofts Yorker).

¹¹¹ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 8022.

¹¹² Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 7983.

A review of Wettlaufer's early years as a nurse is contained in Chapter 3. What we learn from that chapter is consistent with Professor Crofts Yorker's view that profiling is of little use in attempting to identify HCSKs. Wettlaufer's first nursing job was short-lived and ended disastrously when she stole drugs from the hospital at which she was working, consumed them while on the job, and collapsed. But Wettlaufer then enjoyed stable employment with Christian Horizons that lasted for over a decade. While at Christian Horizons, apart from comments found in her first performance review, it appears that Wettlaufer had good relationships with the people for whom she provided care. And, although she was not initially seen as particularly motivated or as socially appropriate in her interactions with peers, she improved with time and effort. By the time she left Christian Horizons after 11 years, she had held increased responsibilities satisfactorily and received favourable peer assessments. The positive reference letter from Christian Horizons appears to be warranted. In sum, there is nothing in Wettlaufer's lengthy period of employment with Christian Horizons to suggest that, within months of leaving there, she would begin intentionally harming residents.

B. HCSKs Target Vulnerable Victims

HCSKs target vulnerable individuals, particularly those who are very young, very old, or very ill. As Professor Crofts Yorker explained in her expert report:

Patients who are critically ill, elderly, mentally compromised, frail, very young or infants are over-represented victim populations in our studies. The reasons for this are similar to the increased vulnerability of these populations to be abused or assaulted in any setting. These patient populations have decreased capacity to recognize abuse, identify perpetrators, speak about it, resist it, or report it. These populations are particularly vulnerable to abuse of any type in a healthcare setting (sexual assault / molestation, elder abuse, battering, starving, neglect and verbal abuse) and even more vulnerable to insidious abuse such as overmedication, injection, smothering, or equipment tampering, as those methods do not leave obvious bruising or signs of physical abuse and neglect. As patients in a healthcare setting, these populations may be further compromised by medications, delirium, dementia, or coma.¹¹³

Beverley Allitt and the possible unidentified HCSK in the SickKids case are examples of HCSKs who targeted babies and children. Shipman targeted elderly individuals who were in poor health and whose deaths would raise little suspicion:

¹¹³ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 7.

Statistically, it is clear that Shipman killed mainly elderly women living alone. He also killed some men and they too were usually elderly and living alone. In general, he killed people who were in poor health. Some of the earliest killings were of patients who were terminally ill or very unwell. Many of his victims were frail and in poor general health.

. . .

I think there was probably another reason why most of Shipman's early victims were terminally ill or in very poor health. For a doctor to give an overdose of opiate to a patient whose death is expected would give rise to very little risk of suspicion or detection.¹¹⁴

It is important to note, however, as Professor Crofts Yorker does, that HCSKs have killed or assaulted healthy and ambulatory patients, including patients who were in the healthcare setting for routine visits or diagnostic tests.¹¹⁵

C. Where HCSKs Operate

Healthcare facilities are filled with powerful drugs, vulnerable and sick individuals who may be expected to die, and healthcare workers with minimal supervision. As such, they provide a setting in which HCSKs can commit murder without detection. Professors Kizer and Crofts Yorker explain:

Patients are often disoriented, sedated, or not aware of their surroundings or what is being done to them. They may be severely weakened and unable to defend themselves. Caregivers often work alone and in private and have ready access to multiple potentially lethal agents, the use of which may not be attributable. Care may involve numerous types of technology used by, or invasive interventions performed by, persons unknown to the patient or other caregivers. In addition, death is a relatively frequent occurrence in health care facilities, so a patient's death initially may not be suspected of being due to a criminal act even when it is unexpected.¹¹⁶

Forensic nurse Mary K. Sullivan adds that the increasing acuity levels of patients as well as the overworked staff with little supervision help to make healthcare settings attractive for HCSKs:

The reality is that most medical facilities across the country are in a crisis mode when it comes to who provides hands-on patient care and how well it is accomplished. In hospitals across the U.S., units are filled to capacity and those patients are sicker. A high patient census with

¹¹⁴ Shipman Inquiry: First Report, pp 189–90, paras 13.58, 13.60.

¹¹⁵ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 7.

¹¹⁶ Kizer and Yorker, "Health Care Serial Murder," 187.

equally high acuity levels combined with fewer licensed registered nurses (RNs) to share the workload makes for a dangerous situation. Rarely do RNs have time to help each other because of their own workloads, and supervisor positions have been cut back in efforts to downsize. Additionally, some applicants are not always completely honest with background histories, and screening efforts do not always catch the discrepancies. Further, there is an overall failure to discipline or terminate marginal employees, and because of short staffing it is often felt that a 'warm body' is better than nobody showing up for work. These all contribute to setting the stage for those who may have something other than the best intention of patients in mind. History has certainly shown that individuals such as former nurse Gilbert and many other former licensed healthcare professionals who have been successfully prosecuted for criminal acts against patients have taken advantage of these dynamics.¹¹⁷

Historically, HCSKs have operated primarily in hospitals. Professor Crofts Yorker's data show that between 1970 and 2006, 70% of the deaths associated with prosecutions of potential HCSKs took place in hospitals, 20% in LTC/nursing homes, and 6% in home care (see Figure 16.2).¹¹⁸

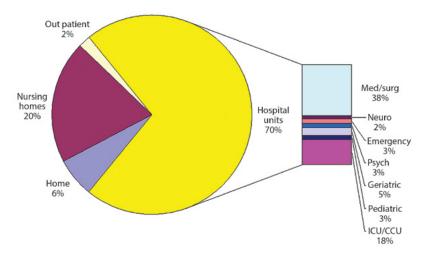


Figure 16.2: Settings of 90 Prosecutions Between 1970 and 2006

Source: Expert Report of Professor Beatrice Crofts Yorker Schumacher, Exhibit 163, Figure 3

Note: Data are based on cases that were reported in LexisNexis, Westlaw, and searchable internet outlets or that otherwise came to Professor Crofts Yorker's attention.

¹¹⁷ Mary K. Sullivan "Forensic Nursing in the Hospital Setting," in Virginia A. Lynch and Janet Barber Duval (eds.), *Forensic Nursing* (St. Louis, Mo.: Mosby, 2006), 562.

¹¹⁸ Expert Report of Professor Beatrice Crofts Yorker Schumacher, pp 8–9.

Some researchers have suggested that hospitals offer an ideal environment for HCSKs:

The ICU is a place of technology, unusual drug formularies and rapid decision-making, all designed to help critically ill patients get better. However, these same factors can create an environment where a healthcare worker might systematically harm a patient without fear of detection or punishment. Such allegations are difficult to substantiate because evidence is so difficult to obtain and criminal prosecutions are rare.¹¹⁹

In recent years, however, HCSKs have increasingly turned to LTC homes and private homes as places in which they commit their wrongdoing. Professor Crofts Yorker's data reveal that between 2006 and May 2018, approximately 36% of deaths associated with prosecuted HCSKs took place in LTC/nursing homes, and 10% in home care (see Figure 16.3).¹²⁰

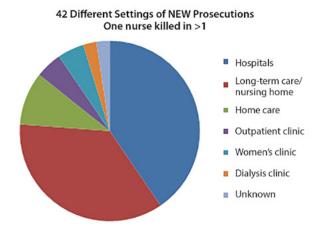


Figure 16.3: Settings Associated with 41 New Prosecutions Between 2006 and May 2018

Source: Expert Report of Professor Beatrice Crofts Yorker Schumacher, Exhibit 163, Figure 4.

Note: Data are based on cases that were reported in LexisNexis, Westlaw, and searchable internet outlets or that otherwise came to Professor Crofts Yorker's attention. Data include one nurse who killed in more than one setting.

¹¹⁹ G.R. Park and S.N. Khan, "Murder and the ICU" (2002) 19 European Journal of Anesthetics 621 at 621.

¹²⁰ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 9.

These data sets are quite limited, and caution must be exercised before drawing any conclusions with respect to trends. In her expert report, Professor Crofts Yorker did, however, provide several reasons why the LTC and home care settings allow for the potential abuse of residents and patients, including:

- there is less oversight and more independence for nursing staff than in a hospital setting;
- patients are expected to die in long-term care;
- patients have diminished capacity, dementia, terminal illnesses, and are physically frail;
- patients in long-term care may also be physically aggressive and/or at higher risk of falls or other injuries, making restraints, sedation, bruising, or injuries more expected; and
- patients in long-term care are typically on a variety of medications that could sedate or alter their mental status.¹²¹

She also noted that LTC homes "may not be adequately equipped to conduct routine surveillance that could provide early detection of abnormal patterns of death or adverse patient events." 122

D. How HCSKs Commit Murder

1. HCSKs Primarily Use Injectable Medications

Injectable medication is the murder weapon of choice for HCSKs (see Figure 16.4). Between 1970 and May 2018, 54 out of 90 convicted HCSKs (65%) committed their murders through the injection of medication. This method includes the use of intravenous lines (IV) and PICC lines (a peripherally inserted catheter, much like an IV), which allow an HCSK to inject a medication into the line's port, leaving no needle mark.

¹²¹ Expert Report of Professor Beatrice Crofts Yorker Schumacher, pp 9–10.

¹²² Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 13.

¹²³ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 10.

¹²⁴ Pyrek, *Healthcare Crime*, 150.

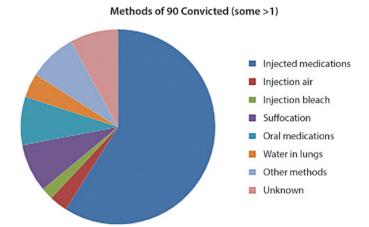


Figure 16.4: Methods Used by 90 Convicted HCSKs Between 1970 and May 2018

Source: Expert Report of Professor Beatrice Crofts Yorker Schumacher, Exhibit 163, Figure 5, p 10.

Note: Data are based on cases that were reported in LexisNexis, Westlaw, and searchable internet outlets or that otherwise came to Professor Crofts Yorker's attention. Some convicted HCSKs used more than one method to kill.

HCSKs have ready access to injectable medications, and the intentional wrongful injection of routinely administered medications is easy to perpetrate and difficult to detect. None of the known convicted HCSKs used their own medications to harm patients; rather, they used injectable medications intended for other patients. Using IV and PICC lines allows healthcare workers to murder patients in a relatively disconnected manner. Professor Crofts Yorker warns:

It is too easy to kill a patient when you don't even have to stick their skin with a needle. You simply put a needle in their IV line with ordinary, soluble, everyday medication. You just need to put in a ml or two more. The brink between toxic and therapeutic doses of what are usually therapeutic medications is so imperceptible. 126

The use of insulin by HCSKs appears to be increasing. In Professor Crofts Yorker's review of prosecutions of HCSKs between 1970 and 2006, insulin was used in 13% of cases. In prosecutions she reviewed between 2006 and May 2018, insulin was used in 40% of the cases (see Figure 16.5).¹²⁷

¹²⁵ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 12.

¹²⁶ Ramsland, *Inside the Minds of Healthcare Serial Killers*, 128 (interview with Beatrice Crofts Yorker).

¹²⁷ Expert Report of Professor Beatrice Crofts Yorker Schumacher, pp 11–12; Crofts Yorker et al., "Serial Murder by Healthcare Professionals," 1370 (Figure 6).

However, some HCSKs, such as Charles Cullen, used different injectable medications for different victims.¹²⁸

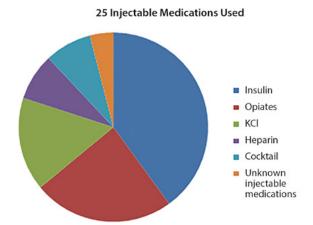


Figure 16.5: Medications Used by Prosecuted HCSKs Between 2006 and May 2018

Source: Expert Report of Professor Beatrice Crofts Yorker Schumacher, Exhibit 163, Figure 6.

Note: Data are based on cases that were reported in LexisNexis, Westlaw, and searchable internet outlets or that otherwise came to Professor Crofts Yorker's attention.

Among convicted (as distinct from prosecuted) HCSKs, insulin is the most commonly used injectable medication, followed by morphine and other opiates.¹²⁹ Some of the most notorious HCSKs have used insulin to kill their victims, including Frans Hooijmaijers, Charles Cullen, and Beverley Allitt.¹³⁰

Professor Crofts Yorker explains that the injection of insulin by HCSKs poses some unique challenges in terms of detection:

Many patients in hospitals and Long-Term Care are on insulin, therefore they have their own supply of this medication, typically in both long acting and short acting forms. Insulin can take hours or days to induce coma or death. The symptoms of hypoglycaemia are non-specific and

¹²⁸ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 11.

¹²⁹ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 11.

¹³⁰ See "Dutch Jail Nurse in 5 Deaths," New York Times, Dec. 8, 1976, https://www.nytimes.com/1976/12/08/archives/dutch-jail-nurse-in-5-deaths.html [accessed April 10, 2019]; Graeber, The Good Nurse, 112–17; Vincent Marks and Caroline Richmond, Insulin Murders: True Life Cases (London: Hodder & Stoughton, 2010), 55–75.

can vary from patient to patient. If detected, it can be reversed with administration of IV Dextrose, which may revive a patient who was given a toxic dose of insulin, without suspicion of wrongdoing. A killer who overdoses a patient on insulin has often been off the premises for several hours or shifts when the patient is adversely affected by the overdose.¹³¹

In addition to killing victims with injectable medications, some HCSKs have injected other deadly substances to kill patients and residents. The Japanese nurse arrested in the summer of 2018, for example, is alleged to have injected disinfectant into intravenous bags, killing approximately 20 patients at a Yokohama hospital. American nurse William George Davis was indicted in 2018 on one charge of capital murder, an additional charge of murder, and several counts of aggravated assault with a deadly weapon for the intentional injection of air into arterial lines of patients recovering from heart surgery, causing them to have stroke-like symptoms. 133

Not all HCSKs use injectable substances to kill. For example, in 2006, German nursing assistant Michaela Giersberg was convicted of killing nine women in a nursing home mostly by suffocating them with cushions or towels.¹³⁴

2. HCSKs Often Operate in the Evenings or at Night

HCSKs typically kill on the evening or the night shift. As Professor Crofts Yorker notes, "There are fewer healthcare providers present, fewer family members are present and a single RN is typically in charge on the evening and night shifts." This observation is even more true of LTC homes than hospitals.

Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 13. See also Affidavit of Dr. Michael Pollanen, para. 102; Testimony of Dr. Michael Pollanen, Transcript, pp 5039–41.

¹³² Julian Ryall, "Japanese nurse investigated over 20 killings at end of shifts to avoid 'nuisance' of telling families of deaths," *The Telegraph*, July 10, 2018, https://www.telegraph.co.uk/news/2018/07/10/japanese-nurse-investigated-20-killings-end-shifts-avoid-nuisance/[accessed March 14, 2019].

¹³³ "Former Hallsville nurse faces additional capital murder charge," Marshall News Messenger, Aug. 31, 2018, https://www.marshallnewsmessenger.com/news/hallsville-man-faces-additional-capital-murder-charge/article_5958275c-29ba-56ce-a026-bc97bc792167.html [accessed March 14, 2019].

^{134 &}quot;Nurse aide gets life in patients' deaths," AP News, Feb. 22, 2006, https://www.apnews.com/ef31bc057a8870ca260f5b8116ff19af [accessed March 14, 2019].

¹³⁵ Expert Report of Professor Beatrice Crofts Yorker Schumacher, pp 2, 14; Crofts Yorker et al., "Serial Murder by Healthcare Professionals," 1365. Some studies have found that HCSKs were most likely to offend between 23:00 and 07:00: see Pyrek, Healthcare Crime, 153, citing D.R. Kent and P.D. Walsh, "Modern U.S. Healthcare Serial Killings: An Exploratory Study and Work in Progress," in V.P. Bunge, C.R. Block, and M. Lane (eds.), Linking Data to Practice in Violence and Homicide Prevention: Proceedings of the 2004 Meeting of the Homicide Research Working Group (Chicago: HRWG Publications, 2004).

While hospitals often remain "lively with activity" during the evening or night shift, LTC homes are usually quiet. 136

Forensic nurse Sullivan has written that the shift change also provides an ideal period for HCSKs to cause intentional harm:

For example, staff members who are getting off duty, especially after a busy shift, may disengage from responsibilities too early, leaving loose ends and incomplete reports. Documentation and oral reports often take precedence over hands-on care activities, increasing the risks for omissions or duplication of tasks, medication administration, or specifically timed one-on-one checks on patients in leather restraints or seclusion. There is often a tendency to assume that the next staff will do it or that the previous staff has done it ... Social interactions may take precedence over professional communications when shift workers merge. Patients as well as visitors are often aware of the confusion and chaos that may occur during a change of shift, and some may take advantage of these opportunities to engage in behavior that is not conducive to the health and welfare of other patients on the unit. Those caregivers who have ideas other than providing healthcare on their minds will also realize that the change of shift provides an optimum time for inappropriate, illegal, or otherwise dangerous behavior. 137

According to a former co-worker, HCSK Kristen Gilbert took advantage of the shift change to commit some of her crimes:

She would love to cause all hell to break loose after a very quiet evening shift ... always at the change of shift. It seems as if she chose the times when the less experienced staff were on duty, especially if the nurse or doctor was new.¹³⁸

E. Wettlaufer and the Common Features of HCSKs

Wettlaufer displayed many of the features common to HCSKs set out above:

- Like 85% of prosecuted HCSKs, Wettlaufer was a member of the nursing staff.¹³⁹
- Wettlaufer had no clear motive for her crimes. She said that she sometimes felt a "surge" that compelled her to inflict harm on her

¹³⁶ Pyrek, *Healthcare Crime*, 153.

¹³⁷ Sullivan, "Forensic Investigations in the Hospital," 134 at 137.

¹³⁸ Sullivan, "Forensic Investigations in the Hospital," 137 (quoting a former co-worker of Kristen Gilbert).

¹³⁹ Expert Report of Professor Beatrice Crofts Yorker Schumacher, pp 6–7.

victims.¹⁴⁰ But she also said that sometimes she harmed or killed because she felt "frustrated" or "angry" at a resident or about her life.¹⁴¹ Other times she just felt it was a particular resident's "time to go." ¹⁴²

- Wettlaufer chose as victims those whom she saw as particularly vulnerable because they would not be able to report what she had done. They were "often suffering from dementia or other progressive diseases." 143
- Like 65% of convicted HCSKs, Wettlaufer committed the Offences by using injectable medication (in her case, by intentionally injecting residents with overdoses of insulin). Wettlaufer deliberately chose insulin because "it wasn't counted, and because [she knew] that it was something that could kill people." 144
- Like many other HCSKs prosecuted between 2006 and May 2018,
 Wettlaufer committed the Offences in LTC homes where she worked rather than in hospitals.¹⁴⁵
- Wettlaufer committed the Offences while she was working on evening and night shifts.¹⁴⁶

The only "completely unprecedented" aspect of Wettlaufer's actions as an HCSK is that she confessed and turned herself in. 147 As I explain in Chapter 1, had she not confessed and turned herself in, it is virtually certain that the Offences would never have come to light. This is one of the most troubling aspects of the Wettlaufer Offences – no one suspected that an HCSK was at work. None of the front-line staff or management in the LTC homes, the victims' families, the Ministry or its inspectors, the College of Nurses of Ontario, the CCACs, the LHINs, the service provider organization, or those involved in the death investigation process, including coroners and pathologists, conceived of the possibility that someone was intentionally and successively harming and killing residents in the LTC system.

¹⁴⁰ "Foundational Document – Agreed Statement of Facts," filed as Exhibit 1 [Agreed Statement of Facts], paras 53, 57, 63, 95, 108, 142.

¹⁴¹ Agreed Statement of Facts, paras 19–20, 36, 45, 122, 134, 142.

¹⁴² Agreed Statement of Facts, paras 36, 53, 74, 86.

¹⁴³ R v Wettlaufer, 2017 ONSC 4347 at 8.

¹⁴⁴ Expert Report of Professor Beatrice Crofts Yorker Schumacher, pp 10–12; Commission interview with Elizabeth Wettlaufer, filed as Exhibit 5, Transcript, Feb. 14, 2018, p 60.

¹⁴⁵ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 9.

¹⁴⁶ Agreed Statement of Facts, paras 20, 37, 44–46, 63–64, 75, 108–9, 123.

¹⁴⁷ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 14.

IV. Protecting Ourselves from HCSKs

A. Awareness - the Critical First Step

Awareness of the HCSK phenomenon is the critical first step in developing system-wide protections against the threat these killers pose. We cannot prevent, deter, or detect intentional harm caused by a healthcare provider unless we first accept that such a thing is possible. In this regard, it is no different from the approach taken to abuse prevention generally, which begins with the premise that awareness is a necessary component of prevention. If abuse is not considered a possibility, "staff will be more likely to miss or dismiss the signs that an abusive situation has arisen. Complaints by patients of sexual abuse or harassment can easily be dismissed as delusions or exaggerated fears. Staff needs to listen to their patients and to be vigilant." Professors Kizer and Crofts Yorker are emphatic that increasing awareness is vital in combatting the HCSK phenomenon:

[W]e believe that health care organizations, accrediting bodies, and licensing agencies should do more to increase awareness of HCSM [healthcare serial murders] among health care professionals. Granted, it is disturbing to think that physicians, nurses, or other healthcare workers might intentionally kill or seriously harm patients entrusted to their care, and there is a fine line between acknowledging the problem and inappropriately frightening patients and undermining public confidence in hospitals and other health care facilities, but the first step in addressing any problem is acknowledging that it exists. 149

In many cases where HCSKs have been caught, other healthcare professionals have been the first to raise suspicions. Professor Crofts Yorker testified that many nurses have triggered investigations after reporting their concerns that patient deaths were linked to the presence of a particular caregiver. However, professionals may be slow to voice their suspicions because they cannot conceive of the possibility that a healthcare provider would murder a patient. As Professor Ramsland puts it, "[W]ho thinks that someone will

¹⁴⁸ Pyrek, *Healthcare Crime*, 57, quoting Royal College of Psychiatrists, *Sexual Boundary Issues in Psychiatric Settings*, College Report CR145 (London: RCP, 2007).

¹⁴⁹ Kizer and Yorker, "Health Care Serial Murder," 189.

¹⁵⁰ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 13.

¹⁵¹ Ramsland, Inside the Minds of Healthcare Serial Killers, 129.

go into the healthcare profession as a murderer? They are not even thinking about that possibility." ¹⁵² Kelly Pyrek explains:

The implicit trust that people have in healthcare professionals is most likely the reason why investigations are not launched until so much damage is already done. And much of the murdering can be accomplished under the guise of medical care and treatment, further obfuscating the crime. ¹⁵³

A lack of awareness that a healthcare provider might intentionally harm patients also contributes to delayed recognition of warning signs that something is seriously amiss. In their review of 37 HCSKs in the United States, David R. Kent and Patrick D. Walsh found: "In a few cases studied, the average monthly mortality may have been about 2.5 deaths by unit, yet administrators and front-line managers were reluctant to cry out when the monthly average jumped [to] between 10 and 15 ICU deaths." Two other examples of delayed recognition and response to warning signs are the cases of Kristen Gilbert and Orville Lynn Manors:

- at the trial of Gilbert who was convicted in March 2001 of four murders and linked to 50 suspicious deaths at a veterans' hospital – a nurse testified that she heard a patient yell at Gilbert, "Stop! Stop! You're killing me!" No investigation was conducted at the time.¹⁵⁵
- in the Majors case, the hospital staff noticed that potassium chloride and epinephrine went missing from 1993 to 1995 – the years in which Majors was employed at the hospital. However, no investigation was undertaken. Majors was eventually convicted of six murders, which he committed by injecting patients with epinephrine and potassium chloride. He was linked to 124 suspicious deaths overall.¹⁵⁶

¹⁵² Pyrek, Healthcare Crime, 185 (interview with Katherine Ramsland); see also Alcina Juliana Soares Barros et al., "Attempted Serial Neonaticides: Case Report and a Brief Review of the Literature" (2016) 61(1) Journal of Forensic Sciences 280 at 282.

¹⁵³ Pyrek, *Healthcare Crime*, 171.

¹⁵⁴ Kent and Walsh, "Modern U.S. Healthcare Serial Killings," 178 at 180 (reference omitted).

¹⁵⁵ Thunder, "Quiet Killings in Medical Facilities," 222; Kizer and Yorker, "Health Care Serial Murder," 187.

¹⁵⁶ Thunder, "Quiet Killings in Medical Facilities," 222; State of Indiana v Majors, Probable Cause Affidavit, Dec. 29, 1997, http://murderpedia.org/male.M/m/majors-orville-affidavit.htm [accessed March 14, 2019]; Crofts Yorker et al., "Serial Murder by Healthcare Professionals," 1364; Tom Davies, "Nurse serving 360 years in prison for killing 6 people at Indiana hospital dies," Chicago Tribune, Sept. 26, 2017, http://www.chicagotribune.com/news/nationworld/midwest/indiana/ct-indiana-nurse-killer-dead-20170925-story.html [accessed March 14, 2019].

B. Previous Public Inquiries Identified the Need to Build Awareness

Previous public inquiries and review processes have consistently recognized the need to build awareness of the HCSK phenomenon in the healthcare system.

The Grange Inquiry found that nurses at SickKids had noticed that some members of the same nursing team were consistently on shift for the deaths of the babies and children, but they felt only sympathy for their colleagues, not suspicion. The SickKids nurses and doctors did not suspect wrongdoing until the death of Kevin Pacsai, the 32nd victim, on March 12, 1981. ¹⁵⁷ In explaining why the deaths had gone uninvestigated for so long, a member of the hospital's administration observed that hospitals simply do not expect foul play on the part of their staff. ¹⁵⁸

The Grange Inquiry also found that the SickKids administration was unaware of a number of striking statistics:¹⁵⁹

- there was a 625% increase in the number of deaths of babies and children on Wards 4A and 4B in the nine-month period from June 1980 to March 1981, compared to the average number of deaths in the two previous and the two subsequent nine-month periods in these same wards;
- 25 of the deaths occurred between 24:00 and 06:00. No other six-hour period during the other periods studied had more than three deaths; and
- of the 36 deaths, all but one occurred when one or more members of a particular nursing team were on duty on Wards 4A or 4B.

The 1983 Dubin Report recommended that SickKids take the following measures to ensure that statistical data on deaths were routinely collected and reviewed:

 establish statistical surveillance of all deaths in the hospital, to trace any significant trends or untoward occurrences. This data should be forwarded monthly to the Risk Management Committee;

¹⁵⁷ Grange Inquiry Report, p 14.

¹⁵⁸ Arthur Johnson, "The Baby Murders," *Maclean's*, April 9, 1984.

¹⁵⁹ Grange Inquiry Report, pp 7–8.

- establish a Mortality Review Committee, with interdisciplinary representation, to meet every month; its findings should be included in the statistical surveillance related to deaths; and
- organize a formal morbidity review system and include its findings in the statistical surveillance.¹⁶⁰

In the United Kingdom, the Allitt Inquiry described the need for heightened awareness of the possibility that healthcare workers might intentionally harm those under their care as the main lesson to be drawn from its work:

The main lesson from our Inquiry and our principal recommendation is that the Grantham disaster should serve to heighten awareness in all those caring for children of the possibility of malevolent intervention as a cause of unexplained clinical events.¹⁶¹

We can learn as well from the Shipman Inquiry, which struggled with the question of how Shipman's killings had gone undetected for over two decades:

It is deeply disturbing that Shipman's killing of his patients did not arouse suspicion for so many years. The systems which should have safeguarded his patients against his misconduct, or at least detected misconduct when it occurred, failed to operate satisfactorily. The esteem in which Shipman was held ensured that very few relatives felt any real sense of disquiet about the circumstances of the victims' deaths. Those who did harbour private suspicions felt unable to report their concerns. 162

Some cautioned the Shipman Inquiry, saying it should "not ... propose any radical changes to the system just because one doctor had been able to evade the existing safeguards." ¹⁶³ In a clinical audit of Shipman's practice, the chief medical officer for England said, "Everything points to the fact that a doctor with the sinister and macabre motivation of Harold Shipman is a once in a lifetime occurrence." ¹⁶⁴

¹⁶⁰ Report of the Hospital for Sick Children Review Committee, 233.

¹⁶¹ Clothier, "The Allitt Inquiry," para 7.8.

¹⁶² Shipman Inquiry: First Report, p 200, para 14.15.

¹⁶³ Shipman Inquiry: Third Report, Foreword, v.

¹⁶⁴ Liam Donaldson, Foreword, in Richard Baker, Harold Shipman's Clinical Practice, 1974–1998: A Clinical Audit Commissioned by the Chief Medical Officer (London: Department of Health, 2001), iv.

However, the Shipman Inquiry rejected the notion that the problem was isolated to a single individual, saying:

[W]e do not know that Shipman is unique. We know that he has killed more people than any other serial killer yet identified, but we do not know how many other doctors have killed one or more patients. Some such killings have come to light; other may remain hidden. If Shipman was able to kill for almost 24 years before he was discovered, who can say with confidence that there are not other doctors, still unknown, who have killed in the past? Who can say that there will be none in the future?¹⁶⁵

In other words, it is vital to recognize the existence of the HCSK phenomenon if we are to protect against it. The fact that Wettlaufer is behind bars does not mean we are safe from HCSKs – it means we are safe from her.

C. A Strategic Plan to Build Awareness

One organization must be made responsible for developing and implementing a strategic plan to build awareness of the HCSK phenomenon within the healthcare system. Without such a plan, the perceived danger of HCSKs is likely to fade away with time. In general, murders by HCSKs "make headlines, but then they recede from our memory." ¹⁶⁶

The Office of the Chief Coroner and the Ontario Forensic Pathology Service (OCC/OFPS) is uniquely positioned to take on this responsibility because of its position in the healthcare system, its mandate, and the functions it performs. Further, giving the OCC/OFPS this responsibility aligns with the recommendations made elsewhere in this Report calling for reforms to the death investigation process for residents in LTC homes and placing responsibility for those reforms on the OCC/OFPS. See Chapters 14 and 18.

As we know from the Ontario experience, HCSKs pose a threat to the healthcare system as a whole – not just to LTC homes. They can strike wherever healthcare is delivered, whether that is in a hospital, an LTC home, or a private home. The SickKids tragedies took place in a hospital. As the research discussed above shows, until recently, HCSKs operated primarily in hospitals. But Wettlaufer committed the Offences in three LTC homes and in one private home, where the resident was receiving publicly funded healthcare after being discharged from the hospital. Thus, awareness that a

¹⁶⁵ Shipman Inquiry: Third Report, Foreword, v.

¹⁶⁶ Thunder, "Quiet Killings in Medical Facilities," 212.

healthcare provider might intentionally harm a patient or resident must be developed throughout the healthcare system – not just the LTC system. The OCC/OFPS plays a critical role in the healthcare system and is integrated into virtually all aspects of it. That alone makes it unique in its ability to take on this responsibility.

The OCC/OFPS's mandate is to serve the public good. This mandate includes developing knowledge related to deaths to improve the care provided to patients and residents. It also includes making recommendations to enhance public safety and prevent deaths in similar circumstances.

In fulfilling its mandate, the OCC/OFPS:

- supports families of deceased in LTC homes by providing answers and information after sudden and unexpected deaths;
- searches for the truth and provides evidence and data to support the administration of justice; and
- advances forensic medicine and public safety through knowledge and capacity development.¹⁶⁷

This mandate, and the way in which the OCC/OFPS fulfills it, are fully consistent with it assuming responsibility for developing a strategic plan to build awareness of the HCSK phenomenon.

Further, the OCC/OFPS has the organizational strengths and capability to successfully undertake this important initiative. Among other things, it has proven leadership and a track record for spearheading major projects involving multiple stakeholders and requiring collaboration. Given the magnitude and complexity of the healthcare system, taking a collaborative approach to the development and implementation of the strategic plan will be crucial.

¹⁶⁷ For example, the OCC's Strategic Plan for 2015–20 states that, among other things, it aims to:

 [&]quot;strengthen ... research capabilities and contributions to death investigation, forensic medicine, public safety and health, while building capacity to partner with other organizations to advance research and recommendations";

 [&]quot;cultivate relationships with key partners to develop strategies that harness [the OCC's] knowledge to create measurable outcomes and make positive impacts on public safety"; and

^{• &}quot;provide partners and organizations with easy access to knowledge, research output and recommendations that will inform public safety and health initiatives."

See Ontario Ministry of Community Safety and Correctional Services, 2015–2020: Strategic Plan for Ontario's Death Investigation System, pp 19–20, https://www.mcscs.jus.gov.on.ca/sites/default/files/content/mcscs/docs/ec168212.pdf [accessed April 15, 2019].

The essential elements of the strategic plan should include:

- The provision by the OCC/OFPS of standardized information on the HCSK phenomenon to institutions and organizations responsible for the delivery of education and training to healthcare providers and allied programs and fields, a matter discussed below. Having the OCC/OFPS provide this information will ensure consistent messaging of accurate information and avoid unnecessary duplication of effort, leading to a waste of time and resources.
- Conducting ongoing research to keep abreast of developments in the HCSK phenomenon, both nationally and internationally, and what is being done to deter and detect them.
- The dissemination of the results of that research, as appropriate.
- Regular monitoring of the delivery of the requisite education and training.

D. The Requisite Education and Training

Awareness alone of the dangers posed by HCSKs is insufficient. It must be translated into action to prevent, deter, and detect intentionally caused harm of patients by healthcare providers. For that (and other) reasons, education and training on the possibility of intentionally caused harm by healthcare providers will be most effective if it is addressed in the broader context of subjects such as professionalism, risk management, patient and resident safety, patient / resident outcomes, and medication incident investigation and analysis.

Because the healthcare system is populated by so many diverse groups, the development and delivery of education and training for the various groups should be done by the stakeholder institutions and organizations themselves. Put another way, apart from providing relevant education and training to coroners and forensic pathologists, I do not envision the OCC/OFPS delivering education and training to those in the healthcare system. That is the role for the stakeholder institutions and organizations, as set out in Figure 16.6.

Resident and patient safety is the concern of all who work in the healthcare system. It will take a commitment to regular, ongoing education and training to ensure that we remain vigilant in protecting against the threat of HCSKs. Education should begin early in the healthcare education process, when students are pursuing their undergraduate university and college education.

Family Councils residents' family **Family Councils** should provide with suitable Residents' Councils to share with information members · should provide Ontario with suitable to share with information residents OARC Geriatric and Longcoroners, forensic **Ferm Care Review** pathologists and members of the should educate management and Committee should educate Licensees of LTC staff, including OCC/OFPS and train agency staff and train homes Delivery of Education and Training on the HCSK Phenomenon train appropriate members of staff, LHINs (or successor organization) provide the appropriate members ensure services agreements with institutions responsible for the delivery of education and training; including care coordinators, and to train appropriate members of service provider organizations accountability agreements to with whom they have service through research, keeps up to date on the HCSK phenomenon; require the service providers agencies and organizations require community support of their staff with training · disseminates research results to stakeholders; and their staff, and and education quality teams monitors the delivery of education and training. LTCH Division inspectors including train staff, and the Director • should **Surgeons of Canada** should educate and train their members **Family Physicians** The Royal College and the College of of Physicians and The College of Nurses should educate and train their members of Ontario and the Ontario College of **Pharmacists** Regulators and staff occupational therapy, healthcare and allied programs (including **HCSK** phenomenon in their curricula for emergency medical pharmacy sciences, police services, and information on the medicine, nursing, personal support care, social work, physiotherapy, · should include **Colleges and** universities

provides key information on the HCSK phenomenon to the organizations and

OCC/OFPS must create a Strategic Plan that:

Figure 16.6: Building Awareness of the HCSK Phenomenon Through Education and Training

Source: Compiled by the Commission.

In her evidence during the hearings, Professor Crofts Yorker argued that educational institutions must promote awareness of the HCSK phenomenon in their curriculum for all healthcare professionals, just as is currently done with education on patient abuse generally, and on elder and child abuse more specifically. ¹⁶⁸ For healthcare professionals who are already in the workforce, the various colleges and governing bodies should deliver the appropriate training and education to their members. All staff members who are working in LTC homes – not just the healthcare staff – should receive training on the HCSK phenomenon. Housekeepers and cooks, for example, may know residents well. Residents' councils and family councils, too, play important roles in LTC homes and should be given appropriate information and opportunities to assist.

RECOMMENDATIONS

Recommendation 64: The Government of Ontario must ensure that a strategic plan is in place to build awareness of the healthcare serial killer phenomenon.

Recommendation 65: The Government of Ontario should make the Office of the Chief Coroner and the Ontario Forensic Pathology Service responsible for developing this strategic plan, working collaboratively with stakeholders in the healthcare and long-term care systems. The strategic plan should set out systematic, ongoing, and measurable steps for developing awareness of the healthcare serial killer phenomenon within the healthcare system.

Recommendation 66: The Government of Ontario should make the Office of the Chief Coroner and the Ontario Forensic Pathology Service (OCC/OFPS) responsible for implementing the strategic plan. The OCC/OFPS should develop standardized information on the healthcare serial killer phenomenon and provide it to organizations and institutions responsible for the delivery of education and training to students, professionals, and staff in the healthcare system and in allied programs and fields.

¹⁶⁸ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 8041.

Recommendation 67: The Office of the Chief Coroner and the Ontario Forensic Pathology Service (OCC/OFPS) should conduct ongoing research on national and international developments concerning the healthcare serial killer (HCSK) phenomenon, including what is being done to deter and detect HCSKs. It should disseminate the results of that research as appropriate, including to organizations and institutions that deliver education and training on the potential for intentionally caused harm by healthcare providers. The OCC/OFPS should engage in regular monitoring to ensure that the requisite education and training are being delivered.

Recommendation 68: The Government of Ontario should provide the Office of the Chief Coroner and the Ontario Forensic Pathology Service with funding for one full-time employee to develop and implement the strategic plan (see Recommendations 65–67). Funding should be sufficient to hire an individual with a strong knowledge and understanding of the healthcare system, including its policy dimensions; demonstrated leadership and organizational skills; an understanding of the importance of evidence-based work; and the ability to consult with, and bring together, diverse stakeholders in the development of the strategic plan.

Recommendation 69: The Government of Ontario should provide the Office of the Chief Coroner and the Ontario Forensic Pathology Service with funding so it can engage a specialist in adult education to work with organizations and institutions responsible for educating and training their respective populations on the healthcare serial killer phenomenon (see Recommendation 70).

Rationale for Recommendations 64-69

 The healthcare serial killer (HCSK) phenomenon is widespread and long standing, with documented cases in five continents. It is a serious public health concern. In terms of the number of victims, HCSKs are among the most prolific serial killers.

- HCSKs target vulnerable individuals with a decreased capacity to recognize, resist, and report abuse and to identify perpetrators.
- Although the number of known HCSKs is small, the magnitude of the harm they inflict is large. In addition to the sheer number of their victims, these killings devastate the victims' families and other loved ones, as well as the communities within which the offences take place. They also erode public trust in the healthcare system and in healthcare workers. In addition, such killings lead to significant financial costs, including expensive criminal investigations, prosecutions, public inquiries, and other review processes.
- There is a general lack of awareness of the HCSK phenomenon. Evidence
 in the public hearings shows that no element in the long-term care (LTC)
 system was alert to the possibility that the Offences were the result of
 intentional wrongdoing by a healthcare provider.
- Awareness that a healthcare worker might intentionally harm those in his
 or her care is the critical first step in protecting against HCSKs.
- The Office of the Chief Coroner and the Ontario Forensic Pathology Service (OCC/OFPS) is uniquely positioned to fulfill the strategic planning role because of its position in the healthcare system, its mandate, and the functions it performs.
- Giving the OCC/OFPS this responsibility aligns with, and reinforces, the
 recommendations elsewhere in this Report on reforming the death
 investigation process for residents in LTC homes and placing responsibility
 for those reforms on the OCC/OFPS.
- Provision of standardized information on the HCSK phenomenon ensures that consistent and accurate information is provided to all those in the healthcare system and avoids needless duplication of effort, thereby saving time and resources.

Recommendation 70: The organizations and institutions responsible for educating and training the groups that make up the healthcare system must be responsible for the delivery of education and training on the possibility that healthcare providers may intentionally harm those in their care. I recommend that the following institutions and organizations provide that education and training, as set out in Figure 16.6:

- colleges and universities;
- regulators, including the College of Nurses of Ontario and the Ontario College of Pharmacists;
- the Royal College of Physicians and Surgeons of Canada and the College of Family Physicians;
- the Long-Term Care Homes Division in the Ministry of Health and Long-Term Care;
- · Local Health Integration Networks or any successor organization;
- licensees of long-term care homes;
- the Office of the Chief Coroner and the Ontario Forensic Pathology
 Service:
- the Ontario Association of Residents' Councils;
- residents' councils;
- · Family Councils Ontario; and
- · family councils.

Recommendation 71: Long-term care homes, residents' councils, family councils, Ontario Association of Residents' Councils, and Family Councils Ontario should collaborate to ensure that the information they deliver is consistent and suitable for their particular audience.

Recommendation 72: The organizations and institutions listed in Recommendation 70 above should address the healthcare serial killer phenomenon in the broader context of such matters as risk management, patient / resident safety, patient / resident outcomes, and/or professionalism, rather than as a stand-alone matter.

Recommendation 73: The organizations and institutions listed in Recommendation 70 above should revise their relevant policies, practices, and procedures to reflect the possibility that a healthcare provider could intentionally cause harm.

Rationale for Recommendations 70–73

- Discussing how to prevent, deter, and detect intentional wrongdoing in
 the healthcare system can be integrated into courses on how healthcare
 providers view death and discuss it with their patients; professionalism
 and what that means in terms of raising concerns about colleagues;
 investigating and analyzing medication errors; risk management; and
 improving patient / resident outcomes. Discussing healthcare serial killers
 in such contexts avoids creating a climate of fear and mistrust while
 ensuring that the necessary awareness and tools are in place to prevent,
 deter, and detect intentional wrongdoing.
- All professionals and staff in the healthcare system must receive appropriate education and training because healthcare serial killers are a threat to the whole healthcare sector, not just the long-term care system.
- Awareness should begin early in the healthcare education process, when students are at the undergraduate and college level.

Deterrence Through Improved Medication Management

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I. Introduction

Like many healthcare serial killers (HCSKs), Wettlaufer committed the Offences by injecting her victims with overdoses of insulin that she had diverted from their intended use. Long-term care (LTC) homes must make changes to the medication management system so it will be more difficult for staff to divert medications and more likely that they will be caught if they do. In this chapter, I focus on those changes and how they will help to deter and detect wrongdoing while at the same time improving overall resident care. As well, in the final section, I address medication management issues in the home care setting.

I begin with a review of the existing medication management system in LTC homes. The *Long-Term Care Homes Act, 2007* (LTCHA),¹ and its regulations (Regulation)² create a detailed regulatory framework governing medication management in LTC homes. The regulatory regime is powerful and effective. However, the regime was not designed to deter and detect healthcare providers who might intentionally harm residents using an injectable medication. That possibility was not on anyone's radar until Wettlaufer confessed to the Offences. Unfortunately, those Offences have made it clear that we must look at the regulatory framework from a different perspective – one that is informed by the knowledge that a wrongdoer used medication to harm residents. As a result of this understanding, I focus on three topics that are significant in terms of my recommendations for strengthening the medication management system in LTC homes: high-alert medications, which include insulin; the disposal and destruction of medications in LTC homes; and the oversight of the medication management system in LTC homes.

In the next section, I discuss medication diversion and three strategies for limiting it in LTC homes: changes to infrastructure; technological enhancements; and having pharmacy professionals play a greater role in the home's medication management system.

In the section that follows, I explain why homes need to adopt an improved incident analysis framework when investigating medication incidents. This change is critical if LTC homes are to improve their ability to detect medication incidents resulting from intentional wrongdoing. Improved incident analysis will also deter wrongdoing because it increases the likelihood that the wrongdoer will be caught.

¹ SO 2007, c 8.

² O Reg 79/10.

The evidence presented in the public hearings shows that the number of registered staff in LTC homes must be increased. I address this topic next. The cry for additional funding for staff is not new: it has been a constant refrain in every review and study of Ontario LTC homes for the past 20 years. But, as I explain in Chapter 1, this need is greater than ever and promises only to increase as the baby boomers age, people live longer, and the prevalence of dementia increases. It is obvious that more frontline staff are needed if Ontario's LTC homes are to adequately meet resident needs – and address the threat to their safety posed by HCSKs.

In the final section of this chapter, I look at the safety of those receiving nursing services in the home care setting. More and more people are choosing to stay at home for as long as possible, and, frequently, they will need help and support within their home, including nursing care. Because Wettlaufer committed her last Offence in a private home in which she was providing publicly funded nursing care, it is important that we improve medication safety in the home care setting.

At the public hearings, I received a report and heard evidence from Julie Greenall, the director of projects and education with the Institute for Safe Medication Practices (ISMP) Canada. Much of the information in this chapter is derived from her report and evidence, as well as the medication management provisions in the LTCHA and the Regulation.

II. Medication Management in LTC Homes

Medication management is "patient-centred care to optimize safe, effective and appropriate drug therapy. Care is provided through collaboration with patients and their health care teams." Sections 114–37 of the Regulation establish detailed requirements for the medication management system in LTC homes.

³ ISMP Canada, "Definition of Terms," available at https://www.ismp-canada.org/definitions.htm (this definition was developed collaboratively in 2012 by the Canadian Pharmacists Association, the Canadian Society of Hospital Pharmacists, the Institute for Safe Medication Practices Canada, and the University of Toronto Faculty of Pharmacy).

A. Pharmacy Service Providers

Pharmacy service providers play an important role in an LTC home's medication management system. The regulatory framework that governs those providers begins with sections 119–21 of the Regulation.

Section 119 of the Regulation dictates that every LTC home licensee must retain an accredited pharmacy service provider for the home and that there is a written contract between the two setting out the pharmacy service provider's responsibilities. The contract must include a provision requiring the pharmacy service provider to provide drugs to the home on a 24-hour basis, seven days a week, or arrange for their provision by another accredited pharmacy. As well, the contract must require the pharmacy service provider to perform all other responsibilities placed on it by the Regulation.

Section 120 of the Regulation makes it mandatory that the pharmacy service provider participate in:

- developing medication assessments, medication administration records and records for medication reassessment, and maintaining medication profiles for each resident in the home;
- evaluating the therapeutic outcomes of drugs for residents;
- risk management and quality improvement activities, including review of medication incidents, adverse drug reactions, and drug utilization;
- developing audit protocols to evaluate the medication management system;
- · educational support to home staff in relation to drugs; and
- drug destruction and disposal.

The pharmacists who participate in these activities in LTC homes are employed by the pharmacy service providers, not by the homes.⁴

Section 121 requires the licensee to develop a system for notifying the pharmacy service provider within 24 hours of the admission, medical absence, psychiatric absence, discharge, and death of a resident.

⁴ Expert Report of Julie Greenall, June 1, 2018, p 28.

B. High-Alert Medications

In theory, any medication used improperly can cause harm.⁵ High-alert medications are those that are more likely to cause harm if used incorrectly.⁶ The list of high-alert medications in LTC homes includes insulin and oral hypoglycemic agents, opioids (narcotics), and anticoagulants.⁷ To reduce the possibility that high-alert medications are incorrectly administered, LTC homes take precautions by limiting access to them and, in some circumstances, requiring independent double-checks at the time they are administered.⁸

Some high-alert medications – such as morphine and hydromorphone – are controlled substances. Special provisions in the Regulation govern controlled substances to ensure that they are carefully monitored, tracked, and disposed of and that access to them is rigorously protected. High-alert medications that are not controlled substances – including insulin – are more readily available to registered staff in LTC homes.

C. An Interdisciplinary Medication Management System

Section 114 of the Regulation requires the licensee to "develop an interdisciplinary medication management system that provides safe medication management and optimizes effective drug therapy outcomes for residents." It also requires that the licensee develop written policies and protocols for the medication management system to ensure the accurate acquisition, dispensing, receipt, storage, administration, and destruction and disposal of all medications used in the home.

Physicians, pharmacists, and nurses all play distinct roles in the medication management system.¹⁰ Figure 17.1 sets out the professional responsibilities of each group.

⁵ Testimony of Julie Greenall, Transcript, Sept. 13, 2018, p 8219.

⁶ Expert Report of Julie Greenall, p 10.

⁷ Expert Report of Julie Greenall, p 10.

⁸ Expert Report of Julie Greenall, p 11.

⁹ See, for example, ss 129(1)(b), 130.3, 136(2)2, 136(3)(a), 136(4).

¹⁰ Testimony of Julie Greenall, Transcript, p 8193.

Physicians: Prescribe medications for long-term-care home residents and review the resident's care plan – including medications – on the basis of the physician's knowledge and skill and the clinical situation of an individual resident. Physicians are accountable to their regulatory body, the College of Physicians and Surgeons of Ontario.

Pharmacists: Dispense medications for long-term-care home residents on the basis of physicians' or other recognized health professionals' prescriptions and the pharmacist's knowledge of the resident and the prescribed drug, in accordance with provincial and federal legislation as well as in accordance with the standards of practice of their regulatory body, the Ontario College of Pharmacists.

Nurses: Apply their knowledge of the resident and the medication when assessing residents, administering medications, evaluating residents' reaction to medications, and planning and documenting the medication administration process, as per the Medication Practice Standard of the College of Nurses of Ontario. Nurses act as the liaison between the physician and pharmacist in relation to medication management for each resident, and collaborate with the health-care team in the long-term-care home to maintain safe medication-management processes.

Figure 17.1: Medication Management – Professional Responsibilities

Source: Ministry of Health and Long-Term Care.

Note: Reproduced in the 2009 Report of the Office of the Auditor General of Ontario, http://www.auditor.on.ca/en/content/annualreports/arreports/en09/2009AR_en_web_entire.pdf

D. The Medication Use Process

There are five principal steps in the medication use process:

- prescribing (sometimes referred to as ordering);
- transcribing (sometimes referred to as transcribing and verification);
- dispensing;
- · administration; and
- monitoring.¹¹

Expert Report of Julie Greenall, p 3; Stacy Ackroyd-Stolarz, Nicole Hartnell, and Neil J. MacKinnon, "Approaches to Improving the Safety of the Medication Use System" (2005) 8 (Special Number) Healthcare Quarterly 59–64 at 60.

1. Prescription

The prescription stage involves the development of a therapeutic plan for a resident. This step requires an assessment and diagnosis of the resident, followed by preparation of a treatment plan. It must account for the resident's medical history, existing conditions, current clinical status, and goals of care. The treatment plan addresses both the ongoing treatment of chronic conditions (e.g., hypertension, diabetes, depression) and the episodic treatment of acute conditions (e.g., injury or decompensation of a chronic condition).

a) Medication Reconciliation on Admission

The first step in the prescription stage is a medication reconciliation, which is done when a person is admitted to an LTC home. A nurse usually performs the medication reconciliation.¹⁵

The cornerstone of the medication reconciliation process is the best possible medication history, and the steps involved in its preparation are set out in Figure 17.2.¹⁶ To begin, the clinician preparing this history reviews the resident's medications – including name, dosage, route, and frequency – in order to capture the medications that the resident was taking before admission.¹⁷ The clinician also conducts interviews with the resident and/or the resident's family, along with a review with at least one other reliable source of information.¹⁸ The best possible medication history is then used to create admission or readmission prescriptions.¹⁹ ISMP Canada notes that this history "relies heavily on clinicians' interview skills, residents' ability to participate, and access to the residents' medication list or community pharmacy dispensing records."²⁰ A poor medication history is responsible for most unintentional discrepancies that may lead to medication errors.²¹

Ackroyd-Stolarz, Hartnell, and MacKinnon, "Approaches to Improving the Safety of the Medication Use System," 60.

¹³ Expert Report of Julie Greenall, p 6.

¹⁴ Expert Report of Julie Greenall, p 6.

Anne Snowdon and Ryan DeForge, "Examining the Impact of Pharmacist-Led Medication Reconciliation in Long-Term Care," Final Report, World Health Innovation Network and University of Windsor, January 15, 2019, 3.

ISMP Canada and CPSI, "Medication Reconciliation in Long-Term Care: Getting Started Kit" (version 3) March 2017 at p 19, available at: http://www.patientsafetyinstitute.ca/en/toolsResources/Documents/Interventions/Medication%20Reconciliation/Long%20Term%20Care/Med%20Rec%20(Long%20Term%20Care%20)%20Getting%20Started%20Kit.pdf.

¹⁷ ISMP Canada and CPSI, "Medication Reconciliation in Long-Term Care," 18, 24.

¹⁸ ISMP Canada and CPSI, "Medication Reconciliation in Long-Term Care," 19.

¹⁹ ISMP Canada and CPSI, "Medication Reconciliation in Long-Term Care," 18.

²⁰ ISMP Canada and CPSI, "Medication Reconciliation in Long-Term Care," 19.

²¹ ISMP Canada and CPSI, "Medication Reconciliation in Long-Term Care," 19.

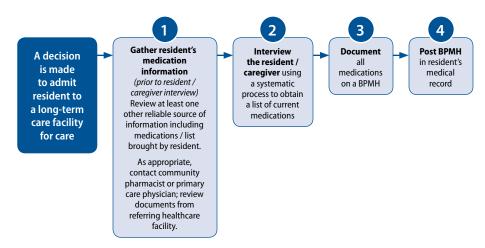


Figure 17.2: Flow Map for Creating a Best Possible Medication History

Source: ISMP Canada and CPSI, "Medication Reconciliation in Long-Term Care: Getting Started Kit" (version 3), March 2017.

Note: BPMH stands for "best possible medication history."

b) Prescription of Medications

After the medication reconciliation is completed, either a physician or a nurse practitioner will assess, diagnose, and prescribe medications for the resident.²² Prescribers handwrite prescriptions, electronically enter them into the resident's health record, or provide them to a nurse over the telephone and co-sign them on their next visit to the LTC home.²³

Nurses are not permitted to administer medications to a resident in an LTC home without an order from a prescriber, even if the medication does not require a prescription (e.g., a regular-strength Tylenol).²⁴

To deal with minor acute ailments (e.g., mild pain, nausea, mild constipation) and emergencies (e.g., anaphylaxis, hypoglycemia), on admission of the resident, prescribers "pre-prescribe" medications through medical directives or order sets.²⁵ Medical directives prescribe medications globally for all residents of the home, to be administered when a resident meets the criteria set out

²² Expert Report of Julie Greenall, p 6.

Expert Report of Julie Greenall, p 7

²⁴ Expert Report of Julie Greenall, p 6; Testimony of Julie Greenall, Transcript, pp 8195–96.

²⁵ Expert Report of Julie Greenall, pp 6–7; Testimony of Julie Greenall, Transcript, p 8199.

in the directives.²⁶ Order sets are similar to medical directives in that they pre-prescribe medications, but they are tailored to specific residents.²⁷ Medical directives and order sets are reviewed at least annually.²⁸

2. Transcription

At the transcription stage, the prescription is copied or converted into whatever form is used by members of the healthcare staff. For example, the prescription is transmitted to the pharmacy by fax or electronically, possibly using a digipen.²⁹ There, a pharmacist, pharmacy technician, or pharmacy assistant transcribes it in two places. The first is the pharmacy's computerized medication profile; this step enables the medications to be dispensed. The second is the medication administration record (MAR), which contains the list of a resident's medications and the schedule for their administration.³⁰

The MAR system is either electronic (eMAR) or a computer-generated document provided by the pharmacy service provider (cMAR).³¹ In an LTC home, the pharmacy's transcription into the MAR is usually checked by two nurses against the original handwritten prescription in the resident's health record. The nurses also document their checks on the prescription.³² As well, nurses transcribe prescriptions onto pharmacy order sheets to order medications.³³

3. Dispensing

At the dispensing stage, the pharmacy service provider dispenses, packages, and delivers medications to LTC homes.³⁴ Nursing staff in the LTC home receive the medications, stock the medication carts, store medications in medication rooms, and prepare medications. These duties are a significant burden for nurses, who generally have no formal training in these tasks.³⁵

²⁶ Expert Report of Julie Greenall, pp 6–7.

²⁷ Expert Report of Julie Greenall, p 7.

²⁸ Expert Report of Julie Greenall, pp 6–7.

²⁹ A digipen is a special electronic pen used by prescribers to write their prescriptions. When the pen is returned to its docking station, it transmits an exact replica of the order to the pharmacy: Expert Report of Julie Greenall, p 7.

³⁰ Expert Report of Julie Greenall, pp 3, 6.

³¹ Expert Report of Julie Greenall, pp 15–16.

³² Expert Report of Julie Greenall, p.7.

³³ Expert Report of Julie Greenall, p 3.

³⁴ Expert Report of Julie Greenall, p 4.

³⁵ Expert Report of Julie Greenall, p 27.

a) The Format and Packaging of Medications in LTC homes

(i) Monitored Dosage System

Section 125 of the Regulation requires LTC homes to use a monitored dosage system. This system enables a medication to be identified from the time it is dispensed through to its administration.³⁶ Its purpose is to "promote the ease and accuracy of the administration of drugs to residents and support monitoring and drug verification activities."³⁷ A monitored dosage system maintains medications (i.e., tablets and capsules) in their original labelled container or package provided by the pharmacy service provider or the Government of Ontario until they are administered to a resident or destroyed.³⁸

The Ontario Pharmacists Association (OPA) produced best-practice guidelines to help homes maintain compliance with the regulations related to the medication management system. These guidelines refer to pouch or strip packaging, blister-card packaging, and DispillTM as examples of permissible forms of the monitored dosage system.³⁹ Strip packages, containing from one to five medications per package, are commonly used in LTC homes.⁴⁰ All the medications to be administered at a specific time for a specific resident are placed in a single package.⁴¹ Each medication in the package is identified with a description on the package, the name of the resident, and the time the medication is to be administered.⁴² The strips are generated automatically by pharmacy service providers and are delivered every week to LTC homes.⁴³ Thus, for each resident there is a weekly supply, comprised of individual packages of medications.⁴⁴

³⁶ Testimony of Julie Greenall, Transcript, p 8205.

³⁷ O Reg 79/10, s 125(2).

³⁸ Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care: Inspections of the Medication Management System," available at https://www.opatoday.com/Media/Default/Tools%20and%20forms%20-%20LTC/2016-06-20%20LTC-TableUpdate_Complete-1.pdf, 14; O Reg 79/10, s 126.

³⁹ Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care," 14.

⁴⁰ Expert Report of Julie Greenall, p 8.

⁴¹ Canadian Society of Hospital Pharmacists, "Glossary," https://www.cshp.ca/glossary (see "Controlled-Dosage System").

⁴² Testimony of Julie Greenall, Transcript, p 8205.

⁴³ Expert Report of Julie Greenall, pp 8–9.

⁴⁴ Testimony of Julie Greenall, Transcript, pp 8206–7.

Studies have shown that dispensing medication in either a single unit or a unit dose in a ready-to-administer format (such as strip packages) reduces medication errors and saves time in drug administration.⁴⁵

(ii) As-Needed and Multi-dose Medications

Two groups of drugs cannot be provided through a monitored dosage system: as-needed (PRN) medications⁴⁶ and multi-dose medications. As-needed medications are non-regularly scheduled ones, such as sleeping pills (which a resident might need only occasionally) and pain medication.⁴⁷ Multi-dose medications are those that come in containers with multiple doses, such as an inhaler, a bottle of eye drops, a cream, and an insulin pen. They are not dispensed in strips. Multi-dose medications are ordered from the pharmacy service provider on an as-needed basis.⁴⁸ For example, inhalers are usually dispensed one at a time, insulin pens in boxes of three, and insulin cartridges in boxes of five.⁴⁹ One-month supplies of these items are typically delivered.⁵⁰

(iii) Government Stock and Emergency Drug Box

As a rule, all medications in LTC homes, even those dispensed as "multi-dose" medications, are prescribed and labelled for individual residents. For example, each resident's insulin pen has a label that sets out the resident's name and the kind of insulin in the pen.⁵¹

There are two exceptions to this rule. First, relatively innocuous medications such as acetaminophen, laxatives, and antacids are supplied in bulk by the Ontario Government Pharmacy.⁵² These government stock medications are generally available to be administered in response to medical directives and order sets. Second, each LTC home must have an emergency drug box, which includes rescue agents (e.g., diphenhydramine, epinephrine, glucagon, naloxone, vitamin K), medications for symptom management

⁴⁵ Ackroyd-Stolarz, Hartnell, and MacKinnon, "Approaches to Improving the Safety of the Medication Use System," 61; D.W. Simborg and H.J. Derewicz, "A Highly Automated Hospital Medication System: Five Years' Experience and Evaluation" (1975) 83 Annals of Internal Medicine 342–46; M. O'Brodovich and P. Rappaport, "A Study Pre and Post Unit Dose Conversion in a Pediatric Hospital" (1991) 44 Canadian Journal of Hospital Pharmacy 5–15, 50.

⁴⁶ PRN is an acronym for the Latin term *pro re nata*, meaning "as needed."

⁴⁷ Testimony of Julie Greenall, Transcript, pp 8207–8.

⁴⁸ Expert Report of Julie Greenall, p 9; Testimony of Julie Greenall, Transcript, p 8208.

⁴⁹ Expert Report of Julie Greenall, p 9.

⁵⁰ Testimony of Julie Greenall, Transcript, p 8264.

⁵¹ Expert Report of Julie Greenall, p 12; Testimony of Julie Greenall, Transcript, p 8231.

⁵² Expert Report of Julie Greenall, p 9.

(e.g., furosemide, prednisone, injectable dimenhydrinate), and medications required outside the daily delivery schedule (e.g., oral antibiotics).⁵³ Narcotics that are part of this supply must be stored with other narcotics, rather than in the box. Emergency drug box medications that require refrigeration are usually stored in the refrigerator in the medication room where the box is stored.⁵⁴

Nurses are required to document the use of medications from the emergency drug box. They must also notify the pharmacy when medications from the box are used so that the medications can be restocked.⁵⁵ These medications can be administered following a prescriber's specific order (e.g., an antibiotic before it is available through a new prescription for the resident) or, when urgently required, pursuant to medical directives and order sets.⁵⁶ The emergency drug box is generally audited monthly by nursing or pharmacy staff.⁵⁷

b) Medication Delivery and Storage

Medications are delivered to LTC homes by the pharmacy service provider.⁵⁸
An LTC home cannot keep more than a three-month supply of medications.⁵⁹

Medications are stored in a secure and locked area or medication cart that is used exclusively for drugs and related items, protects the medications from environmental elements, and complies with manufacturer instructions for storage.⁶⁰ Medications that require refrigeration are stored in a refrigerator in the medication room. Containers for medications that are stable at room temperature (e.g., insulin is stable for 28 days at room temperature) are stored in the medication carts.⁶¹

Areas where medications are stored must be kept locked at all times, and access to these areas is restricted to those in the LTC home who may dispense, prescribe, or administer medications in the home.⁶² Many LTC homes use swipe cards to access medication rooms, and some homes have electronic

⁵³ Expert Report of Julie Greenall, p 9.

⁵⁴ Expert Report of Julie Greenall, p 10.

⁵⁵ O Reg 79/10, s 123; Expert Report of Julie Greenall, p 9; Testimony of Julie Greenall, Transcript, pp 8213–16.

⁵⁶ Expert Report of Julie Greenall, pp 9–10.

⁵⁷ Expert Report of Julie Greenall, p 10.

⁵⁸ Expert Report of Julie Greenall, p 21.

⁵⁹ O Reg 79/10, s 124.

⁶⁰ O Reg 79/10, s 129.

⁶¹ Expert Report of Julie Greenall, p 20.

⁶² O Reg 79/10, s 130.

access to medication carts. These systems allow homes to track individuals who go into the secured areas.⁶³

Controlled substances are stored in a separate double-locked stationary cupboard within the locked area or in a separate locked area within the locked medication cart.⁶⁴ They must be counted at each shift-transfer by the outgoing and incoming nurses, and any discrepancies in expected numbers must be reported immediately and resolved before the outgoing nurse leaves the premises.⁶⁵ The licensee is required to conduct a monthly audit of the daily count sheets of controlled substances to determine if there are any discrepancies and must take immediate action if a discrepancy is discovered.⁶⁶

In the medication carts, there is an individual bin (or compartment) containing the medications for each resident. The carts are locked when not in use. Non-oral medications are placed in a separate designated area in the medication carts. As discussed below, the medication carts are then wheeled through the LTC home as the nurse administers medications.⁶⁷

Nurses check medications against the original prescription and the cMAR or eMAR before storing them in residents' designated bins in the medication cart. Completing these checks and storing the weekly order of medications can take one to two hours of nursing time per LTC home unit.⁶⁸ If an LTC home uses an eMAR, medications are scanned when received to ensure that they match what was ordered.⁶⁹

LTC homes are required to establish, maintain, and keep, for two years a record of all the drugs delivered to the homes, including their prescription number, the name of the resident for whom it is prescribed, and the signature of the person acknowledging receipt of the drug in the home. The controlled substances administered to residents must also be periodically reconciled with the records of drugs received from pharmacies.

⁶³ Expert Report of Julie Greenall, p 20.

⁶⁴ O Reg 79/10, s 129.

⁶⁵ Expert Report of Julie Greenall, pp 20–21.

⁶⁶ O Reg 79/10, s 130.

⁶⁷ Expert Report of Julie Greenall, p 20; Testimony of Julie Greenall, Transcript, pp 8243–45.

⁶⁸ Expert Report of Julie Greenall, p 21.

⁶⁹ Testimony of Karen Routledge, Transcript, June 12, 2018, pp 1281–82.

⁷⁰ O Reg 79/10, s 133; Affidavit of Helen Crombez, para 45.

⁷¹ Testimony of Julie Greenall, Transcript, pp 8248–49.

c) Obtaining Urgently Required Medications

At times, a resident may urgently require a new medication. For example, a prescriber may make an order for antibiotics for a resident during a weekend.⁷² When this happens, the LTC home can:

- send the prescription to the pharmacy service provider or to the designated local pharmacy;⁷³
- borrow a dose of medication from that resident's future doses (with the borrowed dose to be replaced by the pharmacy); this course of action is not the preferred strategy when the resident's future doses are packaged in strips along with other medications, because then "you've messed up all your medication administration" for the next few days;⁷⁴
- borrow a dose of medicine from another resident, with the borrowed dose to be replaced by the pharmacy; this course of action is also not recommended, because it can lead to the risk of a medication error;⁷⁵ and
- use medications from the emergency drug box.⁷⁶

4. Administration

At the administration stage, nurses give residents their prescribed medications through oral ingestion, injection, topical application, or other means.⁷⁷ The administration of medications to residents is "one of the most high-risk activities" in healthcare facilities.⁷⁸ It is also time-consuming. Administering medications to 30 residents can take two-and-a-half to three hours, and the process must be repeated up to four times per day.⁷⁹ When they administer medications, nurses follow the eight "rights": right person, right drug, right dose, right route, right time, right documentation, right reason, and right response.⁸⁰

⁷² Testimony of Julie Greenall, Transcript, pp 8209–10.

⁷³ Expert Report of Julie Greenall, p 9.

⁷⁴ Expert Report of Julie Greenall, p 9; Testimony of Julie Greenall, Transcript, pp 8210–11.

⁷⁵ Expert Report of Julie Greenall, p 9; Testimony of Julie Greenall, Transcript, pp 8211–13.

⁷⁶ Expert Report of Julie Greenall, p 9; Testimony of Julie Greenall, Transcript, pp 8211–13.

⁷⁷ Expert Report of Julie Greenall, p 4.

⁷⁸ Ackroyd-Stolarz, Hartnell, and MacKinnon, "Approaches to Improving the Safety of the Medication Use System," 62.

⁷⁹ Expert Report of Julie Greenall, p 15; Testimony of Julie Greenall, Transcript, p 8239.

⁸⁰ Expert Report of Julie Greenall, p 4. Previously, there were only five "rights"; the "right response" is also sometimes dropped from the list: Affidavit of Tanva Adams, Exhibit A. para 32.

In LTC homes, MARs guide medication administration.⁸¹ MARs are set up on the medication carts, which are pushed through the home during medication passes. The carts contain colour photographs of residents to verify resident identities, and MARs are used to determine what medications to administer to residents.⁸²

To administer medications, the prepackaged medication strip corresponding to a particular resident and a particular administration time is taken from the cart and administered to the resident. If a medication is not administered (e.g., because the resident refused it), this fact must be recorded.⁸³

Some LTC homes have implemented the use of independent double-checks to reduce the likelihood that high-alert medications (including insulin) are incorrectly used.⁸⁴

5. Monitoring

At the monitoring stage, the healthcare staff observe the effects of the medication on the resident. They look for both short-term effects (e.g., an immediate allergic reaction) and long-term effects (e.g., the effect on cholesterol levels over a period of time). 85 All healthcare disciplines have a role to play in the monitoring stage:

Prescribers have overall responsibilities for therapeutic outcomes. Nurses are responsible for immediate monitoring of therapeutic outcomes and potential adverse reactions to medications. Pharmacists provide clinical support (e.g., medication review and consultation) to support achievement of pharmacotherapy goals.⁸⁶

LTC homes are required to ensure that there is monitoring and documentation of residents' responses to drugs and the effectiveness of the drugs.⁸⁷ They must ensure that "appropriate actions are taken in response to any medication incident involving a resident and any adverse drug reaction to a drug or

⁸¹ Expert Report of Julie Greenall, pp 15–16.

⁸² Expert Report of Julie Greenall, pp 15–16.

⁸³ Expert Report of Julie Greenall, p 15.

⁸⁴ Expert Report of Julie Greenall, p 11.

⁸⁵ Expert Report of Julie Greenall, p 4.

⁸⁶ Expert Report of Julie Greenall, p 16.

⁸⁷ O Reg 79/10, s 134(a).

combination of drugs."88 Section 1 of the Regulation defines "adverse drug reaction" and "medication incident"89 as follows:

"adverse drug reaction" means a harmful and unintended response by a resident to a drug or combination of drugs which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function;

...

"medication incident" means a preventable event associated with the prescribing, ordering, dispensing, storing, labelling, administering or distributing of a drug, or the transcribing of a prescription, and includes,

- (a) an act of omission or commission, whether or not it results in harm, injury or death to a resident, or
- (b) a near miss event where an incident does not reach a resident but had it done so, harm, injury or death could have resulted.

LTC homes conduct a comprehensive medication assessment within four to six weeks of admission and reassess the resident's drug regime every quarter. A more in-depth annual review for each resident replaces one of the quarterly reviews. The assessments and reassessments seek to decrease adverse events, ensure that the resident's medication therapy is appropriate, monitor for response and effectiveness of the medications, and improve resident outcomes. 91

Pharmacy service providers, nurses, and prescribers each play a role in assessments and reassessments. Pharmacy service providers develop the forms based on the existing medication profiles; nurses review these forms; and prescribers decide whether to continue or discontinue the medications. The rationale for the constant reassessment of medications is "to make sure that the indications are still relevant, that they're not experiencing side effects, that there aren't other alternatives that might be better tolerated, those kinds of things."

⁸⁸ O Reg 79/10, s 134(b).

⁸⁹ The terms medication "incidents" and "errors" are used interchangeably: see Expert Report of Julie Greenall, fn 43.

Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care" 11; O Reg 79/10, ss 120.1, 134(c).

⁹¹ Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care," 20.

⁹² Expert Report of Julie Greenall, p 8.

⁹³ Testimony of Julie Greenall, Transcript, pp 8197–98.

Pharmacists often take the lead in medication assessments and reassessments. One consultant pharmacist estimated that he spent 60–70% of his time doing assessments and reassessments.⁹⁴ The OPA best-practice guidelines suggest that pharmacists consider input from the healthcare team regarding "resident specific information such as falls, sedation, confusion and pain"⁹⁵ and that physicians complete and sign the assessments in a timely manner.⁹⁶

In addition to conducting assessments and reassessments, pharmacists review health records, check laboratory results, look for drug interactions, check medications against lists of non-recommended medications, educate, perform audits, and participate in the homes' quarterly evaluation meetings.⁹⁷

E. Disposal and Destruction of Medications

Section 136 of the Regulation requires the licensee to develop a written policy that provides for the ongoing identification, destruction, and disposal of, among other things, expired and non-administered medications. A drug is considered to be destroyed when it is altered or denatured to such an extent that its consumption is rendered impossible or improbable."98

In LTC homes, non-controlled medications to be destroyed are typically placed in large open plastic containers located in each medication room.⁹⁹ Medications are destroyed by denaturing them with substances such as soapy water, liquid antacid, liquid laxative, or cough syrup. This procedure is usually carried out each month.¹⁰⁰

Two staff, including one member of the registered nursing staff, must complete the destruction of non-controlled medications. After destruction, the containers are sealed and set aside for removal by an approved waste-disposal company. 102

⁹⁴ Affidavit of Jonathan Lu, Exhibit A, para 42.

⁹⁵ Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care," 11.

⁹⁶ Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care," 11.

⁹⁷ Testimony of Julie Greenall, Transcript, pp 8239–40.

⁹⁸ O Reg 79/10, s 136.

⁹⁹ Expert Report of Julie Greenall, pp 21–22; Affidavit of Helen Crombez, para 50.

¹⁰⁰ Affidavit of Helen Crombez, para 52; Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care," 25.

¹⁰¹ O Reg 79/10, s 136(3).

¹⁰² Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care," 25.

The destruction of controlled drugs must be performed by a physician or pharmacist and a member of the registered nursing staff. They must document the destruction and the reason for destruction in the drug record book. 104

F. Oversight of the Medication Management System

The Regulation sets out a number of oversight mechanisms designed to evaluate the safety and effectiveness of the medication management system, manage risk, and improve therapeutic outcomes for residents in LTC homes.

1. Audits

Licensees and pharmacy service providers are required to develop audit protocols for the service provider to evaluate the medication management system.¹⁰⁵ A number of pharmacists who provide service to LTC homes described performing the following types of audits:

- medication system: to review practices with respect to medication handling, storage, administration, and use of technologies;¹⁰⁶
- resident charts: a resident's chart is randomly picked to ensure that orders are processed completely and accurately, and that controlled drugs are received and accounted for;¹⁰⁷
- medication reconciliations: to review whether proper documentation was filled out on admission;¹⁰⁸
- controlled substances: a controlled substance order is randomly reviewed to check whether the drugs are accounted for and documented on the MAR;¹⁰⁹
- insulin: to review practices on labelling, storage, and documentation of administration of insulin;¹¹⁰ and
- **emergency drug boxes:** to ensure that all items in the box are accounted for, documented, and have not expired.¹¹¹

¹⁰³ O Reg 79/10, ss 120, 136(3).

¹⁰⁴ O Reg 79/10, s 136(4).

¹⁰⁵ O Reg 79/10, s 120.

¹⁰⁶ Affidavit of Tanya Adams, Exhibit A, para 17; Affidavit of Jonathan Lu, Exhibit A, para 25.

¹⁰⁷ Affidavit of Jonathan Lu, Exhibit A, para 26.

¹⁰⁸ Affidavit of Jonathan Lu, Exhibit A, para 27.

¹⁰⁹ Affidavit of Jonathan Lu, Exhibit A, para 28; Affidavit of Tanya Adams, Exhibit A, para 17.

¹¹⁰ Affidavit of Joanne Polkiewicz, para 93.

¹¹¹ Affidavit of Jonathan Lu, Exhibit A, para 29.

The pharmacists who gave evidence at the public hearings testified that audits are conducted in homes every month, with a full set of audits completed every three or six months. Depending on the results of the audits, pharmacy service providers may recommend action plans for improvement. They may also conduct education sessions for LTC home staff, particularly where an audit reveals problems.

2. Medication Incident Analysis

Licensees must ensure that every medication incident or adverse drug reaction is documented, together with a record of the actions taken in response. The home must also ensure that the incident or adverse reaction is reported to the resident, the resident's substitute decision-maker (if any), the director of nursing and personal care (DON), the medical director, the prescriber of the drug, the resident's attending physician or nurse practitioner (a registered nurse in the Extended Class), and the pharmacy service provider. The provider of the drug that the pharmacy service provider.

One nurse testified that the onus is on nurses to self-report medication incidents because, generally, a nurse "is alone with 32 residents." A DON confirmed that it was "absolutely the expectation of the home that medication errors must be self-reported." However, errors may also be identified by the staff working the next shift. Another DON testified that "[t] here was a push by pharmacy, and part of best practices, that nurses should be spoken to but not disciplined over medication errors so they feel comfortable reporting themselves and each other if they make an error ... It's only if there is a recurring pattern that we will discipline because we want staff to report the medication errors. We would also re-educate the staff involved so that the error didn't occur again."

¹¹² Affidavit of Tanya Adams, Exhibit A, para 18; Affidavit of Jonathan Lu, Exhibit A, para 30; Affidavit of Joanne Polkiewicz, para 90.

¹¹³ Affidavit of Joanne Polkiewicz, para 94.

¹¹⁴ Affidavit of Tanya Adams, Exhibit A, para 23; Affidavit of Helen Crombez, para 37.

¹¹⁵ O Reg 79/10, s 135.

¹¹⁶ O Reg 79/10, s 135(1).

¹¹⁷ Affidavit of Karen Routledge, para 25.

¹¹⁸ Affidavit of Melanie Smith, para 27.

¹¹⁹ Affidavit of Karen Routledge, para 25.

¹²⁰ Affidavit of Helen Crombez, para 177.

Licensees must ensure that all medication incidents and adverse drug reactions are reviewed and analyzed.¹²¹ The OPA best-practice guidelines recommend a "medication incident policy ... to ensure there is a *consistent* and *immediate* process for identifying, reporting, reviewing and analyzing all medication incidents involving a resident."¹²² The reason for notifying the pharmacist and the DON is to enable them to do an "immediate investigation."¹²³ Section 120 of the Regulation provides for the involvement of the pharmacy service provider in the review of medication incidents, adverse drug reactions, and drug utilization.¹²⁴

One pharmacist testified that she reviews medication errors of which she is made aware from a "clinical perspective," including the identification of system problems or professional practice problems. In her testimony, she said that her role was "to review the medication incidents to determine if preventative steps could be taken." Another pharmacist observed that because of the workload in LTC homes, it is challenging for the homes to report all errors in a timely fashion to the pharmacy service provider: "For example, if a nurse is administering medication and sees an extra dose in a blister card, he or she may not have time to stop and complete a medication incident form because the medication pass takes priority and residents have to get their medication at the right time." Another pharmacist confirmed that she does not think her pharmacy receives reports of all incidents.

3. Quarterly Evaluations

Section 115 of the Regulation requires every licensee of an LTC home to have an interdisciplinary team that includes the medical director, administrator, DON, and pharmacy service provider. This group is supposed to meet every quarter to "evaluate the effectiveness of the medication management system in the home and to recommend any changes necessary to improve the system." Each brings knowledge of "a different piece of the process," and bringing them together provides a view of the "whole system." 129

¹²¹ O Reg 79/10, s 135(2).

¹²² Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care," 21 [emphasis in original].

¹²³ Testimony of Julie Greenall, Transcript, p 8291.

¹²⁴ O Reg 79/10, s 120.

¹²⁵ Affidavit of Joanne Polkiewicz, paras 77, 82.

¹²⁶ Affidavit of Jonathan Lu, para 51.

¹²⁷ Affidavit of Tanya Adams, para 86.

¹²⁸ O Reg 79/10, s 115.

¹²⁹ Testimony of Julie Greenall, Transcript, p 8362.

The quarterly evaluations involve:

- A review of the drug utilization trends and patterns in the home.

 130 According to the OPA best-practice guidelines, the pharmacist should present statistical reports on medication utilization. The interdisciplinary team should use these statistics for trending, benchmarking, and clinical decision-making to optimize therapeutic outcome for residents. This team should also develop and monitor quality or performance indicators containing historical data for example, on the use of antipsychotic, antibiotic, benzodiazepine, and cytotoxic drugs.

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- A review of all medication incidents and adverse drug reactions in the home.¹³² The OPA best-practice guidelines provide that while medication incidents and adverse drug reactions must be addressed when they occur, the quarterly evaluation provides further oversight. The interdisciplinary team should review all medication incident and adverse drug reports to ensure that steps have been taken to reduce the likelihood of a recurrence.¹³³
- A review of all instances in which residents are restrained by the administration of a drug because immediate action is necessary to prevent serious bodily harm to a resident or others.¹³⁴
- The identification of all changes to improve the system in accordance with evidence-based practices.¹³⁵ The OPA best-practice guidelines suggest that this step should include:
 - the review of written policies, procedures, and audits for the medication management system;
 - the development of medical directives;
 - the review of the emergency drug box;
 - the review of high-alert medications;
 - the identification of educational and training needs for staff; and
 - the introduction of technologies. 136

¹³⁰ O Reg 79/10, s 115(3)(a).

¹³¹ Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care," 6.

¹³² O Reg 79/10, s 115(3)(b).

¹³³ Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care," 6; Testimony of Julie Greenall, Transcript, p 8291.

¹³⁴ O Reg 79/10, s 115(3)(b).

¹³⁵ O Reg 79/10, s 115(3)(c).

¹³⁶ Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care," 6–7.

The home must keep a written record of the results of the quarterly evaluation and any changes that were implemented.¹³⁷ The OPA best-practice guidelines recommend that these meetings also be documented through minutes.¹³⁸

4. Annual Evaluations

In addition to the quarterly evaluations, the home's interdisciplinary team must meet once a year, along with a registered dietitian who is a member of the home's staff.¹³⁹ The OPA best-practice guidelines recommend that the team review the previous year's quarterly evaluations and conduct an assessment to evaluate the effectiveness of the medication management system in the home, using an assessment instrument specifically designed for this purpose.¹⁴⁰

ISMP Canada's "Medication Safety Self-Assessment for Long-Term Care" is an example of an instrument that can be used to conduct the required annual assessment. This assessment is a self-critical online survey, intended to complement the LTC home's ongoing medication safety-related activities. It is designed to heighten awareness of the characteristics of a safe medication system, enable LTC homes to review the safety and risks of their medication management systems, and act as a quality improvement program. The program's goal is to better educate homes on best practices rather than to "name and shame" less compliant homes.

A review of the ISMP Self-Assessments completed by LTC homes over the years shows that there are many areas of strength in LTC homes. Widely implemented practices and strategies include:

- dispensing medications to care units in labelled, ready-to-use single doses or in resident-specific unit-of-use containers;
- completing a best possible medication history and medication reconciliation at admission, using a standardized process;

¹³⁷ O Reg 79/10, s 115(5).

¹³⁸ Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care," 6.

¹³⁹ O Reg 79/10, s 116.

¹⁴⁰ Ontario Pharmacists Association, "OPA Best Practice Guidelines for Long-Term Care," 8.

¹⁴¹ ISMP Canada, "Medication Safety Self-Assessment for Long-Term Care," https://www.ismp-canada.org/lmssa/. Another tool that complies with the regulation is the Ministry's "medication audit tool": Testimony of Julie Greenall, Transcript, p 8254.

¹⁴² ISMP Canada, "Medication Safety Self-Assessment for Long-Term Care," https://www.ismp-canada.org/lmssa/.

- having prescribers available to assess the needs of residents and review medications as required;
- limiting "after hours" and emergency stocks of medications;
- having a pharmacist on call to respond to questions and come into the home if needed;
- · defining and identifying high-alert medications;
- allergy screening by pharmacy information systems and having medication allergies listed on every page of a resident's MAR; and
- establishing and consistently using standard medication administration times, including "dosing windows" to adjust dosing when the first dose is given at a non-standard time.¹⁴³

III. Diversion

At the public hearings, I received a report and heard evidence from Professor Beatrice Crofts Yorker, a qualified expert on the healthcare serial killer (HCSK) phenomenon. Her analysis of 131 cases shows that HCSKs typically operate through the diversion of medications. Her well-authorized through the diversion of medications are well-authorized through the diversion of medications. Her well-authorized through the diversion of medications are well-authorized through the diversion of medications are well-authorized through the diversion of medications are well-authorized through the diversion of the diver

Diversion occurs when medication under the control of a regulated person or facility is transferred from the intended recipient to another person for illicit use. ¹⁴⁵ It occurs in three ways:

Theft. A medication can be stolen, for example, from bulk containers or
waste buckets. This method relies on lax security and lack of oversight or
control of medications. Wettlaufer used insulin dispensed for the intended
resident as well as other residents which was stored in the medication
room refrigerator and not counted.¹⁴⁶

¹⁴³ Expert Report of Julie Greenall, p 19.

¹⁴⁴ Expert Report of Professor Beatrice Crofts Yorker Schumacher, May 27, 2018, p 12.
Professor Crofts Yorker Schumacher generally does not use "Schumacher" when giving her name.
For this reason, she is referred to as Professor Crofts Yorker throughout the text in this Report; in citations to her expert report and testimony, her full name is used.

¹⁴⁵ Expert Report of Julie Greenall, p 23.

¹⁴⁶ Expert Report of Julie Greenall, p 25.

- Fraud. Methods of perpetrating fraud to divert medications include ordering excess amounts from the pharmacy and falsifying prescriptions.
 A medication can also be documented as wasted and then kept for one's own purposes.¹⁴⁷
- **Deception.** Examples include giving a resident regular-strength Tylenol rather than a Tylenol 3 tablet, and replacing an active drug in a syringe with a clear fluid or other drug. In both cases, the perpetrator keeps the resident's medication for other purposes. ¹⁴⁸

Diversion causes multiple harms:

Harm can occur to the practitioner or staff member through misuse and addiction. Harm also occurs both directly to the resident if a practitioner is impaired and is incapable of performing the health care duties, and indirectly, if a resident does not receive their medicines and suffers a worsening condition or quality of life. Harm occurs at an institutional level with increased costs, reduced morale, eroded trust in the institution, and impacted resident care. 149

Opioids are the most commonly diverted class of medications,¹⁵⁰ but other medications are also diverted.¹⁵¹ As I discuss in Chapter 16, HCSKs often use injectable medications – especially insulin – to commit murder. An insulin overdose can lead to serious hypoglycemia and progress to loss of consciousness, seizures, and death.¹⁵²

A 2012 Mayo Clinic study showed that many healthcare workers are unaware that drug diversion in healthcare facilities is a serious problem.¹⁵³ As noted by the Canadian Society of Hospital Pharmacists, however, healthcare leaders are beginning to recognize that diversion is "common and often preventable."¹⁵⁴

¹⁴⁷ Expert Report of Julie Greenall, p 25.

¹⁴⁸ Expert Report of Julie Greenall, p 25.

¹⁴⁹ Expert Report of Julie Greenall, p 23; K.H. Berge, K.R. Dillon, K.M. Sikkink, et al., "Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention," (2012) 87(7) Mayo Clinical Proceedings 674–82.

¹⁵⁰ Expert Report of Julie Greenall, p 23; Berge, Dillon, Sikkink, et al., "Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime," 674.

¹⁵¹ Testimony of Julie Greenall, Transcript, pp 8262–63.

¹⁵² Expert Report of Julie Greenall, p 11.

¹⁵³ Berge, Dillon, Sikkink, et al., "Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime," 678.

¹⁵⁴ Canadian Society of Hospital Pharmacists, "Controlled Drugs and Substances in Hospitals and Healthcare Facilities: Guidelines on Secure Management and Diversion Prevention," Draft Guidelines for Public Consultation, 2018, 4.

Reports examining diversion have recommended that healthcare facilities undertake broad educational efforts and implement comprehensive prevention and detection efforts on diversion. One factor that increases the likelihood of diversion in LTC homes relates to medication storage — medication room doors may be left unlocked or open, and drug carts may be left unlocked and unattended while staff are at the bedside.

Medications are easier to divert when they are stocked in large quantities. They are particularly vulnerable to diversion when packaged in "bulk" instead of in strips because it makes it more difficult to identify medication that has been wrongfully taken.

The variety and quantity of medications in LTC homes make it difficult to completely prevent diversion and misuse of medications, particularly insulin: "The ubiquitous use of, and requirement for, insulin in a variety of dosage forms constrains opportunities within existing medication distribution systems in both LTC Homes and hospitals to mitigate the potential for intentional harm from insulin misuse." ¹⁵⁷ Moreover, the fact that insulin is available without a prescription means that even if its access is restricted in LTC homes, it is easily accessed elsewhere. ¹⁵⁸

The limited oversight of staff and the expanded role of nurses in LTC homes can also facilitate diversion. Nurses mostly practise independently in LTC homes, meaning that they are minimally supervised. There is even less supervision on the night shift – a fact that may explain why many HCSKs operate at night, as discussed in Chapter 16.¹⁵⁹ Also, nurses in LTC homes play a significant role not only at the medication administration stage (as is typical for most nurses) but also at the dispensing stage, which gives them additional opportunities to divert medications – for example, when they are stocking them.

¹⁵⁵ See Berge, Dillon, Sikkink, et al., "Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime," 678; see also Canadian Society of Hospital Pharmacists, "Controlled Drugs and Substances in Hospitals and Healthcare Facilities," 32.

¹⁵⁶ Expert Report of Julie Greenall, p 24.

¹⁵⁷ Expert Report of Julie Greenall, p 26.

¹⁵⁸ Expert Report of Julie Greenall, pp 26–27.

¹⁵⁹ Expert Report of Professor Beatrice Crofts Yorker Schumacher, pp 2, 14; Beatrice Crofts Yorker et al., "Serial Murder by Healthcare Professionals" (November 2006) 51(6) *Journal of Forensic Sciences* 1362 at 1365; Mary K. Sullivan, "Forensic Nursing in the Hospital Setting," in Virginia A. Lynch (ed.), *Forensic Nursing* (New York: Mosby, 2006), 559–61.

The high number of residents with cognitive impairment in LTC homes also facilitates diversion. Such residents may be less aware and/or less able to express concern if they do not receive the correct medications.¹⁶⁰

Reducing diversion provides benefits beyond deterring those who seek to harm residents. As reviewed above, staff members who divert medications for personal use risk harming themselves and, if they are working while impaired, risk harming residents. As well, residents can be harmed if they do not receive the medication they need. Further, medication diversion leads to increased costs, and it erodes trust in the healthcare staff and home. All these things are ameliorated by reducing diversion.

Below I suggest three strategies to reduce diversion in LTC homes: changes to infrastructure to increase visibility; technological innovations to improve the medication management system; and an increased role for pharmacy professionals. These strategies will also lead to other benefits because they will reduce medication errors and enable nurses to spend more time on direct resident care.

IV. Strategies to Limit and Prevent Diversion

A. Changing Infrastructure to Increase Visibility

The use of security cameras in LTC homes and the presence of glass doors, walls, and/or windows in medication rooms are effective methods of deterrence. These measures increase the visibility of the preparation, storage, transportation, and administration of medications.

Security cameras in LTC homes' common areas, medication rooms, entrances, and exits announce to those seeking to divert medications the fact that their behaviour is being recorded – a deterrent in itself. As well, if a medication incident or suspicious event takes place, camera footage can be reviewed for unusual behaviour and to see who was close by in the lead-up to the event, making it more likely that wrongdoers are apprehended. Professor Beatrice Crofts Yorker testified that video surveillance recently helped to catch a nurse who was injecting air emboli that caused strokes in patients.¹⁶²

¹⁶⁰ Expert Report of Julie Greenall, p 25.

¹⁶¹ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 22.

¹⁶² Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, Sept. 12, 2018, p 8030.

Glass doors, windows, and/or walls in medication rooms permit staff and residents to observe activities taking place inside those rooms, including attempts to divert medications. When interviewed by Commission counsel, Wettlaufer said that she might not have been able to get away with diverting insulin had the medication rooms in which it was stored been made of glass. 163

B. Using Technology to Improve Medication Management

A number of technologies can strengthen the medication management system in an LTC home by reducing the quantity of medications within it and improving the overall tracking and auditing of medications. Use of one or more of these technologies should limit diversion and result in fewer medication incidents, so that those that do occur stand out and lead to thorough investigations. In addition, technology can free nurses from some medication obligations, enabling them to spend more time on direct resident care.

Hospitals are increasingly moving toward implementing closed-loop electronic medication management systems to improve overall medication safety. ¹⁶⁴ These closed-loop systems comprise "electronic system components that support all stages of medication management including prescribing, dispensing and medication administration." ¹⁶⁵ While it may not be feasible for LTC homes to immediately implement all components of a closed-loop system, they can move closer to it by integrating one of the technologies discussed below into their existing medication management systems. This section will highlight two technologies that form part of a closed-loop system: automated dispensing cabinets (ADCs) and barcode-assisted medication administration (BCMA). Although these technologies are discussed separately, they cannot be considered in isolation. Rather, the nature of the whole system and the role of each form of technology in that system must be considered before they are implemented.

In 1999, the US Institute of Medicine released a landmark report called *To Err Is Human: Building a Safer Health System*, which noted that medication incidents

¹⁶³ Commission Counsel interview with Elizabeth Wettlaufer, February 14, 2018, p 67.

¹⁶⁴ Jodie A. Austin, Ian R. Smith, and Amina Tariq, "The Impact of Closed-Loop Electronic Medication Management on Time to First Dose: A Comparative Study Between Paper and Digital Hospital Environments" (2018) 26 International Journal of Pharmacy Practice 526 at 526.

¹⁶⁵ Austin, Smith, and Tariq, "Impact of Closed-Loop Electronic Medication Management on Time to First Dose," 526.

are widespread in healthcare institutions. ¹⁶⁶ The authors assessed technology as superior to humans in some aspects: "Good machines can question the actions of operators, offer advice, and examine a range of possibilities that humans cannot possibly remember." ¹⁶⁷ However, in a more recent article that discusses the benefits and challenges of automating the medication use process, the authors observed that technological enhancements dropped in "with little understanding of the overall impact and complexity introduced when the solution is not envisioned as part of a whole system" are not the answer. ¹⁶⁸ They go on to suggest that the following matters are necessary for a new technology to be successfully introduced:

- a strong clinical and executive leadership to drive change;
- a consideration of the entire medication use process, not just the particular pieces being affected by the technologies contemplated for implementation;
- an understanding of the state, technologies, processes, strengths, and weaknesses in the existing medication use process, before planning and design;
- before implementation of these technologies, a shared vision of what the ultimate medication use process will look like and its impact on all involved clinicians, to drive the planning efforts;
- a focus on clinical change management, including communication;
- a unified design, created by a multidisciplinary team, including the information system, work processes, corresponding policies, and supporting technologies;
- extensive design and implementation planning to reduce the risk of adverse outcomes and false starts in the implementation process;
- appropriate infrastructure in place to support rapid communication and integration among systems; and
- organizational commitment to dedicating resources to ensure full implementation.¹⁶⁹

¹⁶⁶ L.T. Kohn, J.M. Corrigan, and M.S. Donaldson (eds.), *To Err Is Human: Building a Safer Health System* (Washington, D.C.: National Academies Press, 2000).

¹⁶⁷ Kohn, Corrigan, and Donaldson (eds.), *To Err Is Human*, 62.

¹⁶⁸ Dave Troiano, Julie Morrison, Frank Federico, and David Classen, "Safely Automating the Medication Use Process: Not as Easy as It Looks" (2009) 23(4) *Journal of Healthcare Information Management*, 17 at 17.

¹⁶⁹ Troiano, Morrison, Federico, and Classen, "Safely Automating the Medication Use Process," 20.

1. Automated Dispensing Cabinets

ADCs are a form of technology used to manage medication access and support the correct selection of medications. ¹⁷⁰ The Australian Commission on Safety and Quality in Health Care distinguishes among three types of automated dispensing systems: pharmacy-based automated dispensing systems (which dispense medications at the pharmacy), ward-based automated dispensing systems (which dispense individual medications at the hospital, LTC home, or other healthcare facility), and automated unit-dose dispensing systems (which dispense a patient's or resident's medication into a sealed strip package). ¹⁷¹ The type of system under consideration here is the ward-based system.

ADCs are commonly used in hospitals, in both Canada and the United States – and they have been for more than 20 years.¹⁷² As of 2009–10, ADCs were in use in at least 53% of Canadian hospitals and approximately 89% of US hospitals.¹⁷³ ADCs are being used in the US long-term care sector, but less so in the Ontario context.¹⁷⁴

ADCs can be used to establish a central supply process for dispensing medications. As-needed medications such as insulin pens, for example, could be stored in the ADC. When a resident needs a new pen, it could be signed out of the ADC, labelled for that resident, and stored in the resident's bin within the medication cart.¹⁷⁵

ADCs can incorporate refrigerated units, allowing for the secure and monitored storage of insulin pens. ¹⁷⁶ While the ADC itself would not be refrigerated, it would include a secured refrigerator that could not be opened except through the ADC. ¹⁷⁷

¹⁷⁰ Expert Report of Julie Greenall, p 27.

¹⁷¹ Australian Commission on Safety and Quality in Health Care, "Automated Dispensing Systems" (2013) 1(2) *Evidence Briefings on Interventions to Improve Medication Safety* 1. See also K.L. James et al., "The Impact of Automation on Workload and Dispensing Errors in a Hospital Pharmacy" (2013) 21(2) *International Journal of Pharmacy Practice* 92.

¹⁷² Élise Rochais, Suzanne Atkinson, Mélanie Guilbeault, and Jean-François Bussières, "Nursing Perception of the Impact of Automated Dispensing Cabinets on Patient Safety and Ergonomics in a Teaching Health Care Center" (2014) 27(2) *Journal of Pharmacy Practice* 150 at 151.

¹⁷³ Nicole W. Tsao et al., "Decentralized Automated Dispensing Devices: Systematic Review of Clinical and Economic Impacts in Hospitals" (2014) 67(2) Canadian Journal of Hospital Pharmacy 138 at 139

¹⁷⁴ Testimony of Julie Greenall, Transcript, p 8247.

¹⁷⁵ Testimony of Julie Greenall, Transcript, pp 8269–70.

¹⁷⁶ Expert Report of Julie Greenall, p 27.

¹⁷⁷ Testimony of Julie Greenall, Transcript, p 8318.

a) ADCs Reduce Stocks of Drugs

The current system of dispensing medications on a per resident basis with supplies delivered weekly (for medications dispensed through a monitored dosage system) or monthly (for multi-dose medications) results in significant stocks of medication in the home and leads to significant medication waste. This system makes it easier to divert medication. Using ADCs effectively allows a home to reduce both medication stocks and medication waste. Where ADCs are used to store narcotics and other controlled substances in unit doses, for example, one dose is dispensed at a time. Multiple residents can draw on the same store of narcotics, which can be smaller because the pharmacy service provider does not need to dispense a month's worth per resident at a time. It also means that when a resident dies, there is a smaller quantity of unused narcotics to be destroyed.

ADCs can also store high-alert medications, rescue medications, medications that would otherwise be kept in the emergency drug box, and the 50 to 100 medications most commonly administered in the LTC home (to be used for first doses).

Reducing stocks of medication and wasted medication makes diversion more difficult. "When there is a lot of something, people think that no one will notice if a little bit is missing. When you have a smaller amount and something is missing, it becomes more obvious. And it just creates the idea that someone is paying attention to this." 178

b) ADCs Limit Access to Medications

ADCs limit access to medications through the use of smaller compartments within the overall cabinet.¹⁷⁹ If a nurse requests a particular medication from an ADC, the nurse is not given access to all medications within the ADC. Where the ADC has unit dose dispensing, it may be that the medication ordered is dispensed individually, as from a vending machine. In other cases, the nurse may gain access to a drawer with multiple compartments but be able to open only one compartment within the drawer. Finally, in cases of more innocuous medications, the nurse may gain access to all the compartments within a particular drawer. Limiting access through ADCs makes diversion more challenging and improves the traceability of medications, because a nurse has to electronically request a specific medication before obtaining it.

¹⁷⁸ Testimony of Julie Greenall, Transcript, p 8272.

¹⁷⁹ Expert Report of Julie Greenall, p 21.

c) ADCs Improve Tracking of Medications Other Than Opiates

ADCs track all medications that they contain. A nurse obtains access to an ADC through a swipe card, a unique passcode, or a fingerprint scanner. Where the ADC is tied to patient profiles, the ADC also documents the resident for whom the medication has been dispensed.

The improved tracking of medications allows for the easier detection of discrepancies related to medications that are currently not tracked, such as insulin. In a situation where a nurse requests one insulin cartridge from an ADC but takes two, for example, the ADC tracks the number of medications that have been inserted into it and removed and is able to print reports containing this information. The insulin cartridges are therefore more easily tracked and, with regular audits, the likelihood increases that the discrepancy will be caught and investigated. The ADC can also require a nurse to record the number of pens in the compartment, and not just the number being removed. This feature could lead to earlier identification of discrepancies.

ADCs permit easier tracking of medication use patterns and can help identify potential medication incidents, including those resulting from intentional harm. Records can be reviewed for particular medications, so that an LTC home can identify anomalous trends as well as potential medication incidents. For instance, an LTC home could program an ADC to send an alert when glucagon is used, enabling it to track the overall use of glucagon within the home. Automated tracking has the potential to simplify quarterly evaluations of the medication management systems in the home, making it easier to report on medication use patterns and trends. Systems that routinely print out "anomalous usage reports" can help in the early detection of drug diversion by a nurse. 181

d) ADCs Improve Quality of Care

In addition to their uses in preventing intentional harm, ADCs have the potential to improve quality of care for residents. Where an ADC is stocked with the 50 to 100 medications most commonly prescribed within a home, but which are not tied to a particular resident, ADCs allow for quicker access

¹⁸⁰ Expert Report of Julie Greenall, p 30.

¹⁸¹ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 21.

to first doses of medication (e.g., when a resident arrives at an LTC home or when a new medication is prescribed).¹⁸² Instead of waiting for medication to be delivered by the pharmacy service provider, nurses are able to access the necessary medications through the cabinet.

ADCs may also free up nursing time, allowing nurses more time to care for residents. Nicole Tsao and her colleagues conducted a review of eight studies that addressed the clinical and economic impact of using ADCs in hospitals. 183 They found that ADCs appeared to reduce the amount of time nurses spent completing inventories of controlled substances, although there was no definitive evidence that nurses then spent more time with patients. 184 In the LTC home context, nurses would no longer need to perform the controlled substance counts at the end of each shift; the ADC would produce daily count sheets for audit.

ADCs may also reduce medication incidents, although evidence in this area is inconclusive, particularly because there are limited data on the impact of ADCs on medication incidents in LTC homes. In the hospital setting, although Tsao and her colleagues found that ADCs reduced medication storage errors, there was no definitive evidence of a reduction in medication errors that led to patient harm.¹⁸⁵ The Australian Commission on Safety and Quality in Health Care conducted a literature review related to ADCs in hospitals and reached a similar conclusion.¹⁸⁶

e) Limitations of ADCs

The effective implementation and management of ADCs is a complex process and can end up with an ADC becoming "a cupboard with a lock on it." ¹⁸⁷ If ADCs are not used appropriately, they will not lower the risks associated with manual ward stock systems. ¹⁸⁸

¹⁸² Troiano, Morrison, Federico, and Classen, "Safely Automating the Medication Use Process," 23.

¹⁸³ Tsao et al., "Decentralized Automated Dispensing Devices," 138.

¹⁸⁴ Tsao et al., "Decentralized Automated Dispensing Devices," 138.

¹⁸⁵ Tsao et al., "Decentralized Automated Dispensing Devices," 138.

¹⁸⁶ Australian Commission on Safety and Quality in Health Care, "Automated Dispensing Systems," 1.

¹⁸⁷ Testimony of Julie Greenall, Transcript, p 8275.

¹⁸⁸ Expert Report of Julie Greenall, p 27.

The elements that ensure effective implementation and use of ADCs include:

- linking the ADC to patient profiles so that the ADC records which medications were taken out for which resident;
- basing what can be taken out on medication orders already entered into and approved within the system;
- having unit dose packaging so that the nurse has access to only one dose at a time; and
- interfacing the ADCs with the pharmacy service provider system to provide for pharmacist review.¹⁸⁹

Power or system outages have the potential to disrupt ADC accessibility. Homes using ADCs must make contingency plans in their medication management system to account for such emergencies.

2. Barcode-Assisted Medication Administration

BCMA is a medication administration process that uses barcode technology to support the accurate administration of medication. A BCMA system includes a barcode on the medication itself, one on the medication record, and, ideally one on the recipient of the medication.¹⁹⁰

Ms. Greenall was not aware of any LTC home in Ontario currently using a BCMA, but she testified that "it certainly could be" adopted more widely. 191 BCMA is used in LTC homes in other jurisdictions. For example, a 2011 study examined the first BCMA system specifically developed for use in UK residential and nursing homes. 192 The authors described the system as follows:

The pharmacy-managed, barcode medication administration system differs from a simple eMAR system in its design and functionality ... All data management is undertaken centrally by the pharmacy outside the care home setting. At the end of each week a report is sent to the care home manager with details of all potential administration errors and the member of staff involved. During a medication round, the user first scans each patient's barcode identifier using a hand-held device to ensure the correct drug file is recalled and to visually confirm identification of the resident. The user then scans each dispensed item prior to administration.

¹⁸⁹ Testimony of Julie Greenall, Transcript, pp 8273–75.

¹⁹⁰ Testimony of Julie Greenall, Transcript, p 8227.

¹⁹¹ Testimony of Julie Greenall, Transcript, pp 8209, 8235.

¹⁹² Ala Szczepura, Deidre Wild, and Sara Nelson, "Medication Administration Errors for Older People in Long-Term Residential Care" (2011) 11 BMC Geriatrics 82.

The system carries out a number of checks based on both bar codes to ensure the following are correct (i) resident, (ii) medication, (iii) time, (iv) dose, (v) quantity and (vi) in date. If administration is outside any parameter, the system alerts the member of staff immediately to the potential error. If administration of a medicine within the correct time window lapses the system enters this as a 'missing record.' The system records all deviations between the medication as prescribed and that finally administered. 193

a) BCMA Improves Tracking of Medication and Provides Heightened Degree of Protection for Residents Depending on Their Awareness

BCMA has the potential to protect against intentional harm by tracking medication to the point of administration. If a nurse must scan a resident's wristband before administering medication, the administration would be recorded and, therefore, be traceable. This record has the potential to deter those seeking to harm residents intentionally.

Of course, a nurse could choose not to scan the resident's barcoded wristband before administration, meaning the medication would not be documented. However, residents who are aware of the requirement to scan the wristband and have the capacity to identify deviations from that requirement could report instances where a nurse did not scan their wristbands.

b) BCMA Reduces Medication Errors

In addition to deterring intentional harm, BCMA has the potential to reduce medication incidents. In particular, BCMA is "extremely effective in eliminating administration errors." ¹⁹⁴ In a literature review assessing the impact of BCMA systems on medication errors in acute care, Gillian Strudwick and her colleagues found that most studies noted a statistically significant decrease in medication errors following the introduction of BCMA technology. ¹⁹⁵ Because these studies were limited to the acute care context, however, the authors cautioned that additional research was needed to understand the potential impact of BCMA systems in other care settings. ¹⁹⁶

¹⁹³ Szczepura, Wild, and Nelson, "Medication Administration Errors for Older People in Long-Term Residential Care," 83. Residential homes have no on-site nursing staff, while nursing homes appear analogous to long-term care homes – even requiring a registered nurse on site 24 hours a day (82).

¹⁹⁴ Troiano, Morrison, Federico, and Classen, "Safely Automating the Medication Use Process," 23.

¹⁹⁵ Gillian Strudwick et al., "Factors Associated with Barcode Medication Administration Technology That Contribute to Patient Safety: An Integrative Review" (2018) 33(1) Journal of Nursing Care Quality 79 at 81; see also Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 18.

¹⁹⁶ Strudwick et al., "Factors Associated with Barcode Medication Administration Technology That Contribute to Patient Safety," 83.

Barcoding technologies can reduce the potential for error and have "demonstrated time-savings in work processes and fewer system errors." They may also reduce the time that nurses spend reporting and documenting. At the public hearings, both Professor Crofts Yorker and Ms. Greenall stated that the benefits of BCMA would do little to assist with errors involving insulin (Wettlaufer's weapon of choice) because of the variability in doses. However, if there were an overall reduction in the number of medication incidents, it would make those that occur more evident.

c) Limitations of BCMA

From a technical standpoint, BCMA "is extremely complex and expensive to implement, requiring significant changes in the dispensing, storage and administration processes, as well as a significant investment in supporting technologies such as mobile medication carts, PCs, scanners and bar-code labeling." ¹⁹⁹

Different factors have been associated with improved medication safety through the use of BCMA. These include:

- · workstations on wheels;
- systems supported by ADCs;
- non-tethered barcode scanners;
- monitoring nurse scanning rates;
- medication administration record system features and functionalities (e.g., allowing nurses to document deviations in administration);
- nurse training;
- patient education; and
- nurse involvement in the implementation process.²⁰⁰

Effectively implementing BCMA – as is the case for all technologies considered in this section – requires "buy-in" from all those involved in the system, including nurses. The opinion of residents is another critical factor. Throughout

¹⁹⁷ Ackroyd-Stolarz, Hartnell, and MacKinnon, "Approaches to Improving the Safety of the Medication Use System," 62.

¹⁹⁸ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 8037; Testimony of Julie Greenall, Transcript, p 8227.

¹⁹⁹ Troiano, Morrison, Federico, and Classen, "Safely Automating the Medication Use Process," 23.

²⁰⁰ Strudwick et al., "Factors Associated with Barcode Medication Administration Technology That Contribute to Patient Safety," 82.

the public hearings and the consultation process, I heard concerns that barcoded wristbands would create an unwanted institution-like feeling in LTC homes. These considerations must be addressed in any plan to implement BCMA within a home.

C. Increasing the Role of Pharmacy Professionals in LTC Homes

Pharmacists are part of the interdisciplinary team in an LTC home that oversees the medication management system. However, in many homes, the pharmacist is on-site only one day a week.²⁰¹ Increasing the role of pharmacy professionals (pharmacists and/or pharmacy technicians) in LTC homes can help limit diversion, thereby serving to deter those who wish to inflict harm using medications. It can also lead to a reduction in the number of medication incidents and to improved resident care, as nurses have more time to spend with residents.

1. Pharmacists

a) Prevention / Reduction of Medication Incidents

Because pharmacists currently spend little time in the homes, they use the time they have to meet immediate resident needs. They have "little involvement in medication distribution or oversight, beyond assisting with destruction of narcotics and controlled drugs." ²⁰² Working in the home more frequently would allow pharmacists to play a significant role in identifying adverse drug events and medication incidents that might otherwise not be caught.

Hospital studies show that medication incidents are reduced when pharmacists review medication orders and lead medication reconciliations. A recent report from the University of Windsor in Ontario (University of Windsor report) on the impact of pharmacist-led medication reconciliation in long-term care concluded that these reconciliations are more efficient and have the potential to prevent more adverse drug events than those conducted by nurses. 204

²⁰¹ Expert Report of Julie Greenall, p 16.

²⁰² Expert Report of Julie Greenall, p 28.

²⁰³ Kohn, Corrigan, and Donaldson (eds.), *To Err Is Human*, 40; Sajani Patel et al., "Satisfaction with Medication Reconciliation Completed by Pharmacy Technicians in an Emergency Department" (2018) 43(7) *Pharmacy and Therapeutics* 423–28.

²⁰⁴ Snowdon and DeForge, "Examining the Impact of Pharmacist-Led Medication Reconciliation in Long-Term Care."

Pharmacists can also lead proactive risk assessment projects in the home to identify vulnerabilities in the medication management process. The home's interdisciplinary team can then use that information to address the system's vulnerabilities.²⁰⁵ Identifying and addressing vulnerabilities also reduce opportunities for diversion and medication incidents in LTC homes.

Having pharmacists spend more time in the homes will increase their ability to respond to medication incidents as they happen. Being on-site would increase their availability to offer advice as the incident unfolds.²⁰⁶ This counselling should reduce the impact of medication incidents and allow the pharmacist to more quickly conduct an incident analysis.

b) Optimizing Resident Care in LTC Homes

A greater presence of pharmacists in LTC homes could also "support optimization of medication management to improve health outcomes for LTC residents." ²⁰⁷ Pharmacist-led medication reconciliations are faster and more likely to result in the modification and/or discontinuation of medications. They also free up nurse time and lead to residents receiving their first administration of medications more quickly. The University of Windsor report found that each pharmacist-led medication reconciliation saved three hours of a nurse's time, which could then be used for direct resident care. ²⁰⁸

Greater pharmacist involvement also helps to optimize resident care because pharmacists look for ways to reduce the number of medications that residents take:

What we know from this report from the Canadian Institute of Health Information [is that] our long-term care residents are often taking more than ten medications. I think there's a lot of opportunity for pharmacists to look at whether there are other alternatives; whether we could consider other medication regimens; whether there are medications that could be de-prescribed; whether an indication is no longer valid; or you start to look at the risk-benefit for medications that you've been on for a long time, and does that indication still really exist.²⁰⁹

²⁰⁵ Testimony of Julie Greenall, Transcript, pp 8181–82.

²⁰⁶ Testimony of Julie Greenall, Transcript, p 8280.

²⁰⁷ Expert Report of Julie Greenall, p 28.

²⁰⁸ Snowdon and DeForge, "Examining the Impact of Pharmacist-Led Medication Reconciliation in Long-Term Care."

²⁰⁹ Testimony of Julie Greenall, Transcript, p 8242.

In *To Err Is Human*, the authors note that inappropriate prescribing is a significant factor in medication errors. "In an analysis of 1987 National Medical Expenditure Survey data, it was found that physicians prescribe potentially inappropriate medications for nearly a quarter of all older people living in the community."²¹⁰

Hospital studies confirm that paying pharmacists to optimize medication use produces cost savings because of the reduction in the quantities of medications administered.²¹¹ Reducing medication use also increases resident safety because medications are dangerous substances:

There's really a whole movement towards de-prescribing in the elderly, to really look at reducing the burden of medication use, because medication use itself is a risk. So medications are not fully innocuous, and they can cause other unintended effects.²¹²

De-prescribing medications also reduces the stocks of medications in the home; smaller quantities of medications reduce the opportunities for diversion. Reducing the number of medications also benefits the workload of the nursing staff:

One area where pharmacists have had a positive impact in LTC homes is assisting in rebalancing medication passes to help manage nursing workload through increased use of long-acting medications, where appropriate, and shifting of medication administration time, particularly for once-daily medications, to a lighter medication pass time (e.g., noon).²¹⁴

As well, in terms of optimizing care, if pharmacists spend more time in LTC homes, they have more opportunities to educate staff on medications. In an Ontario study of LTC homes, nurses indicated that because of the significant number of medications that they must administer, they sometimes lack necessary knowledge about them.²¹⁵

²¹⁰ Kohn, Corrigan, and Donaldson (eds.), *To Err Is Human*, 37–38.

²¹¹ Expert Report of Julie Greenall, p 28; T. De Rijdt, L. Willems, and S. Simoens, "Economic Effects of Clinical Pharmacy Interventions: A Literature Review" (2008) 14(12) *American Journal of Heath-System Pharmacy* 1161–72.

²¹² Testimony of Julie Greenall, Transcript, p 8242.

²¹³ Expert Report of Julie Greenall, p 28.

²¹⁴ Expert Report of Julie Greenall, p 28.

²¹⁵ Wendy Ellis, Sharon Kaasalainen, Pamela Baxter, and Jenny Ploeg, "Medication Management for Nurses Working in Long-Term Care" (2012) 44(3) *Canadian Journal of Nursing Research* 128–49.

2. Pharmacy Technicians

Pharmacy technicians are college-educated, independently regulated healthcare providers with specific training in medication management systems, including training on medications and dosage forms, strengths, and administration schedules.²¹⁶ Given their specialized training, employing pharmacy technicians to perform medication activities otherwise carried out by nurses may reduce medication incidents and diversion.

Pharmacy technicians could complete best possible medication histories (BPMHs) for residents, a task that nurses currently perform. Pharmacists could use these histories when completing the medication reconciliations. In the University of Windsor report, pharmacy technicians finalized the BPMHs, which the pharmacists then used when completing the medication reconciliations. The salaries for pharmacy technicians are lower than those of pharmacists and, with sufficient training and oversight, their BPMHs are as accurate, effective, and safe as those done by pharmacists.²¹⁷

Pharmacy technicians could also help with other medication management system activities such as receiving and storing medications, disposing of non-controlled medications, taking inventory of medications, stocking medication carts, and preparing medications. These tasks are currently performed by nurses and take a significant amount of time.²¹⁸

V. Improving Incident Analysis

As mentioned, the Regulation requires the reporting of medication incidents and their review by an interdisciplinary team. The evidence at the public hearings shows that LTC homes are not consistent in their approach to conducting medication incident analysis or in their response to the use of glucagon when a resident experiences severe or uncontrollable

²¹⁶ Testimony of Julie Greenall, Transcript, pp 8277–78; Patel et al., "Satisfaction with Medication Reconciliation Completed by Pharmacy Technicians in an Emergency Department," 423–28; Shahileen Remtulla et al., "Best Possible Medication History by a Pharmacy Technician at a Tertiary Care Hospital" (2009) 62(5) Canadian Journal of Hospital Pharmacy 402–5.

²¹⁷ Rochelle Johnston et al., "Best Possible Medication History in the Emergency Department: Comparing Pharmacy Technicians and Pharmacists" (2010) 63(5) Canadian Journal of Hospital Pharmacy 359–65; Remtulla et al., "Best Possible Medication History by a Pharmacy Technician at a Tertiary Care Hospital," 402–5; Patel et al., "Satisfaction with Medication Reconciliation Completed by Pharmacy Technicians in an Emergency Department," 423–28; Expert Report of Julie Greenall, pp 27–28.

²¹⁸ Expert Report of Julie Greenall, pp 27–28.

hypoglycemia. As I discuss below, use of a standardized incident analysis process and expanding the definition of medication incident to include the use of glucagon and the presence of severe hypoglycemia will help to identify incidents resulting from intentional harm. Having a robust incident analysis process in place in LTC homes may also serve to deter an HCSK because it increases the likelihood that wrongdoing through the improper use of medication will be detected and the wrongdoer identified.

A. Fostering a Just Culture in LTC Homes

According to the authors of the Canadian Incident Analysis Framework, discussed below, fostering a just culture in a healthcare facility is an important precondition to effective medication incident analysis. ²¹⁹ The premise underlying a just culture is that a punitive response is not an effective way to deal with human error. ²²⁰ When an error is made, a common reaction is to blame someone. However, few people are willing to admit they have made an error and report it "when they face the full force of their corporate disciplinary policy, a regulatory enforcement scheme, or our onerous tort liability system." ²²¹ Medication errors are often the result of a number of contributing factors and they are likely to recur, regardless of whether someone is blamed: "People working in healthcare are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that the system needs to be made safer."

The just culture is founded on the assumption that all human beings make mistakes, and that those mistakes give us insight into how to avoid repeating them in the future. In a just culture, a distinction is drawn among intentional acts, reckless acts, and acts that arise from unforeseen circumstance or complications of care.²²³ A just culture shifts away from blaming individuals for errors and embraces a "no shame, no blame" approach

²¹⁹ Canadian Incident Analysis Framework; available at https://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework. PDF p 17.

²²⁰ Kohn, Corrigan, and Donaldson (eds.), *To Err Is Human*, 56.

²²¹ David Marx, *Patient Safety and the "Just Culture": A Primer for Health Care Executives* (New York: Columbia University, 2001), 3.

²²² Kohn, Corrigan, and Donaldson (eds.), *To Err Is Human*, 49.

²²³ Canadian Incident Analysis Framework, p 17.

that focuses on creating safe systems to prevent future errors.²²⁴ Individuals are held accountable for their actions in the system, but not for the overall system design.

A just culture encourages employees to promptly report all medication incidents. In turn, this transparency enables the healthcare institution to address systemic vulnerabilities and increase patient safety.²²⁵ It recognizes that the prevention of errors and the improvement of patient safety require modification of the systemic conditions that contribute to errors.

In a just culture, the entire team focuses on the safety of the patients or residents. The knowledge that errors are used to improve safety rather than to assess the personal competence of staff reinforces the need to report "any kind of unusual occurrence, whether it's reached the level of harming a resident or not." In LTC homes, in the context of medication management, a reportable occurrence should be "anything that has the capacity to cause harm."

Fostering a just culture also helps deter and detect acts of intentional harm in LTC homes because it creates an environment in which healthcare professionals feel safe to report suspicious behaviour on the part of their colleagues, as part of an institutional culture of accountability.²²⁸ The National Health Service document entitled "A Just Culture Guide" is included in this volume as Appendix G. It provides an example of the just culture principles in practice and is notable for its first question: "Was there any intention to cause harm?" In light of the Offences, the possibility that deliberate harm may have led to the patient safety incident is an extremely important consideration.

A just culture provides the most effective context for the incident analysis process because care providers know they will be treated fairly while still held accountable for their actions and behaviours. The culture is largely based on an organization "possessing a collective understanding of where the line should be drawn between blameless and blameworthy actions."²²⁹

²²⁴ Kohn, Corrigan, and Donaldson (eds.), *To Err Is Human*, 5; Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 8033.

²²⁵ Testimony of Julie Greenall, Transcript, pp 8294–95; Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 8035.

²²⁶ Testimony of Julie Greenall, Transcript, p 8292.

²²⁷ Testimony of Julie Greenall, Transcript, p 8296.

²²⁸ Kelly M. Pyrek, *Healthcare Crime: Investigating Abuse, Fraud, and Homicide by Caregivers* (Boca Raton, Fla.: CRC Press, 2011), 272.

²²⁹ Canadian Incident Analysis Framework, p 17.

B. Using a Standardized Incident Analysis Framework for Medication Incidents

A standardized, rigorous incident analysis framework should be used when investigating medication incidents – and the Canadian Incident Analysis Framework provides an excellent example. It was developed collaboratively by the Canadian Patient Safety Institute, ISMP Canada, Saskatchewan Health, and Patients for Patient Safety Canada, among others. The following explanation shows why LTC homes should adopt it or a similar model for investigating medication incidents:

The Framework is an analytic tool for performing a system-based review of incidents, including but not limited to medication incidents. It utilizes well-established methods of analysis designed to help determine the contributing factors to an event and to identify strategies for implementing system improvements. The goals of incident analysis are to determine (i) what happened, (ii) why it happened, (iii) what can be done to reduce the likelihood of a recurrence; and (iv) what has been learned and can be shared to broadly enhance safety. Effective incident analysis can prevent healthcare organizations from undertaking cursory reviews that focus too heavily on the performance of individuals at the "sharp end" of the health care system (the point where care is delivered). The use of incident reporting and learning systems at local, provincial and national levels, with mechanisms for shared learning, is key to overall system safety.²³⁰

While the primary goal of the Canadian Incident Analysis Framework is quality improvement, it also helps to identify situations of intentional harm so that leading healthcare managers can consider the following questions:

- Is the event thought to be the result of a criminal act?
- Is the event a purposefully unsafe act (an act where care providers intend to cause harm by their actions)?
- Is the event related to substance abuse by the provider / staff member?
- Does the event involve suspected patient abuse of any kind?²³¹

²³⁰ Expert Report of Julie Greenall, p 31.

²³¹ Expert Report of Julie Greenall, pp. 31–32. See also Incident Decision Tree, NHS Just Culture Guide; available at https://improvement.nhs.uk/documents/2490/NHS_0690_IC_A5_web_version.pdf

C. Treating the Use of Glucagon and the Development of Severe Hypoglycemia as Medication Incidents

In this section, I explain why both the use of glucagon and the development of severe hypoglycemia should be treated as medication incidents for the purposes of the LTCHA and the Regulation.

The 2009 Report of the Ontario Auditor General recommended that LTC homes should "develop and implement policies to ensure consistent identification and documentation of adverse drug reactions, so that action can be taken to prevent future occurrences." 232 Ms. Greenall testified that the use of rescue medications, such as glucagon, provides an opportunity to identify a potential adverse drug event or medication incident. She also testified that severe hypoglycemia suggests the possibility of an adverse event or medication incident. By treating the use of glucagon and the presence of severe or unresponsive hypoglycemia as medication incidents within the meaning of section 1 of the Regulation, homes will meet the Auditor General's recommendation that LTC homes have "policies" to ensure consistent identification and documentation of adverse drug events.

The utility of this approach can be seen in relation to three of Wettlaufer's victims – Clotilde Adriano, Wayne Hedges, and Arpad Horvath – all of whom were treated with glucagon for hypoglycemia. In at least the cases of Mr. Hedges and Mr. Horvath, glucagon was administered after Wettlaufer intentionally injected them with insulin overdoses. Although the Offences against Ms. Adriano and Mr. Hedges took place before the LTCHA came into effect, in the case of Mr. Horvath, had the use of glucagon been treated as a medication incident, section 135 of the Regulation would have required the home to document, report, analyze, and review the incident. As well, section 135 would have required the incident to be subject to the quarterly review. These actions increase the likelihood that homes will detect incidents resulting from intentional wrongdoing. The strength of this approach is enhanced if the homes use an incident analysis framework such as the Canadian Incident Analysis Framework.

²³² Ontario Office of the Auditor General, *Annual Report*, 2009 (Toronto: Queen's Printer, 2009), s 4.10, http://www.auditor.on.ca/en/content/annualreports/arreports/en09/2009AR_en_web_entire.pdf.

²³³ Glucagon acts in the body to stimulate the liver to produce glucose: Expert Report of Julie Greenall, p 30.

A similar line of reasoning applies to Maureen Pickering, who experienced severe hypoglycemia after Wettlaufer injected her with an overdose of insulin. Had the home treated her severe hypoglycemia as a medication incident, it would have had to follow the dictates of section 135 of the Regulation – to document, report, analyze, and review the incident – thereby increasing the likelihood of identifying the root cause of Ms. Pickering's severe hypoglycemia.

VI. Increasing the Number of Registered Staff

Nursing staff in LTC homes are stretched thin. In an Ontario study of LTC homes, some nurses describe the administration of medications as a "race against time." ²³⁴ Nurses also report having to strategize and prioritize when administering medications because of the number of medications to be administered, the number of residents to whom they must be administered, and the challenges of administering medications to residents who often have cognitive impairment, dementia, and/or difficulty swallowing. The medication administration task is made more difficult because nurses may have to administer medications about which they have little or no knowledge. All these factors increase the chances of medication errors. ²³⁵

Improved staffing ratios would provide more oversight in the homes and could play a role in deterring wrongdoers from intentionally harming residents. ²³⁶ Ms. Greenall gave evidence on the importance of staffing to prevent diversion. She noted that nurses work independently, and it is uncommon for more than one nurse to be involved in administering medications. She also noted that a single registered nurse is frequently in charge of an entire LTC home on evenings and nights, another factor that increases the risk of diversion.

²³⁴ Ellis, Kaasalainen, Baxter, and Ploeg, "Medication Management for Nurses Working in Long-Term Care," 142.

²³⁵ Ellis, Kaasalainen, Baxter, and Ploeg, "Medication Management for Nurses Working in Long-Term Care," 137–42.

²³⁶ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 15; Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, pp 8024–25, 8065–66, 8119.

To adequately provide for resident safety, the number of registered staff on each shift must be examined. Numerous reports and reviews have called for additional funding for staff in the last 15 years:

- In 2001, PricewaterhouseCoopers prepared a report based on a study it carried out for the Ontario Long Term Care Association and AdvantAge Ontario (then known as the Ontario Association of Non-Profit Homes and Services for Seniors). The report compared levels of service and responses to need in a sample of Ontario LTC homes and selected comparators. It found that residents in Ontario LTC homes have higher care needs than many of the comparator jurisdictions and that they receive less nursing, aide, and therapy care than the majority of comparators.²³⁷
- In 2004, Monique Smith's *Commitment to Care* report recommended "[i]ncreased staff funding and a move towards ensuring more full-time staff to provide consistent, resident-knowledgeable care." ²³⁸
- In 2006, the jury in the Coroner's Inquest into the deaths of Ezzeldine El Roubi and Pedro Lopez called for changes to the funding model for LTC homes to ensure staffing that was adequate to meet the needs of residents with dementia and/or mental health issues.²³⁹
- In 2008, the Sharkey report recommended "[p]rovincial guidelines to support funding increases for resident care over the next four years."²⁴⁰
- In 2012, the Donner Report concluded "there are not enough direct-care staff to meet the needs of all long-term care residents safely" and called for the implementation of the Sharkey report "on strengthening staff capacity for better care."²⁴¹

²³⁷ PricewaterhouseCoopers, Report of a Study to Review Levels of Service and Responses to Need in a Sample of Ontario Long Term Care Facilities and Selected Comparators (Toronto: Prepared for the Ontario Long Term Care Association and the Ontario Association of Non-Profit Homes and Services for Seniors, 2001).

²³⁸ Ontario, Ministry of Health and Long-Term Care, Commitment to Care: A Plan for Long-Term Care in Ontario, prepared by Monique Smith, parliamentary assistant (Toronto, 2004), 6.

²³⁹ Ontario, *Report on the Inquest into the Deaths of Ezzeldine El Roubi and Pedro Lopez* (Toronto: Office of the Chief Coroner, July 2006), recommendations 26–33.

²⁴⁰ See Ontario, Ministry of Health and Long-Term Care, People Caring for People: Impacting the Quality of Life and Care of Residents of Long-Term Care Homes, Report of the Independent Review of Staffing and Standards for Long-Term Care Homes in Ontario (S. Sharkey, facilitator) (May 2008), 9. Shirlee Sharkey, the president and CEO of Saint Elizabeth Health Care, began her independent review of staffing and care standards at the request of the minister in 2007.

²⁴¹ Ontario, Long-Term Care Task Force on Resident Care and Safety, "Report: An Action Plan to Address Abuse and Neglect in Long-Term Care Homes," May 2012 (Gail Donner, chair).

 In 2016, in a review of a homicide in an LTC home, the Geriatric and Long-Term Care Review Committee (a committee of the Office of the Chief Coroner of Ontario), recommended that the Ministry of Health and Long-Term Care consider "increasing staffing level requirements in long-term care settings given the high prevalence of dementia patients with psychosis."²⁴²

Wettlaufer committed the Offences on evening and night shifts, times when there were few or no other registered staff on duty. On the evidence presented at the public hearings, this fact may have contributed to her ability to commit the Offences. Thus, the Offences that led to the establishment of this Inquiry are yet another reason that additional funding for staff in LTC homes is necessary: to ensure the safety and security of LTC home residents.

VII. Medication Management in Home Care

In Chapter 1, I discuss the increased numbers of people who are aging at home. Many are now receiving healthcare services at home that would previously have been provided in hospitals and LTC homes. Service provider organizations under contract to Local Health Integration Networks (LHINs) arrange for healthcare professionals – including registered nurses, registered practical nurses, and personal service workers – to provide care for clients in their homes.²⁴³ In Chapters 8 and 12 of this Report, I discuss home care service providers and the LHINs in detail and also make recommendations for improving the safety of those receiving nursing services in the home care setting.

Unlike the heavily regulated medication management system in an LTC home, in the home care setting the client is in his or her own home and in control of the environment, including medications. As a result, medication management in home care is largely the client's responsibility, although caregivers who go into the home may offer some guidance. Although caregivers who go into the home may offer some guidance. Although care settlaufer committed her last Offence while delivering home care nursing services, we must take steps to minimize the opportunities for wrongdoing in the home care setting. After briefly describing the medication management process in the home care setting, I will explore two strategies for improved medication safety in home care.

²⁴² Ontario, Office of the Chief Coroner, Geriatric and Long-Term Care Review Committee, 2016 Annual Report (October 2017), p 14.

²⁴³ Expert Report of Julie Greenall, p 33.

²⁴⁴ Testimony of Julie Greenall, Transcript, p 8332.

A. Medication Management in the Home

1. Dispensing

Home care clients receive their medications, including insulin, from their usual pharmacy.²⁴⁵ If the client needs to have intravenous or injectable medications, they "are commonly provided by a specialty pharmacy contracted to provide medication preparation services for a particular geographic region."²⁴⁶ The pharmacy sends the necessary supplies and equipment to the client's home.²⁴⁷ Thus, by the time a nurse arrives at the client's home to provide nursing services, the client's medications are already in the home.

2. Storage

Clients are responsible for storing their medications. Nurses who work in home care do not set up medication storage areas but may offer suggestions about safe storage.²⁴⁸

There are special rules for opioids that are administered in the home care setting – their delivery to the home is tracked, and only nurses can program any opioid infusion devices or pumps. However, there is no tracking of insulin's use or disposal. Once medications are in the home, "there are no controls or limited controls ... on who can access the medications, and diversion can occur." Family members and visitors to the home may be able to access the client's medications, thereby creating the risk of diversion.

3. Administration

In LTC homes, registered nurses administer all the medications to all the residents. In the home care setting, however, nurses administer only some medications to the client. For example, they administer intravenous antibiotics and intravenous or subcutaneous opioid infusions for pain management.²⁵¹

²⁴⁵ Expert Report of Julie Greenall, p 33; Testimony of Tamara Condy, Transcript, June 27, 2018, p 3908.

²⁴⁶ Expert Report of Julie Greenall, p 33.

²⁴⁷ Expert Report of Julie Greenall, p 33; Testimony of Tamara Condy, Transcript, p 3907.

²⁴⁸ Testimony of Julie Greenall, Transcript, p 8305; Testimony of Tamara Condy, Transcript, pp 3908–9; Testimony of Donna Ladouceur, Transcript, Aug. 8, 2018, pp 7694–95.

²⁴⁹ Testimony of Tamara Condy, Transcript, p 3909.

²⁵⁰ Expert Report of Julie Greenall.

²⁵¹ Expert Report of Julie Greenall, p 33. See also Testimony of Donna Ladouceur, Transcript, p 7692.

While most medications do not require a nurse to administer them, nurses may play a role in helping clients learn to self-administer new medications. For example, a person newly diagnosed with diabetes may need a nurse's help in learning how to self-administer insulin injections.²⁵² Apart from these matters, the client is responsible for self-administering all medications.

Unlike LTC homes in which a variety of staff are present, in home care, normally a single nurse provides nursing services. Other healthcare providers are not present to check when the nurse administers medication. Some organizations encourage the client's family member to be there to provide that check. Others use "remote checks," particularly for pump settings, allowing healthcare professionals located off-site to confirm the settings through a cell phone or Skype. Saint Elizabeth Health Care, a service provider that delivers publicly funded home care, requires its nurses to call in whenever they perform a medication calculation.

4. Monitoring

Medication incidents and adverse drug events pose a risk in the home care setting.²⁵⁸ While home care clients may be visited by nurses and other staff who work for service provider organizations, they do not receive around-the-clock care.²⁵⁹ Apart from times when service provider staff are in the home, the client and any family members who may be present are responsible for monitoring the outcomes of medication administration. Thus, it is important that clients and their family members are aware of and alert to the signs and symptoms of toxicity. Ms. Greenall emphasized that "whenever we're prescribing medication for anyone, or dispensing it, we have a responsibility to educate that person about the medication, about the signs and symptoms of problems, and when they should seek medical attention."²⁶⁰

²⁵² Testimony of Julie Greenall, Transcript, p 8306; Testimony of Donna Ladouceur, Transcript, p 7692.

²⁵³ Testimony of Donna Ladouceur, Transcript, p 7712.

²⁵⁴ Expert Report of Julie Greenall, p 33.

²⁵⁵ Expert Report of Julie Greenall, p 33.

²⁵⁶ Testimony of Julie Greenall, Transcript, p 8307.

²⁵⁷ Testimony of Tamara Condy, Transcript, p 3832.

²⁵⁸ Expert Report of Julie Greenall, p 33.

²⁵⁹ Testimony of Donna Ladouceur, Transcript, p 3832.

²⁶⁰ Testimony of Julie Greenall, Transcript, p 8313.

It appears that there is insufficient awareness of the need for education that Ms. Greenall describes. ISMP Canada conducted a review of 45 deaths associated with medication incidents that took place outside regulated healthcare facilities – in an individual's home, a group home, and another residential setting.²⁶¹ In these incidents, medications had been administered by the client, a family member, or other unregulated provider. A key theme identified in the review is a deficit of knowledge related to the signs and symptoms of toxicity. "Unfortunately, in many of the incidents, caregivers or family members did not recognize warning symptoms of toxicity, resulting in missed opportunities for rescue measures." ²⁶²

5. Disposal

As discussed above, LTC homes must comply with strict regulations concerning the disposal of medications, especially controlled substances. These regulations do not apply in the home care setting. As Ms. Greenall observed:

Large supplies of unused medications left in the home after a patient dies can be particularly problematic – processes for ensuring return of these medications to a community pharmacy or other safe means of disposal are not consistently available or followed. Most rely on family members to return unused medications, rather than scheduled pick-ups. ²⁶³

Any leftover or unused medications in a home present a risk of diversion. They may be taken by others and used in a way other than intended.²⁶⁴

²⁶¹ Expert Report of Julie Greenall, p 34.

²⁶² Expert Report of Julie Greenall, p 34.

²⁶³ Expert Report of Julie Greenall, p 34.

²⁶⁴ Testimony of Julie Greenall, Transcript, pp 8307–8.

B. Improving Medication Safety in the Home Care Setting

Two strategies can help improve medication safety in the home care setting. These strategies form the basis of recommendations found in Chapter 12.

First, clients and their families should be educated generally on the signs and symptoms of toxicity and when they should seek medical attention.²⁶⁵ Specifically, those who take insulin should be educated about hypoglycemia and the importance of dealing with it immediately.²⁶⁶

Second, clients and their families should be told about MedsCheck at Home, a program in which a pharmacist reviews medications in private homes. Through this program, a community pharmacist goes to a person's home and reviews the medications that the individual is taking and where they are stored. The pharmacist will remove and dispose of expired medications and those that the individual is no longer taking. Through the MedsCheck at Home program, the pharmacist learns about the client and is able to assess the risks and challenges that the individual faces in safely storing medications.

The MedsCheck at Home program is voluntary. It is funded by the Government of Ontario.²⁶⁸ Anyone who is taking more than three regularly prescribed medications is eligible for the program.²⁶⁹

²⁶⁵ Expert Report of Julie Greenall, p 36.

²⁶⁶ Testimony of Julie Greenall, Transcript, p 8313.

²⁶⁷ Expert Report of Julie Greenall, p 35.

²⁶⁸ The Ministry of Health and Long-Term Care has proposed changing the eligibility criteria of the MedsCheck Program, limiting it to patients who are in "transitions between care" (e.g., hospital to home) and focusing resources according to risk of medication-related errors and impact on patient outcomes during transition between care settings: see Ministry of Health and Long-Term Care Drugs and Devices Division, Notice: Proposals to Establish More Efficient Pharmacy Reimbursement Policies, April 25, 2019, p 2.

²⁶⁹ Testimony of Julie Greenall, Transcript, pp 8309–10.

RECOMMENDATIONS

A three-pronged approach should be taken to deter wrongdoers from intentionally harming residents through the use of medication:

- strengthen the medication management system in long-term care (LTC) homes;
- · improve medication incident analysis in LTC homes; and
- increase the number of registered staff in LTC homes.

Strengthen the Medication Management System in Long-Term Care (LTC) Homes

Recommendation 74: The Minister of Health and Long-Term Care should issue a policy directive clarifying that a licensee must ensure that the long-term care home's written policy for the destruction and disposal of drugs covers insulin cartridges.

Recommendation 75: During the annual resident quality inspections in long-term care homes, Ministry of Health and Long-Term Care inspectors should confirm that the licensee's written policy on drug destruction and disposal includes the destruction and disposal of insulin cartridges and that the registered staff in the home are complying with that policy.

- The evidence at the public hearings shows an inconsistency in how registered staff in long-term care (LTC) homes dispose of insulin cartridges, including those that still contain insulin. The insulin in these cartridges can be diverted and used for wrongdoing.
- Section 136 of the Regulation requires licensees to develop a written policy that provides for the ongoing identification, destruction, and disposal of, among other things, medications that "are in containers that do not meet the requirements for marking containers specified under subsection 156(3) of the *Drugs and Pharmacies Regulation Act.*" The provision appears to encompass insulin cartridges once they are removed from pens. Given the importance of limiting diversion of insulin in LTC homes, a policy directive will ensure that licensees are aware of their obligation to establish a written policy on the destruction and disposal of insulin cartridges and to educate staff on the policy.
- Having inspectors include this matter in their annual resident quality inspections will underscore the need for licensees to address it in their policy and training.

Recommendation 76: The Ministry of Health and Long-Term Care should establish a program, to run for a three-year period, under which long-term care homes can apply for a grant to fund one or more of the following:

- installation of glass doors, windows, and/or walls in medication rooms and other rooms in which medications are stored;
- installation of security cameras in medication rooms and other rooms in which medications are stored, as well as in common areas and at entrances and exits;
- purchase or upgrade of integrated automated dispensing cabinets;
- · purchase of a barcode-assisted medication administration system;
- hiring, on a full-time or part-time basis, of a staff pharmacist and/or pharmacy technician.

Note: This recommendation must be read in conjunction with Recommendation 19, which seeks an immediate expansion of the funding parameters of the nursing and personal care envelope to permit long-term care homes to use those funds to pay for a broader spectrum of staff, including pharmacists and pharmacy technicians.

Recommendation 77: The amount of the Ministry of Health and Long-Term Care grant described in Recommendation 76 above should be tied to home size as follows:

- small home (64 beds or fewer): a maximum of \$50,000 each over the three-year period;
- medium home (more than 64 but fewer than 129 beds): a maximum of \$125,000 each over the three-year period; and
- large home (129 beds or more): a maximum of \$200,000 each over the three-year period.

Details

- A "one size fits all" approach to strengthening homes' medication
 management systems would not be effective; each home is unique in
 terms of its culture and needs. The design of the grant program needs to
 take this diversity into consideration.
- Long-term care (LTC) homes should be permitted to apply for the grant funds at any point in the three-year period and on more than one occasion. The grant funding should allow for the ongoing maintenance costs associated with an integrated automated dispensing cabinet (ADC).
- The grant program should specify that the Ministry of Health and Long-Term Care (Ministry) has the discretion to provide additional funding if a home can demonstrate that the funding cap is insufficient.
- The grant program should expressly permit LTC homes to apply jointly
 for grant funds so they can take advantage of economies of scale (e.g.,
 a licensee that operates multiple homes) and share pharmacists and/
 or pharmacy technicians between homes (e.g., where two homes would
 each benefit from a part-time pharmacist on staff).
- Regardless of whether an LTC home has any or all of the options listed above, it should be permitted to apply for grant funding for other innovations that the home demonstrates, and the Ministry accepts, are targeted at limiting medication diversion and/or reducing medication incidents in the home.
- In their grant applications, LTC homes should be required to demonstrate
 how they will integrate the requested option(s) into the home's existing
 medication management system and describe the change management
 strategy to be used on implementation.
- The different grant amounts, tied to home size, reflect the cost of an integrated ADC (which, depending on the number of residents supported by the cabinet, is approximately \$35,000) and the ability of LTC homes to work together to share the costs of salaries for pharmacists and/or pharmacy technicians.

- Like other healthcare serial killers, Wettlaufer committed the Offences using diverted insulin in the homes. Steps must be taken to stop the diversion of all medications, including insulin.
- The options listed above will deter potential wrongdoers and limit diversion of medications. Changing the infrastructure in homes (placing glass windows and doors in medication rooms and cameras in common areas) will increase visibility around medications and key locations in the home. The options that harness the power of technology (ADCs and barcode-assisted medication administration systems) will assist in detecting medication diversion, improve the tracking and auditing of medications, and lead to reduced stocks of medications in the home.
 Some of these options (e.g., security cameras and ADCs) will also help homes in their medication incident investigations.
- Giving pharmacists and pharmacy technicians an expanded role in LTC homes should lead to reduced stocks of medications in the home, thereby limiting the opportunity for diversion; improved medication reconciliations on admission and improved quarterly and annual medication management reviews; and more efficient tracking and auditing of medications. The quality of resident care will be improved because of fewer medication errors and because nurses will be able to spend more time with residents and less time on tracking and recording medications. The University of Windsor report described in this chapter found that each pharmacist-led medication reconciliation saved three hours of nursing time, which could then be used for direct resident care.
- Pharmacists can also play a key role in investigating, documenting, analyzing, and reporting medication incidents that is, they can improve medication incident analysis, the second prong in my strategy for deterring wrongdoers from intentionally harming residents. They can assist in implementing new technology; train staff on medication-related obligations under the *Long-Term Care Homes Act, 2007*, and its regulations; and provide residents, substitute decision-makers, and family members with information about medications and their side effects. The pharmacist's involvement will reduce management workload, leaving management with more time for oversight, staff supervision, and resident care initiatives.
- A staff pharmacist will generate significant cost savings and improved resident outcomes through deprescribing initiatives and faster discontinuance of unnecessary medications.

Improve Medication Incident Analysis in LTC Homes

Recommendation 78: Management in long-term care homes should cultivate a "just culture" – one in which human error is dealt with openly rather than punitively.

Rationale for Recommendation 78

- In a just culture, team members discuss errors and maintain a focus on the safety and well-being of residents, rather than worrying about the consequences of making honest mistakes.
- Fostering a just culture helps deter acts of intentional harm because team members feel able to report staff members' suspicious or concerning behaviours.

Recommendation 79: Long-term care homes should analyze medication incidents and adverse drug events through an incident analysis framework that includes screening for the potential of intentional harm.

- Licensees should ensure that staff executing section 135 reviews and participating in the quarterly evaluations of the medication management system required by the Regulation are trained in incident analysis.
- The Canadian Incident Analysis Framework (CIAF) or other such proven framework should be used, and suitable training should be provided on it.
- While the primary goal of the CIAF is quality improvement, it specifically helps to identify situations of intentional harm.

Recommendation 80: The Minister of Health and Long-Term Care should issue a policy directive requiring long-term care homes to treat the use of glucagon as a medication incident, as that term is described in section 1 of Ontario Regulation 79/10.

Details

The policy directive should specify that, by treating glucagon as a
medication incident as described in section 1, licensees must then
comply with all regulatory requirements relating to medication incidents,
including those in sections 107, 115, 116, and 135 of the Regulation.

- The use of glucagon falls within the legislative intention underlying
 the regulatory scheme governing medication incidents. Because the
 description of "medication incident" in section 1 is ambiguous, a Minister's
 policy directive is needed to ensure that licensees understand that they
 must treat the use of glucagon as a medication incident.
- Three of Wettlaufer's victims Clotilde Adriano, Wayne Hedges, and Arpad Horvath – were treated with glucagon for hypoglycemia. (Only the Offence against Mr. Horvath was committed after section 135 of the Regulation came into effect.) Investigating the incidents in accordance with section 135 of the Regulation increases the likelihood of detecting the root cause for the incident.
- If the use of glucagon is treated as a medication incident and the resident
 is taken to hospital as a result of the glucagon incident, section 107(3) of
 the Regulation applies, with the result that the licensee must inform the
 Director (a position created by the Long-Term Care Homes Act, 2007, and
 filled by a person in the Ministry) and file a Critical Incident report.

Recommendation 81: The Long-Term Care Homes Division of the Ministry of Health and Long-Term Care must advise long-term care homes that the use of glucagon constitutes a medication incident and is subject to the requirements of section 135 of Ontario Regulation 79/10.

Rationale for Recommendation 81

- Section 135 reviews require the licensee to document, report, review, and analyze incidents. Such reviews provide an opportunity to detect intentional harm. And they act as a deterrent because potential wrongdoers will know their actions are likely to come to light.
- In addition to deterring and detecting intentional harm, conducting
 a section 135 review in response to the use of glucagon may improve
 the quality of care for residents. Medication incidents resulting from
 pharmacologic incompatibility and accidental medication errors may be
 identified and possible similar future mistakes may be reduced.

Recommendation 82: Long-term care homes should document and track the use of glucagon to identify patterns and trends, and they should flag where further investigation should be undertaken.

- Documenting and tracking all cases in which glucagon is used will
 allow the home to detect patterns and trends. The home can use this
 information when considering whether further investigation is needed to
 determine the root causes of the incidents.
- Such patterns and trends should be reviewed during the home's quarterly evaluation of the effectiveness of the medication management system mandated by section 115 of the Regulation.

Recommendation 83: The Long-Term Care Homes Division of the Ministry of Health and Long-Term Care should consult with organizations such as the Institute for Safe Medication Practices Canada to develop a comprehensive list of rescue agents and "trigger tools" that identify potential medication incidents. It should consider whether, like glucagon, use of these rescue agents and trigger tools ought to be treated as medication incidents. If so, that information should be given to the long-term care homes with appropriate explanations and instructions on how to use it.

Rationale for Recommendation 83

Insulin is not the only medication that healthcare serial killers (HCSKs)
have used. If insulin overdosing is identified by investigating the use of
glucagon, an HCSK might switch to using other medications. Those in the
long-term care system need to stay up to date about any medications that
can be used to intentionally harm residents as well as the trigger tools or
rescue agents that are associated with medication incidents.

Recommendation 84: The Minister of Health and Long-Term Care should issue a policy directive requiring long-term care homes to treat severe or unresponsive hypoglycemia as a medication incident, as that term is described in section 1 of Ontario Regulation 79/10.

Details

 The policy directive should specify that, by treating severe or unresponsive hypoglycemia as a medication incident as described in section 1, licensees must comply with all regulatory requirements relating to medication incidents, including those in sections 107, 115, 116, and 135 of the Regulation.

Rationale for Recommendation 84

 The presence of severe or unresponsive hypoglycemia falls within the legislative intention behind the regulatory scheme governing medication incidents. Because the description of medication incident in section 1 is ambiguous, a Minister's policy directive is needed to provide clarity and ensure that licensees understand they must treat severe or unresponsive hypoglycemia as a medication incident.

Increase the Number of Registered Staff in LTC Homes

Recommendation 85: The Ministry of Health and Long-Term Care should conduct a study to determine adequate levels of registered staff in long-term care (LTC) homes on each of the day, evening, and night shifts. The Minister of Health and Long-Term Care should table the study in the legislature by July 31, 2020. If the study shows that additional staffing is required for resident safety, LTC homes should receive a higher level of funding overall, with the additional funds to be placed in the nursing and personal care envelope.

- Wettlaufer committed the Offences on evening and night shifts when few or no other registered staff were on duty. On the evidence presented, this may have contributed to Wettlaufer's ability to commit the Offences without detection.
- The current level of funding for nursing and personal care in long-term care (LTC) homes is such that, without an overall funding increase, a recommendation to increase the number of registered staff on the evening and night shifts could lead to fewer registered staff being assigned to work the day shift, where they are particularly needed to provide residents with care. Given the demands on those working days shifts, I do not recommend simply reallocating registered staff from day shifts to evening and night shifts.
- The number of registered staff in LTC homes required on each shift to ensure that residents are safe needs to be determined based on evidence.
- The Ministry has funded some staffing increases in recent years, but these
 increases have not kept pace with the growing demands on those who
 work in LTC homes, owing both to the increasing acuity of residents and
 the regulatory burdens associated with the implementation of the LongTerm Care Homes Act, 2007.

Detecting Intentionally Caused Resident Deaths

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I. Introduction

Even the best-crafted measures of deterrence may not always prevent a healthcare serial killer (HCSK) from harming residents. Steps must be taken to strengthen Ontario's death investigation process, as it relates to residents in long-term care (LTC) homes, so that it is better equipped to detect intentionally caused resident deaths. Those steps are the primary focus of this chapter.

I begin the chapter by addressing two contextual considerations that inform the resident death investigation process. First, it is important to understand the challenges to detecting intentionally caused resident deaths. Second, it is useful to consider the methods by which HCSKs have been detected in the past and why they are inadequate to meet the threat posed by such killers.

After providing this context, I look at the number of resident death investigations conducted in the province annually and explain why that number has declined significantly in the past decade. I then make the case for increasing the number of resident death investigations and propose that an "informed" resident death investigation process is the means to achieve that objective.

The informed resident death investigation process would rely on two primary sources of information. The first source of information is the redesigned, evidence-based Institutional Patient Death Record (IPDR) called for in Chapter 14 of this Report. The second is the Ministry of Health and Long-Term Care's data analytics project to determine when LTC homes have higher than expected death rates. In the sections that follow the description of the informed death investigation process, I describe the redesigned IPDR and the Ministry project, and the role that each are to play in strengthening Ontario's death investigation process for residents.

I conclude the chapter with a discussion of whether the informed death investigation process for residents – or some part of it – might be adapted for use in the home care sector.

II. The Challenges to Detecting Intentionally Caused Resident Deaths

Four factors make it particularly challenging to detect deaths in LTC homes resulting from intentional wrongdoing. First, it is not unusual for residents, who are often ill and of advanced age, to die while living in an LTC home. As a result, their deaths are rarely seen as suspicious and warranting investigation. Second, residents are vulnerable and often unable to "sound the alarm" if a staff member intentionally harms them. Even if they do raise concerns, they may not be believed. Third, much medication is administered in LTC homes: medication is a ready means of inflicting harm, and its use in the homes does not arouse suspicion. Fourth, there is limited supervision of staff in LTC homes, which means there are more opportunities for wrongdoing and less likelihood of its detection. I explore each of these factors below.

A. Deaths in LTC Homes Are Often Expected

Approximately 20% of residents in Ontario LTC homes die each year.¹ As a result, the death of a resident in an LTC home is an "often expected … outcome."²

Because deaths in LTC homes are often expected, they are rarely investigated. Older victims tend to fall through the cracks of the death investigation process because their deaths are frequently recorded as "natural." One coroner testified at the public hearings that it is not helpful to ask if a resident's death was "sudden and unexpected," as is now done on the IPDR, because residents typically have many co-morbid conditions.⁴

Another result of resident deaths being expected is that potential evidence relating to those deaths is neither routinely collected nor stored. Professor Beatrice Crofts Yorker gave expert evidence on the HCSK

¹ Testimony of Dr. Michael Hillmer, Transcript, Sept. 14, 2018, p 8430.

² Expert Report of Professor Beatrice Crofts Yorker Schumacher, May 27, 2018, p 13.

³ David R. Kent and Patrick D. Walsh, "Modern U.S. Healthcare Serial Killings: An Exploratory Study and Work in Progress," in Valerie Pottie Bunge, Carolyn Rebecca Block, and Michael Lane (eds.), Linking Data to Practice in Violence and Homicide Prevention: Proceedings of the 2004 Meeting of the Homicide Research Working Group (Chicago: HRWG Publications, 2004), 178.

⁴ Testimony of Dr. William George, Transcript, July 18, 2018, pp 4672–74.

phenomenon in this Inquiry.⁵ Professor Crofts Yorker explained, "Healthcare settings are not treated as potential crime scenes, thus medical supplies and equipment that could provide important evidence are not routinely preserved."

B. LTC Home Residents Are Vulnerable

As discussed in Chapters 1 and 4, the acuity of LTC home residents has consistently risen over the past decade and it will continue to rise as people live longer. Many residents have diminished capacity, making it more challenging for them to recognize, resist, or report abuse or intentional harm. This diminished capacity may be compounded by dementia, delirium, and the effects of medications, which can leave residents sedated or in an altered mental state. Moreover, bruises left from abuse that might otherwise raise alarms may be dismissed if the resident has required restraints or sedation because of responsive behaviours or physical aggression. All these matters make LTC residents particularly vulnerable to deliberate harm.

Wettlaufer said that she chose vulnerable residents because they would not be able to report her deeds: "Every patient I ever picked had some dementia and that was part of what became my criteria. If they had dementia ... they couldn't report or if they reported they wouldn't be believed." When sentencing Wettlaufer for the Offences, Justice Thomas found that the residents she targeted were all "exceedingly vulnerable" to abuse.

The Coroner's Investigation Manual recognizes that residents in LTC homes are vulnerable, and instructs coroners to be alert to this fact:

While the vast majority of their deaths are uncomplicated, the coroner needs to be open to the possibility of injury, abuse and neglect, in the same way as one would when investigating the death of a child or other vulnerable member of society. 10

Professor Crofts Yorker Schumacher generally does not use "Schumacher" when giving her name. For this reason, she is referred to as Professor Crofts Yorker throughout the text of this Report. She was qualified as an expert witness in the areas of "studies of healthcare serial killing" and "nursing education." Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, Sept. 12, 2018, p 7967.

⁶ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 13.

⁷ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 7.

⁸ Commission interview with Elizabeth Wettlaufer, Feb. 14, 2018, p 60.

⁹ R v Wettlaufer, 2017 ONSC 4347, p 2.

¹⁰ Coroner's Investigation Manual, chap. 11, in Affidavit of Dirk Huyer, Exhibit W, p 1.

C. Detection Challenges Associated with Medication Administration

Julie Greenall was qualified in the public hearings to give expert testimony in the areas of medication management in long-term care and medication safety management more generally. In her expert report, ¹¹ Ms. Greenall explained that most residents in LTC homes take multiple medications daily: "Nearly two-thirds (60.9%) of Canadians aged 65 and older who live in LTC homes take 10 or more different prescription drugs."

Nurses have the primary responsibility for administering medications to residents in LTC homes. As a result, they have easy access to many medications. There can be a fine line between a therapeutic and a toxic dose of medication. In an interview with psychologist Katherine Ramsland, Professor Crofts Yorker noted, "The brink between toxic and therapeutic doses of what are usually therapeutic medications is so imperceptible." 13

The intentional wrongful administration of injectable medication can be difficult to detect. In LTC homes, the administration of such medication is common, and most residents are expected to have needle marks. The wrongful injection of medications through intravenous (IV) or PICC (a peripherally inserted central catheter, much like an IV) lines is even more difficult to detect because it allows a person to inject a medication into the line's port, leaving no needle mark.

Like many other HCSKs, Wettlaufer committed the Offences by injecting her victims with overdoses of insulin. In LTC homes, detecting the wrongful use of insulin is made more challenging because:

- Insulin is commonly found in LTC homes, with several insulin-dependent residents on every unit within the home.¹⁴
- The dose of insulin for each resident is different. Even for the same resident, there can be variation on a dose-by-dose basis. While some people may require as little as four units of insulin per day, others may need over 300 units daily. The dosage frequency also varies from resident

¹¹ Expert Report of Julie Greenall, June 1, 2018.

¹² Expert Report of Julie Greenall, p 16.

¹³ See also Katherine Ramsland, *Inside the Minds of Healthcare Serial Killers: Why They Kill* (Westport, Conn.: Praeger, 2007), 128.

¹⁴ Expert Report of Julie Greenall, p 14.

to resident. Some residents may need insulin only once a day, while others can require four or more injections per day. Because of the lack of standard dosing, insulin pens must be easily manipulated in terms of the quantity delivered.¹⁵

- The symptoms exhibited as a result of hypoglycemia following an overdose of insulin are non-specific, making it difficult to distinguish deaths resulting from insulin overdoses from natural deaths. 16 Dr. Michael Pollanen, Ontario's chief forensic pathologist, described these non-specific symptoms: "In mild hypoglycemia, the symptoms are confusion, pallor, diaphoresis, shakiness, irritability, anxiety, tachycardia, dizziness, headache, weakness and reduced level of consciousness. In severe hypoglycemia, there can be irreversible brain damage with coma and death, which is called hypoglycemic encephalopathy. Persons with hypoglycemic encephalopathy may appear to have had a stroke, both in terms of clinical presentation and imaging." 17
- Often, there will be a lag between the injection of an overdose of insulin
 and the resulting harm or death. This lag makes it more difficult to connect
 the resident's harm or death to a particular caregiver, whose shift may have
 ended several hours or days before the adverse outcome occurs.¹⁸

In her expert report prepared for this Inquiry, Professor Crofts Yorker summarized the challenges to detecting harm caused through the intentional injection of an overdose of insulin:

Many patients in hospitals and long-term care are on insulin, therefore they have their own supply of this medication, typically in both long acting and short acting forms. Insulin can take hours or days to induce coma or death. The symptoms of hypoglycemia are non-specific and can vary from patient to patient. If detected, it can be reversed with administration of IV Dextrose, which may revive a patient who was given a toxic dose of insulin, without suspicion of wrongdoing. A killer who overdoses a patient on insulin has often been off the premises for several hours or shifts when the patient is adversely affected by the overdose. 19

¹⁵ Expert Report of Julie Greenall, pp 12, 14.

¹⁶ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 13.

¹⁷ Affidavit of Dr. Michael Pollanen, para 102.

¹⁸ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 13.

¹⁹ Expert Report of Professor Beatrice Crofts Yorker Schumacher, pp 5, 13.

D. Limited Supervision in LTC homes

LTC homes have little direct supervision of nursing staff on evening and night shifts, where there may be only one registered nurse (RN) on duty. Professor Crofts Yorker explained the contrast between staff supervision in LTC homes and in hospitals as follows:

Less direct supervision. Less ancillary personnel. So in a hospital you'll have respiratory therapists coming in and out, you'll have dieticians, you'll have a variety of interdisciplinary staff. It's a hustling, bustling place with a lot of people. And when you get to long-term care there are less daily opportunities for interaction, less people going in and out of patients' rooms, just less eyes of credentialed people.²⁰

As a result, wrongdoing in LTC homes is less likely to be observed by colleagues or supervisors.²¹

III. Existing Methods for Detecting Healthcare Serial Killers

Despite these challenges, HCSKs have been detected in the past. In general, three methods have led to their detection: investigations prompted by suspicions expressed by patients or their families, or healthcare workers (primarily nurses); toxicology testing; and the identification of anomalous death patterns or elevated death rates in healthcare settings. All three methods have serious limitations, as I explain below. In light of the Offences, it is clear that these methods are insufficient to meet the threat posed by an HCSK such as Wettlaufer. See Chapter 1 in which I explain how the Offences would have gone undetected had she not confessed.

A. Suspicious Residents, Families, or Healthcare Workers

In her expert report, Professor Crofts Yorker describes several cases in which patients or family members complained that just before the patient experienced an adverse event – such as a cardiac arrest or death – they saw a nurse give the patient an injection.²² American nurse Richard Angelo is an example. Angelo was apprehended after a patient survived a cardiac arrest and

Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, Sept. 12, 2018, pp 8091–92.

²¹ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 9.

²² Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 12.

reported that he had seen Angelo inject something into his IV just before he stopped breathing.²³ Angelo was ultimately convicted of murdering four patients.

Although voicing concerns about care is important, this method cannot be relied on for detecting intentionally caused harm by a healthcare provider. Patients, residents, and families have much to occupy their attention, especially if the person receiving care takes a turn for the worse. Moreover, it is important that their relationships with caregivers are not undermined by the suspicion that the caregivers may intend to cause harm.

There are also cases in which healthcare workers have suspected wrongdoing, with the result that investigations have been undertaken and HCSKs detected. Professor Crofts Yorker found that it was often nurses who triggered investigations after reporting their suspicions that patient deaths were linked to the presence of a particular caregiver.²⁴ One example is American nurse Kristen Gilbert, who was suspected of killing as many as 50 patients by spiking IV bags with epinephrine in a hospital. Gilbert was ultimately convicted, in 2001, of four murders and two attempted murders.²⁵ Staff had become suspicious of the number of deaths when Gilbert worked the evening shift and raised the alarm, ultimately leading to her arrest.

American nurse Orville Lynn Majors is another example. Majors was linked to 124 suspicious deaths. In 1999, he was convicted of the murder of six patients in a rural Indiana hospital, by injecting them with epinephrine and potassium chloride. From 1990 to 1993, there were between 24 and 31 deaths each year in the 56-bed intensive care unit. However, in 1994, the year after Majors was hired, 101 patients died even though the number of admissions remained constant. On her own initiative, the director of the intensive care unit started tracking mortalities and shifts. Variety Nurses had also noticed a link between suspicious deaths and Majors, which they reported, assisting in his apprehension.

²³ Expert Report of Professor Beatrice Crofts Yorker Schumacher, Tab F; Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, pp 7988–89, 8022–23.

²⁴ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 13.

Elizabeth Mehren, "Ex-VA nurse is spared death penalty," Los Angeles Times, Mar. 27, 2001, https://www.latimes.com/archives/la-xpm-2001-mar-27-mn-43272-story.html [accessed Apr. 2, 2019]; Kenneth W. Kizer and Beatrice C. Yorker, "Health Care Serial Murder: A Patient Safety Orphan" (2010) 36(4) The Joint Commission Journal on Quality and Patient Safety 187.

²⁶ Expert Report of Professor Beatrice Crofts Yorker Schumacher, Tab F; "Nurse guilty of killing six of his patients," New York Times, Oct. 10, 1999.

²⁷ James M. Thunder, "Quiet Killings in Medical Facilities: Detection & Prevention" (2003) 18(3) Issues in Law & Medicine 223.

²⁸ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 8011.

In light of these examples, Professor Crofts Yorker emphasized the importance of educating healthcare workers about the difference between "an expected, normal, or a good death" and "an atypical or abnormal death" for different populations in LTC homes.²⁹ She maintains that this education helps healthcare workers assess whether a resident's death has "unexpected" elements.³⁰

Although healthcare staff sometimes detect wrongdoing, they too can play only a limited role. Their heavy workload keeps them fully occupied, leaving little time to speculate about the conduct and motives of others on the healthcare team. Further, healthcare workers must work collaboratively if they are to provide residents with the best possible care. The College of Nurses of Ontario's professional standards require nurses to establish "respectful, collaborative, therapeutic, and professional relationships" with clients, colleagues, and employers.³¹ Working collaboratively does not fit with a culture of suspicion and, indeed, is likely to be counterproductive. In this regard, we can learn from the Ontario Inquiry into Pediatric Forensic Pathology, which showed the dangers that flow from forensic pathologists "thinking dirty" when conducting autopsies. 32 It would be poor policy to ask healthcare workers to "think dirty" about their colleagues in LTC homes, especially as the overwhelming majority are well-intentioned and doing their utmost to provide residents with the best possible care. Having said this, there are methods for raising awareness among healthcare providers that increase the possibility of detection without fostering a culture of suspicion. As discussed in the recommendations in Chapter 16, education and training on the HCSK phenomenon should not be dealt with as a stand-alone matter. Rather, it should be integrated into training on risk management, patient / resident safety, patient / resident outcomes, and professionalism. In this way, awareness of the possibility that a healthcare provider may intentionally harm those for whom they provide care is raised without creating a climate of fear and mistrust.

²⁹ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 8057.

³⁰ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, pp 8051–52.

³¹ College of Nurses of Ontario, Professional Standards, Revised 2002 (Toronto: CNO, 2018), p 3 (footnotes omitted).

Ontario, Report of the Inquiry into Pediatric Forensic Pathology in Ontario, Vol. 1: Executive Summary (4 vols., Toronto: Ontario Ministry of the Attorney General, 2008) (Commissioner Stephen T. Goudge), 33, 43.

B. Toxicology Testing

There are circumstances where toxicology samples taken at the time of an adverse patient incident or death reveal the presence of a toxic amount of medication and help detect an HCSK. However, toxicology samples taken after the lapse of even a short period of time after death are generally unhelpful. As Professor Crofts Yorker explained:

Toxicology evidence can absolutely nail it if you get it immediately after a cardiac or pulmonary arrest and you show extremely high levels of a respiratory paralyzing agent that was not ordered. Those are cases that will go to court and be clear and convincing and often are guilt beyond a reasonable doubt.

Where it gets tricky is hours after a patient dies, and particularly on exhumation, because there's been no clinical trials, no real good data collection.

So if you can get the toxicology evidence right after a code, right after resuscitation, or right after a death, and it happens to show a substance like an opiate that is in toxic levels that wasn't ordered or even if it was ordered is in toxic levels, then it can be very helpful.³³

Further, toxicology testing can detect only a limited number of substances. Professor Crofts Yorker testified that the drugs most commonly used by healthcare workers to harm patients or residents, such as insulin, are the most difficult to detect.³⁴ While opiates or respiratory paralyzing agents are easier to detect, insulin is "particularly difficult" to trace.³⁵

Dr. Pollanen gave evidence that performing routine toxicology testing on residents when they die is not workable. There is no such a thing as "routine" toxicology testing because the substances to be tested for must be decided on a case-by-case basis, depending on the history of the case and the findings of an autopsy. Toxicology tests performed in the absence of a medical and scientific foundation are highly unlikely to produce any meaningful information.³⁶

Dr. Pollanen also explained that testing blood after death for irregularities in insulin levels is not an option. The Centre of Forensic Sciences (CFS), which conducts toxicology testing for death investigations in Ontario, does not

³³ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 7986.

³⁴ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 7986.

³⁵ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 7987.

³⁶ Testimony of Dr. Michael Pollanen, Transcript, July 23, 2018, pp 5000–2.

perform insulin testing nor does any forensically accredited laboratory in Ontario at this time.³⁷ Even if the CFS were to acquire the instrumentation needed to test for insulin, it is unlikely to provide any meaningful information in the absence of also performing a comprehensive death investigation autopsy. Insulin is naturally present in the body, and changes that occur after death make it difficult to distinguish between naturally produced insulin and synthetic insulin.³⁸ The fact that death can occur days after the insulin was administered also makes its detection virtually impossible.³⁹ As Dr. Pollanen explained, detecting the presence and level of insulin in a post mortem sample would be very challenging, such that the testing "may not meet the forensic requirement for reproducibility and reliability."⁴⁰ To prevent deleterious changes, post mortem blood samples would have to be taken immediately upon death and immediately frozen and stored.⁴¹ For reasons described in Chapter 19, this is impractical.

C. Using Data to Detect Unusual Spikes, Patterns, and Clusters of Deaths

Unusual mortality patterns have, in several cases, led to the detection of HCSKs. For example, in 1984 in St. Petersburg, Florida, the medical examiner was alerted to 12 deaths in a 54-bed nursing home, which occurred over less than two weeks. No more than three deaths would have been expected in that time period. The medical examiner asked the Florida Department of Health and Rehabilitation Services, Office of the State Epidemiologist, to assist in the investigation. The investigation team found no increase in hospital-acquired infections and no change in the age, gender, or race of the patients that could account for the increased number of deaths. 42 However, when the

³⁷ Affidavit of Dr. Michael Pollanen, paras 105–7. Dr. Pollanen reported that under the *Forensic Laboratories Act, 2018* (SO 2018, c 3, Schedule 8 – not yet in force as of June 29, 2018), insulin tests will not be allowed in legal proceedings unless the laboratory is accredited by a body prescribed by the regulations (which are anticipated to require international accreditation standards for forensic laboratories). Dr. Pollanen also noted that he is not aware of any accredited forensic laboratory in Ontario at this time that would be able to do this type of insulin testing: Affidavit of Dr. Pollanen, para 107.

³⁸ Affidavit of Dr. Michael Pollanen, paras 106–7.

³⁹ Affidavit of Dr. Michael Pollanen, para 107.

⁴⁰ Affidavit of Dr. Michael Pollanen, para 106.

⁴¹ Affidavit of Dr. Michael Pollanen, para 106.

⁴² Jeffrey J. Sacks et al., "A Cluster of Unexplained Deaths in a Nursing Home in Florida" (1988) 78(7) American Journal of Public Health 806–7. Data on monthly deaths and death rates per 1,000 residents in all 69 nursing homes in the county were also considered for the period 1976–84.

team examined patterns related to the timing of deaths and the presence of particular staff members, it found two nurses had the strongest and most consistent association with the deaths:

In this study, 67 per cent of the epidemic deaths occurred between 3:00 a.m. and 11:00 a.m. compared to 36 per cent of previous deaths. Moreover, 58 per cent of the epidemic deaths had onset of the terminal event on the night shift compared to 4 per cent of previous deaths ... Nurses 7 and 18 had the strongest and most consistent associations with the time of onsets of terminal events and deaths.⁴³

This investigation ultimately led to the apprehension and conviction of HCSK Bobbie Sue Dudley, in 1988, for the murder of four residents by strangling them or injecting them with insulin overdoses.⁴⁴

Another example is the detection and conviction of nurse Genene Jones. In March 1983, the commissioner of the Texas Department of Health asked the Centers for Disease Control to help them evaluate the apparent increased mortality in the pediatric intensive care unit of a San Antonio hospital. The consequent epidemiological and clinical investigation revealed that one nurse, Genene Jones, was associated with the increased number of deaths. She was ultimately prosecuted and convicted in 1984 of one murder, and later confessed to having killed several more patients.

The academic literature confirms that a close surveillance of mortality clusters,⁴⁷ death spikes, and adverse outcomes in hospitals and LTC homes can be helpful in detecting HCSKs. In her report filed for the Inquiry, Professor Crofts Yorker noted that, in five published cases, the Centers for Disease Control investigated suspicious clusters of deaths and identified the presence of a specific nurse as the most strongly linked correlation to these epidemics.⁴⁸ David R. Kent and Patrick D. Walsh further reviewed the literature, media reports, and legal proceedings in 37 cases involving HCSKs in the

⁴³ Sacks et al., "A Cluster of Unexplained Deaths," 808.

Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 8010; Michael Farrell, Criminology of Serial Poisoners (Cham, Switzerland: Palgrave MacMillan, 2018), 57; "Nurse pleads guilty to four murders," UPI, Feb. 24, 1988, https://www.upi.com/Archives/1988/02/24/Nurse-pleads-guilty-to-four-murders/4501572677200/ [accessed April 10, 2019].

Expert Report of Professor Beatrice Crofts Yorker Schumacher, Tab F; Gregory R. Istre et al., "A Mysterious Cluster of Deaths and Cardiopulmonary Arrests in a Pediatric Intensive Care Unit" (1985) 313 New England Journal of Medicine 205–11, 211.

^{46 &}quot;Prosecutor: Former Texas nurse confessed in deaths of babies," Associated Press, April 19, 2018, https://apnews.com/885f5d5dd27c43daa95605c0b2cb82f8 [accessed April 12, 2019].

⁴⁷ A cluster of deaths occurs, for example, when a particular ward or unit experiences a larger than usual number of deaths concentrated during a particular shift.

⁴⁸ Expert Report of Professor Beatrice Crofts Yorker Schumacher, p 12.

United States, ⁴⁹ and concluded that many had involved suspicious clusters of deaths, including:

- a case in Michigan where 35 patients stopped breathing on 51 occasions in six weeks;
- a case in Indiana where there were 67 deaths in a five-month period one death for every 23.1 hours the suspect worked;⁵⁰
- a case in Massachusetts where there were 63 suspicious deaths on one ward in four months; and
- a case in Maryland where the HCSK was the caregiver in 57 of 144 cardiac arrests at the hospital.⁵¹

A number of epidemiological studies have recommended a close surveillance of mortality clusters, death spikes, and adverse patient outcomes in healthcare institutions.⁵² According to Kent and Walsh, HCSKs are increasingly detected through the observation of clusters of deaths, particularly because the number of autopsies conducted on those who die while in healthcare facilities has declined:

Several recent cases were brought to light purely through analytical examination of historical mortality figures that identified the exact shift and precise department where the abnormally high patient-deaths were occurring. Since hospitals no longer routinely perform autopsies, the only method of raising legitimate suspicion was by the linkage between the out of proportion mortality data that clustered by ward and time of day. Rate ratios and relative risk appraisals have been employed to ascertain the frequencies at which patients seized while the various nursing complements were on duty, compared to when each worker was off duty.⁵³

⁴⁹ Kent and Walsh, "Modern U.S. Healthcare Serial Killings," 178 at 180.

⁵⁰ In this case, patients were 49.2 times more likely to perish when the suspect was on duty.

⁵¹ In this case, patients on the HCSK's shift were 47.5 times more likely to suffer cardiopulmonary arrest. This number increased to 100 times more likely to suffer cardiopulmonary arrest on the 23:00 to 07:00 shift.

⁵² Sacks et al., "A Cluster of Unexplained Deaths," 806, 808; Jeoffrey K. Stross, D. Michael Shasby, and William R. Harlan, "An Epidemic of Mysterious Cardiopulmonary Arrests" (1976) 295(20) New England Journal of Medicine 1107–10, 1110; Gregory R. Istre et al., "A Mysterious Cluster of Deaths and Cardiopulmonary Arrests in a Pediatric Intensive Care Unit" (1985) 313 New England Journal of Medicine 205–11, 211; James W. Beuhler et al., "Unexplained Deaths in a Children's Hospital: An Epidemiologic Assessment" (1985) 313(4) New England Journal of Medicine 211, 215–16; Jeffrey J. Sacks et al., "A Nurse-Assisted Epidemic of Cardiac Arrests in an Intensive Care Unit" (1988) 259(5) JAMA 689–95, 695; A. Franks et al., "A Cluster of Unexplained Cardiac Arrests in a Surgical Intensive Care Unit" (1987) 15(11) Critical Care Medicine 1075–76; Kenneth J. Rothman, "Sleuthing in Hospitals" (1985) 313(4) New England Journal of Medicine 258–60, at 259.

⁵³ Kent and Walsh, "Modern U.S. Healthcare Serial Killings," 178 at 179.

Although the statistical surveillance of deaths cannot, in itself, determine whether deaths are the result of intentional harm,⁵⁴ it can help flag deaths for further investigation, which may ultimately reveal the existence of an HCSK.⁵⁵ As Kent and Walsh explained:

Once the mortality figures indicate an inordinately elevated death incidence, epidemiologists begin looking for the source and cause of the trouble. The first indicator is usually a suspicious cluster of patient deaths that can be associated with one particular shift.⁵⁶

Data can provide a viable basis for inspection, leading to detection. Rather than relying solely on human suspicion, appropriate data analysis is a basis for informed inquiry into deaths in LTC homes. The limitation to this method of detection is quite simple: LTC homes are not equipped to collect the appropriate data, analyze it, and use it.

IV. Strengthening the Death Investigation Process for Residents

A. The Need for Increased Numbers of Resident Death Investigations

The full death investigation process consists of three steps: a preliminary consultation, a death investigation, and a post mortem examination, also known as an autopsy. The first two steps are conducted by coroners and the third by forensic pathologists. A brief summary of each step follows. Those wishing a fuller description are directed to Chapter 14.

When notified of a death, a coroner must decide whether to accept the case for a death investigation. To do this, the coroner conducts a preliminary consultation to determine if there is an appropriate foundation for the death investigation, based on the criteria set out in section 10 of the *Coroners Act*. The criteria in section 10(1) are intended to capture deaths that are not natural – for example, that are the result of violence, misadventure,

⁵⁴ Sacks et al., "A Cluster of Unexplained Deaths," 808.

Expert Report of Professor Beatrice Crofts Yorker Schumacher, pp 12–13; Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 7975.

⁵⁶ Kent and Walsh, "Modern U.S. Healthcare Serial Killings," 178 at 180.

negligence, misconduct, or malpractice, or that occur "suddenly and unexpectedly." Other provisions in section 10 relate to deaths that are the result of medical assistance in dying, and those taking place in particular settings or locations, such as correctional institutions and psychiatric facilities. In the preliminary consultation, the coroner makes appropriate inquiries of relevant healthcare professionals and others, such as family members.⁵⁷

If a case is accepted for death investigation, the coroner attends at the scene of the death, whenever feasible, and examines the body. The coroner records his or her observations about the body including its location and position; a description of the deceased's clothing and physical state; type and pattern of lividity; the presence or absence of petechiae (tiny, round spots on the skin resulting from bleeding under the skin); decomposition changes; injuries or signs of trauma; and ligatures, if present. Once the investigating coroner finishes examining the body, he or she must determine whether to order an autopsy. An autopsy is an investigative procedure performed by a forensic pathologist to determine such things as the identity of the deceased, and the cause and means of death; address relevant medico-legal issues; and gather and document forensic evidence for purposes of the criminal justice system. The scope of an autopsy depends on the circumstances of each case. It may include external and internal examinations of the body, toxicology testing, and ancillary testing.⁵⁸

In recent years, many fewer death investigations have been conducted in Ontario on LTC home residents, and even fewer autopsies. Only about 8–9% of resident death investigations in Ontario result in autopsies, whereas autopsies are performed in about 40% of all Ontario death investigations.⁵⁹ Less than 1% of all autopsies conducted by Ontario Forensic Services pathologists in 2015 were of residents in LTC homes.⁶⁰ Table 18.1 summarizes the number of resident death investigations and post mortem examinations conducted in Ontario in the years 2007–17. It shows a marked decrease in both the number of resident death investigations and autopsies performed.

The numbers in Table 18.1 are usefully contrasted with the numbers of overall death investigations and post mortem examinations in Ontario for the same years. Table 18.2 contains that information.

⁵⁷ Affidavit of Dr. Dirk Huyer, paras 54–55, 65–66.

⁵⁸ Affidavit of Dr. Dirk Huyer, paras 68, 70.

⁵⁹ Affidavit of Dr. Dirk Huyer, para 134.

⁶⁰ Affidavit of Dr. Michael Pollanen, para 96.

Table 18.1: Number of Resident Death Investigations and Post Mortem
Examinations by Year

YEAR	LTC HOME DEATH INVESTIGATIONS	POST MORTEM EXAMINATIONS
2007	3,326	160
2008	3,117	111
2009	2,907	111
2010	3,045	84
2011	2,971	77
2012	2,665	81
2013	2,031	77
2014	905	67
2015	927	81
2016*	943	91
2017*	886	86

Source: Affidavit of Dr. Dirk Huyer, para 134, prepared for the public hearings.

Some brief history is needed to understand why the number of resident death investigations in Ontario is dropping.

Until 1995, section 10(2) of the *Coroners Act* required a coroner to investigate every death that occurred in a home for the aged or a nursing home. Amendments to the Act that came into force on March 1, 1995, repealed that provision but added section 10(2.1). This section maintained the home's obligation to report the deaths to a coroner but gave the coroner the discretion to determine whether to investigate the death. (The home's obligation to notify a coroner is fulfilled through its submission of the IPDR to the Office of the Chief Coroner.)⁶¹ The exercise of discretion by a coroner was based on the section 10 criteria described above. However, at the same time, the OCC/OFPS adopted a policy of automatically performing a death investigation on every 10th death that took place in an LTC home, regardless of whether a coroner had investigated any of the previous nine deaths. These were known as "threshold death investigations."

^{*} In Dr. Huyer's affidavit, the figures associated with 2016 and 2017 were described as preliminary and subject to change.

⁶¹ Affidavit of Dr. Dirk Huyer, paras 36–39.

Table 18.2: Number of Death Investigations and Post Mortem Examinations in Ontario by Year

YEAR	TOTAL DEALTHS INVESTIGATED	POST MORTEMS PERFORMED
2007	18,308	6,949
2008	17,528	6,591
2009	16,926	6,392
2010	16,415	6,112
2011	16,298	5,703
2012	16,576	5,708
2013	16,815	5,955
2014	15,115	5,874
2015	15,023	6,138
2016	15,899	6,858
2017	17,154	7,635

Source: Affidavit of Dr. Dirk Huyer, para 85, prepared for the public hearings.

In 2013, the OCC/OFPS stopped conducting threshold death investigations. Those death investigations had accounted for approximately 12% of all OCC/OFPS death investigations, and their elimination led to a significant decrease in resident death investigations and, consequently, autopsies on residents. ⁶² If you refer to Table 18.1, above, you will see this by comparing the information for 2012 with that for 2014. In 2012, there were 2,665 resident death investigations and 81 autopsies, but in 2014 there were only 905 resident death investigations and 67 autopsies.

The Ontario move to conducting fewer resident death investigations and autopsies is consistent with a worldwide trend toward fewer death investigations and autopsies of the elderly.⁶³ Academic literature suggests

⁶² Affidavit of Dr. Dirk Huyer, para 113.

⁶³ Amy Gruszecki et al., "Investigation of Elderly Deaths in Nursing Homes by the Medical Examiner Over a Year" (2004) 25 American Journal of Forensic Medical Pathology 209–12 at 210; Babak Shokrani and Marie N. Fidelia-Lambert, "Geriatric Autopsy Findings in the Last 10 Years: An Urban Teaching Hospital Experience" (2005) 97(3) Journal of the National Medical Association 390–93 at 392–93; Leslie S. Libow and Richard R. Neufeld, "The Autopsy and the Elderly Patient in the Hospital and the Nursing Home: Enhancing the Quality of Life" (2008) 63(12) Geriatrics 14–18; P. Lindström et al., "Declining Autopsy Rate in Sweden: A Study of Causes and Consequences in Malmö, Sweden" (1997) 242 Journal of Internal Medicine 157–65.

that rates of resident death investigation and autopsies are too low.⁶⁴ Over two decades ago, Dr. Randy Hanzlick observed, "[t]here is little doubt that the autopsy is underused as a method for evaluating mortality patterns, the health of the aging population, and the subset of such patients in nursing homes or long-term care facilities."⁶⁵ Without autopsies, it can be difficult to ascertain the true cause of death.⁶⁶ Dr. Anthony Galanos noted that "an erroneous cause of death is almost twice as common in patients 70 years old and older than in those younger than that age," and autopsies can successfully disclose erroneous clinical diagnoses of causes of death.⁶⁷ A study dating back to 1983 concluded:

It is not unlikely that a number of elderly persons found dead have not died from the ubiquitous labels "cerebrovascular disease" or "arteriosclerotic heart disease" but from drug overdose – accidental or self-induced – or even homicide. One wonders if the low autopsy rate for death caused by "other accidents" is masking such cases. 68

The autopsy is recognized as "the ultimate index of the quality of healthcare in general and that of the geriatric patient in particular." Increasing the number of autopsies will increase knowledge about geriatric care, which will in turn inform future understanding of disease, mortality, and morbidity. As autopsies must be preceded by a death investigation, for these reasons alone it is desirable that an increased number of resident death investigations be conducted.

From the perspective of this Inquiry, however, increasing the number of resident death investigations is important because the low number now being conducted may mean that suspicious deaths are missed. Dr. Michael Pollanen,

See, for example, Aileen Wiglesworth, "Draft Final Technical Report: Coroner Investigations of Suspicious Elder Deaths," 5, submitted to the U.S. Department of Justice, July 1, 2012, grant number 2008-MU-MU-0021; J.C. Ahronheim, A.S. Bernholc, and W.D. Clark, "Age Trends in Autopsy Rates: Striking Decline in Late Life" (1983) 250(9) JAMA 1182–1186 at 1186.

⁶⁵ Randy Hanzlick, "Case of the Month: Complications of Therapy, Nursing Homes, and the Elderly" (1998) 158 Archives of Internal Medicine 695–96 at 695; John A.H. Puxty, Michael A. Horan, and Roy A. Fox, "Necropsies in the Elderly" (1983) The Lancet 1262–64.

⁶⁶ Luiz Eugênio Garcez Leme, "Autopsy in the Elderly" (2018) 8(3) *Autopsy Case Reports* (São Paolo).

⁶⁷ Anthony N. Galanos, William A. Gardner, and LeRoy Riddick, "Forensic Autopsy in the Elderly" (1989) 82(4) *Southern Medical Journal* 462–66.

⁶⁸ Ahronheim, Bernholc, and Clark, "Age Trends in Autopsy Rates," 1182–86 at 1186.

⁶⁹ Shokrani and Fidelia-Lambert, "Geriatric Autopsy Findings in the Last 10 Years," 390–93 at 392–93.

Libow and Neufeld, "The Autopsy and the Elderly Patient in the Hospital and the Nursing Home,"14–18; Hanzlick, "Case of the Month," 695–96 at 695; Luiz Eugenio Garcez Leme, "Autopsy in the Elderly."

Ontario's chief forensic pathologist, gave evidence in the public hearings that forensic pathology can be used to detect "secret homicides" – homicides in which the perpetrator "obscures the death," thereby "misdirecting people from the truth." As I explain in Chapter 1, that is precisely the situation for Wettlaufer's murder victims. If Wettlaufer had not confessed to the murders, no one would have known that the victims had been killed and not died of natural causes.

B. Creating an Informed Death Investigation Process

Resident deaths that meet the section 10 criteria in the *Coroners Act* are generally investigated. However, for the reasons given above, the number of resident death investigations must be increased. Thus, the question becomes: How should the OCC/OFPS decide what other resident deaths to investigate? Three possible answers to this question were explored in the consultations conducted in part 2 of the Inquiry. The first was for the OCC/OFPS to resume conducting threshold death investigations. The second was for the OCC/OFPS to conduct additional death investigations on a random basis. The third was to devise a process through which the OCC/OFPS would receive relevant information, beyond that related to the section 10 criteria, and use that information to decide which resident deaths to investigate. I call this the "informed death investigation process."

I rejected the notion of reinstituting threshold death investigations in LTC homes. On the evidence at the public hearings, such investigations were ineffective and used substantial coroner resources (human and financial) without providing a demonstrable public safety benefit.⁷³ They did not identify specific concerns that would not otherwise have been detected.⁷⁴ Further, conducting threshold death investigations can lead to investigative fatigue, which can undermine the utility of the death investigation. And, importantly, investigating threshold deaths does not serve as either a deterrent or detection measure because a person who wishes to kill a resident can evade the threshold simply by timing the killing so that the victim is not the home's 10th death.

⁷¹ Testimony of Dr. Michael Pollanen, Transcript, July 23, 2018, pp 5086–87.

⁷² Testimony of Dr. Michael Pollanen, Transcript, July 23, 2018, p 5085.

⁷³ Affidavit of Dr. Dirk Huyer, para 113.

⁷⁴ Affidavit of Dr. Dirk Huyer, para 113.

I rejected the random death investigation model because, without a sound scientific or medical reason for conducting a death investigation, it is highly unlikely the investigations will provide meaningful information. The vast majority of resident deaths are due to natural causes, and conducting random death investigations would simply confirm that.

It became apparent that an informed death investigation process was what was needed to address the low number of resident death investigations in a meaningful way. Such a process is dependent on the OCC/OFPS receiving relevant information beyond that which it currently receives through the Institutional Patient Death Record. Thus, the challenge was to determine what additional information the OCC/OFPS could be given that would better enable it to decide which resident deaths to investigate. Two types of information would be of assistance.

The first type of additional information relates to the resident, particularly in respect of the period leading up to death. It is not enough to receive information related to the section 10 criteria. The OCC/OFPS needs evidence-based information, including clinical observations and assessments about a resident's death. As well, it needs information based on the subjective observations and concerns of nurses, PSWs, and family members. The source of this additional information is the redesigned IPDR, which I recommend in Chapter 14 and discuss below.

The second type of information is about the LTC home in which the resident is living at the time of death. This information can be obtained from the Ministry data analytics project to identify LTC homes with a higher than expected mortality rate. The Ministry data analytics model is also discussed below.

Support for the use of data analytics in the death investigation process comes from other healthcare contexts in Canada in which data analytics are being used to improve quality of care. The Canadian Institute for Health Information (CIHI) has been calculating a hospitalized standardized mortality ratio (HSMR) for most hospitals in Canada for approximately the past 10 years. The HSMR – the ratio of the actual number of acute in-hospital deaths to the expected number of in-hospital deaths, for conditions accounting for about 80% of in-patient mortality⁷⁵ – adjusts for factors that might affect mortality rates, such as patient age, sex, diagnosis, length of stay, co-morbidities,

⁷⁵ Hospital Standardized Mortality Ratio: Technical Notes, May 2018 (Ottawa: CIHI, 2018), 2.

and admission status,⁷⁶ and allows CIHI to compare mortality rates across Canadian hospitals.⁷⁷ CIHI maintains that the HSMR is both "an important measure to improve patient safety and quality of care in Canadian hospitals" and an indication of "how successful hospitals and health regions have been in reducing inpatient deaths – leading to improved patient care."⁷⁸

Used in combination, the redesigned IPDR and the Ministry data analytics model will enable the OCC/OFPS to focus investigative resources on the most suspicious or unexpected deaths. The redesigned IPDR will give the OCC/ OFPS both evidence-based data and subjective information on a particular resident, and the Ministry model will give it statistical data analysis about mortality rates in the home. Used together, that information will enable the OCC/OFPS to make an informed decision on which resident deaths should be investigated – even when those deaths do not otherwise trigger "warning bells." For example, even if all questions on the redesigned IPDR are answered "no," when a resident dies while living in a home that has been identified as having a higher than expected rate of death, the OCC/OFPS may nevertheless decide to trigger a coroner consultation and, potentially, a death investigation. Further, when a question on the redesigned IPDR is answered "yes" in a home with a higher than expected rate of death, it makes it more likely both that a coroner will be assigned to perform a preliminary consultation on the resident's death and that a death investigation will be conducted.

C. Using the Redesigned Institutional Patient Death Record

The redesigned IPDR will underpin the informed death investigation process. In Chapter 14, I describe how and why the IPDR should be redesigned and here I will provide only the following brief summary.

Section 10(2.1) of the *Coroners Act* requires LTC homes to immediately report all resident deaths to the OCC/OFPS. To facilitate this reporting, the OCC/OFPS created the IPDR for the homes to complete and send to it. The current IPDR essentially tracks the language of section 10(1). Thus, through it, the OCC/OFPS gets information that assists it in determining whether a death investigation should be undertaken based on the section 10(1) criteria.

⁷⁶ https://www.cihi.ca/en/cihis-hospital-standardized-mortality-ratio#_Methodology

⁷⁷ Affidavit of Dr. Michael Hillmer, para 23.

⁷⁸ https://www.cihi.ca/en/cihis-hospital-standardized-mortality-ratio#_Methodology

The redesigned IPDR will provide information that goes well beyond that related to the section 10 criteria. It will have questions that prompt the person completing it to include clinical observations and assessments. It will also prompt the person completing it to speak with the family and other caregivers in the home, such as PSWs, about the resident's health and medical status in the period leading up to death.

The additional information in the redesigned IPDR will be of use to the LTC home, a coroner conducting a preliminary consultation, and the OCC/OFPS. In terms of the home, the redesigned IPDR will assist staff in the home in determining whether the death should be reported to a coroner. If a coroner is appointed to conduct a preliminary consultation, the information in the redesigned IPDR will help the coroner to decide whether to conduct a death investigation. Used in conjunction with the data analytics information, the information in the redesigned IPSR will enhance the OCC/OFPS's ability to decide which deaths warrant further investigation.

As I also explain in Chapter 14, the OCC/OFPS should provide training on the redesigned IPDR for those in LTC homes who will complete it. The better their understanding of what information the OCC/OFPS needs, the more likely it is that they will record that information on the redesigned IPDR.

I have further recommended a change in the process that homes follow in terms of the redesigned IPDR. When the home sends the redesigned IPDR to the OCC/OFPS, it should also be required to send copies to other designated healthcare providers, including the home's medical director and director of nursing, the resident's treating physician or nurse practitioner, and the home's pharmacist. On the face of the redesigned IPDR, there should be a note to the other healthcare providers, directing them to review its contents and alert the OCC/OFPS if anything about the resident's death causes them concern or raises questions. This change in process should also lead to the OCC/OFPS receiving more information about resident deaths – information that it would not otherwise have at that vital point in the process: when it is deciding whether to assign a coroner to perform a preliminary consultation on the death.

I recommend that the OCC/OFPS use data analytics to aggregate and analyze the information in the redesigned IPDR to detect unusual spikes, patterns, and clusters of deaths. As I explain above, this data can be helpful in detecting HCSKs. At present, that is not done because not all homes submit the IPDR electronically. One of the reasons that the OCC/OFPS directed LTC homes to submit the IPDRs electronically was precisely so that it could aggregate and analyze the information in the IPDRs, "The idea was that if a full set of data was obtained (i.e. 100% compliance), the OCC could evaluate for trends or patterns of deaths within institutions and/or within regions. The contemplated goal was the creation of an evaluative mechanism utilizing existing data." Because not all homes submit the IPDRs electronically, the OCC/OFPS does not have a full set of data and is unable to do this tracking. As I recommend in Chapter 14, the OCC/OFPS must take steps to ensure that all LTC homes submit the redesigned IPDRs electronically.

The aggregated data from the redesigned IPDRs should allow for more timely detection of unusual spikes, patterns, and clusters of deaths in individual LTC homes. The IPDR is completed immediately upon death, whereas the aggregated Resident Assessment Instrument – Minimum Data Set (RAI-MDS) data used in the Ministry models are provided to the Ministry quarterly. Researchers have emphasized the importance of analyzing clusters, spikes, and patterns of deaths in healthcare institutions in real time, as opposed to retrospectively.⁸⁰ Professor Crofts Yorker notes that the real-time review and detection of suspicious death clusters and spikes would require a system in which the data can be kept and reviewed.⁸¹

These changes to the IPDR and its use will assist in improving the Ontario resident death investigation process but, alone, they are insufficient. The informed resident death investigation process must also use data and technology if it is to detect intentionally caused resident deaths. With this mind, I turn now to consider the Ministry's data analytic models for identifying LTC homes with a higher than expected mortality rate.

Affidavit of Dr. Dirk Huyer, paras 102–4; Testimony of Dr. Dirk Huyer, Transcript, pp 4215–19. Aggregated IPDR data might identify an unusual spike or cluster of deaths in a home, making it more likely that a coroner would be assigned to do a preliminary consultation on a resident's death in a particular home and to conduct a death investigation. As well, information showing an unusual spike or cluster of deaths in a home may trigger the OCC/OFPS to send a multidisciplinary team to investigate. (Such an investigation is discussed below.)

Mary K. Sullivan, "Forensic Investigations in the Hospital," in Virginia A. Lynch and Janet Barber Duval (eds.), Forensic Nursing Science (2nd ed., St. Louis, Mo.: Mosby, 2011), 134–43 at 139.

⁸¹ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, p 8012.

V. Using Data Analytics – the Ministry's Project to Detect Elevated Death Rates in LTC Homes

In January 2017, not long after learning about the Offences, a team of epidemiologists in the Ministry's Health Analytics Branch⁸² undertook a project to determine whether a statistical model could have detected the Offences and whether such a model could be used to detect similar crimes in the future. The project led to the creation of four models with the potential to identify LTC homes with higher than expected mortality rates. Dr. Michael Hillmer, executive director of Information Management, Data and Analytics in the Health System Information Management (HSIM) Division, supervised this project and gave evidence about it at the public hearings.

In developing the models, the team of epidemiologists drew on work that had been done in the Shipman Inquiry. (See Chapter 16 for a discussion of this inquiry.) In the Shipman Inquiry, Dr. Paul Aylin created a model to signal higher than expected mortality rates by doctors working as general practitioners (GPs). Before discussing the Ministry models, I will briefly discuss the Aylin model.

A. The Aylin Model for Detecting Elevated Mortality Rates

The Shipman Inquiry was launched shortly after Dr. Shipman was convicted, in January 2000, of having murdered 15 of his patients in the United Kingdom.⁸³ The Inquiry concluded that Shipman had actually killed 215 of his patients over the course of his career, starting in 1975, most frequently through the injection of a lethal dose of an opiate such as diamorphine (heroin).⁸⁴ It identified a further 45 deaths associated with Dr. Shipman as suspicious.⁸⁵

⁸² Now named the Health Analytics and Insights Branch (Affidavit of Dr. Michael Hillmer, para 6).

⁸³ Great Britain, Shipman Inquiry, *The Shipman Inquiry: First Report* (Manchester: Shipman Inquiry, [2002]), para 1.48 (Dame Janet Smith, chair).

⁸⁴ Shipman Inquiry: First Report, pp 2, 297–316.

The large number of suspicious deaths is supported by the conclusions of Professor Richard Baker, who published a statistical review of Dr. Shipman's clinical practice in January 2001 comparing the death rates among Dr. Shipman's patients with those of other comparable general practitioners. Professor Baker estimated the number of excess deaths "about which there should be concern" at 236: The Shipman Inquiry: First Report, p 198, paras 14.6–14.7.

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The Shipman Inquiry commissioned Dr. Paul Aylin, an epidemiologist, to develop a data analytics model to prospectively⁸⁶ monitor the mortality rates of GPs to identify those with higher than expected rates.⁸⁷ Dr. Aylin's model provided promising evidence that data analytics could be used to identify excessive death rates associated with particular GPs.⁸⁸

The Aylin model was designed to identify troubling mortality rates by signalling when the mortality rate associated with a GP's practice crossed an alarm threshold. The model set two different alarm thresholds. The first threshold was designed to pick up a "lower level excess of mortality rates and would constitute an 'early warning,' signalling a GP whose mortality rate was at the extreme end of the normal distribution." As Dr. Aylin explained, this lower threshold might merit a low-level investigation. The second threshold was higher. It was set to identify when the mortality rates of a GP diverged from the normal distribution and meant to trigger a more detailed investigation. Dr. Aylin also examined the likelihood that the models would trigger false alarms.

Using the model, Dr. Aylin and his team analyzed the mortality rates for 1,009 GPs, including Shipman, for the period from 1993 to 1999. Dr. Aylin concluded that Shipman would have first triggered the lower threshold alarm

Prospective monitoring "involves monitoring continuously over time, rather than taking a single snapshot look and comparing performance at one time point. Data is accumulated over time and the analysis is repeated at every time point": Great Britain, Shipman Inquiry, The Shipman Inquiry: Fifth Report – Safeguarding Patients: Lessons from the Past – Proposals for the Future (London: Stationery Office, 2004) (Dame Janet Smith, chair), para 14.35.

⁸⁷ Shipman Inquiry, Fifth Report, paras 14.23, 14.34. The technical details of the model itself are reflected in a paper published by Dr. Aylin and his team: Paul Aylin et al., "Following Shipman: A Pilot System for Monitoring Mortality Rates in Primary Care" (2003) The Lancet, https://www.thelancet.com/pb-assets/Lancet/extras/03art6478web.pdf.

Shipman Inquiry, Fifth Report, paras 14.38, 14.48–14.54. In addition to this "prospective" model, the Shipman Inquiry also commissioned an audit of Shipman's practice from 1974 to 1998 by the Chief Medical Office for England (Richard Baker, "Harold Shipman's Clinical Practice, 1974–1998: A Clinical Audit Commissioned by the Chief Medical Officer" (London: Department of Health, 2001) (Baker Report). The Baker Report compared the number of deaths among Shipman's patients (the "observed number of deaths") to the number of deaths one would have expected to see in such a group (the "expected number of deaths"). It concluded that the observed number of deaths among Shipman's patients exceeded the expected number, and that the excess did not appear to be based on differences in the demographic or health profiles of his patients. Notably, the excess numbers of deaths could be seen at an early stage of Shipman's career as a general practitioner and existed in most years of his practice.

⁸⁹ Shipman Inquiry, Fifth Report, paras 14.40–14.42, 14.57.

⁹⁰ Shipman Inquiry, Fifth Report, para 14.58.

⁹¹ Shipman Inquiry, Fifth Report, para 14.58.

⁹² Shipman Inquiry, Fifth Report, para 14.59.

in 1996, and the higher threshold alarm in 1997.⁹³ Shipman was convicted of murdering seven people in 1997 and six people in 1998. The Shipman Inquiry found that Shipman killed an additional 30 people in 1997⁹⁴ and 12 people in 1998.⁹⁵ An alarm triggered even at the very end of 1996 would have preceded at least 55 of the deaths.⁹⁶

It is important to note that the Aylin model was not designed to determine the *causes* of the excessive deaths. The model signalled unusual patterns of mortality, but further investigation would be required to determine the reason for the unusual mortality rates.⁹⁷ For instance, unexpectedly high death rates could be caused by substandard medical care, instead of by intentional harm, or by variances in the patient populations of individual doctors.

B. The Ministry Models

The Ministry of Health and Long-Term Care tested four different statistical models to identify LTC homes with a higher than expected number of deaths. Instead of just using average mortality rates for LTC homes, and identifying homes with above average rates, these models use the health data of individual residents in LTC homes to estimate the number of deaths that would have been expected in each home in the previous 12 months, given the health profile of the residents. This "expected" number of deaths is then compared to the actual number of deaths in each home.

To develop the models, the Ministry began by evaluating health data to determine which were the most predictive of resident deaths in LTC homes. The models drew primarily from data available from the Resident Assessment Instrument – Minimum Data Set (RAI-MDS), a standardized assessment routinely done for all LTC homes residents since 2005. 98 The RAI-MDS includes information on every resident's age, gender, diagnoses, care needs, mobility

⁹³ Shipman Inquiry, Fifth Report, para 14.60.

⁹⁴ He was suspected of killing another two people in 1997.

⁹⁵ Shipman Inquiry, First Report, 314–16.

⁹⁶ The results demonstrated a trade-off based on the alarm threshold chosen. At the lower threshold, a larger number of GPs would trigger the alarm, with some of those turning out to be statistical false alarms. The higher threshold would identify a smaller number of GPs and have a very low rate of statistical false alarms, but also risk missing some GPs with an excess of deaths. See Shipman Inquiry, Fifth Report, paras 14.63–14.64.

⁹⁷ Shipman Inquiry, Fifth Report, para 14.66.

The RAI-MDS assessment is completed for each LTC home resident 14 days after admission, and then quarterly, on any change in status, and annually. CIHI, an independent not-for-profit organization, provides LTC homes with data collection standards to be used in completing the assessments.

status, changes in weight, hospitalizations, pain status, cognitive status, presence of pressure ulcers, and measures of social inclusion, among other things. The HSIM Division gets a quarterly compilation of the RAI-MDS data from the Canadian Institute for Health Information, which gets the data directly from the LTC homes.

To determine what health data were most predictive of deaths in LTC homes, the first model used a "traditional statistical" approach, based on a literature review and consultation with experts. The three other models relied on machine-learning algorithms. 99 In his testimony at the public hearings, Dr. Hillmer explained why the models used health data to predict deaths rather than simply counting the number of deaths in each home and comparing them to an average:

You can imagine one home that has older and sicker residents and just naturally ... more of them will die than a home that has a comparatively younger and less sick population. And if you were just to look at that number and make some conclusion that the home had a higher percentage of people dying, it would have nothing to do with the home but everything to do with the characteristics of the residents that live there.¹⁰⁰

Using their own individual algorithms, all four models identified a similar set of variables that best predicted deaths of individual residents. ¹⁰¹ Each model then used the algorithm to predict the probability of the individual resident's death within the following 12 months. ¹⁰² One of the three machine-learning models, known as the "Extreme Gradient Boosting" model, was found to predict most accurately individual mortality outcomes, although each model "ultimately produced similar results." ¹⁰³

Each model then aggregated the probabilities of dying for individual residents in each LTC home to come up with an "expected number of deaths" in the home for a 12-month period. ¹⁰⁴ Dr. Hillmer explained the rationale underlying the model's design as follows:

⁹⁹ These were "Decision Tree," "Random Forest," and "Extreme Gradient Boosting."

¹⁰⁰ Testimony of Dr. Michael Hillmer, Transcript, pp 8430-31.

¹⁰¹ Affidavit of Dr. Michael Hillmer, para 48.

¹⁰² Affidavit of Dr. Michael Hillmer, para 40.

¹⁰³ Affidavit of Dr. Michael Hillmer, para 49; Testimony of Dr. Michael Hillmer, Transcript, p 8439.

¹⁰⁴ The 12-month period was used because the Ministry thought it would provide them with enough deaths to generate meaningful results: Testimony of Dr. Michael Hillmer, Transcript, p 8444-45.

[T]he rationale is that if you're looking at a given home and you understand the residents there, you can generate the expected number of people who die, and then any actions of somebody like Elizabeth Wettlaufer would be extra additional deaths that would be unexpected and would make the actual number of deaths observed higher.¹⁰⁵

The models then generated a standardized mortality ratio for each LTC home, by dividing the actual number of deaths in an individual home over the previous 12 months (based on data from Ministry databases) by the expected number of deaths in that home for that time period, as generated by the models.¹⁰⁶

Where the standardized mortality ratio is higher than 1.0, the LTC home had more deaths than expected. Where the ratio is lower than 1.0, the LTC home had fewer deaths than expected. As Dr. Hillmer explained, "An LTC Home with 10 observed deaths and 10 expected deaths would have a ratio of 1.0. An LTC Home with 10 observed deaths and 20 expected deaths would have a ratio of 0.5, which means that there were 50% fewer deaths than expected." 107

The standardized mortality ratio allows LTC homes to be compared on an "apples to apples" basis, ¹⁰⁸ ensuring that differences between the homes are not based on differences in resident populations:

In the case of applying the standardized mortality ratio to LTC Homes, risk adjustment ensures that the impact of factors such as age, sex, and level of sickness are equalized across all LTC homes. Any remaining impact on death is then attributable to factors related to a specific LTC home. ¹⁰⁹

Each of the four models generated a similar list of LTC homes with a higher than expected number of deaths. 110 Dr. Hillmer testified that the three machine-learning approaches are the preferable models to pursue because they can be run automatically. 111

¹⁰⁵ Testimony of Dr. Michael Hillmer, Transcript, p 8427, 8429.

¹⁰⁶ Such deaths were defined as either deaths in LTC homes or deaths in other institutions within 30 days of discharge from an LTC home in order to ensure that they captured all deaths of LTC residents regardless of whether the death occurred in the LTC home or another institutional setting. In the context of Wettlaufer's murders, for example, Mr. Horvath passed away in hospital seven days after he was transferred from his LTC home because he had fallen into a hypoglycemic coma.

¹⁰⁷ Affidavit of Dr. Michael Hillmer, para 26.

¹⁰⁸ Testimony of Dr. Michael Hillmer, Transcript, p 8431.

¹⁰⁹ Affidavit of Dr. Michael Hillmer, para 25.

¹¹⁰ Affidavit of Dr. Michael Hillmer, para 48.

¹¹¹ Affidavit of Dr. Michael Hillmer, para 49.

Although the models have the potential to signal outliers in terms of mortality rates in an LTC home, they are not able to determine causes of death or identify processes contributing to deaths. The models rely on observational data and reveal "associations" rather than cause and effect analysis. Thus, there is no reason to label the excessive deaths flagged by the models as suspicious. To determine why certain homes have higher than expected mortality rates or why certain residents died, it is necessary to investigate further. As Dr. Hillmer emphasized in his testimony at the public hearings, "[I]f anybody takes anything out of this, that's the conclusion I would like them to take away, that ... this is just one view, and you need to go ask more questions."

The Ministry concluded that the models have produced a "methodologically sound" and "potentially valuable" approach to calculating excessive rates of mortality. ¹¹⁶ While the models do not determine causes of death, they have the potential to provide useful statistical analysis which could trigger additional investigations and assist in the detection of intentionally caused deaths.

C. The Models' Other Benefits

As explained above, beyond the possible detection of an HCSK, data analytics can be used for quality assurance purposes and improvement. In terms of improving quality of care, the Shipman Inquiry suggested that the monitoring of mortality data could be (i) used for quality assurance purposes, meaning the data could be monitored to flag abnormalities and potential performance problems; and (ii) analyzed by practitioners to suggest possible avenues for quality improvement in their own practices. ¹¹⁷ In the LTC home context, when data analytics detect higher than expected death rates in a home, further investigation may reveal factors that contributed to excessive mortality, including quality of care concerns, possible infectious outbreaks (and, perhaps, poor infection control practices related to outbreaks), or a lack of compliance with legislative or regulatory requirements.

In addition to these benefits, use of a Ministry model promises two additional benefits.

¹¹² Affidavit of Dr. Michael Hillmer, para 57.

¹¹³ Affidavit of Dr. Michael Hillmer, para 56; Testimony of Dr. Michael Hillmer, Transcript, p 8470.

¹¹⁴ Testimony of Dr. Michael Hillmer, Transcript, p 8478.

¹¹⁵ Testimony of Dr. Michael Hillmer, Transcript, p 8512.

¹¹⁶ Affidavit of Dr. Michael Hillmer, para 50.

¹¹⁷ Shipman Inquiry, Fifth Report, para 14.144.

First, the very existence and use of the model could deter potential wrongdoers. The Shipman Inquiry found that the threat of detection through a mortality rate monitoring system was "likely to deter" a healthcare professional "from criminal activities such as those of Shipman." ¹¹⁸ (The deterrent effect is presumably dependent on healthcare workers knowing that data analytic models are being used.)

Second, the OCC/OFPS could use information from the model to conduct an interdisciplinary investigation of homes identified as having higher than expected long-term mortality rates,¹¹⁹ even in the absence of a specific death investigation.¹²⁰ An interdisciplinary investigation, led by a coroner and forensic pathologist from the OCC/OFPS, could include public health inspectors, epidemiologists, police, long-term care experts, and inspectors from the Ministry's Long-Term Care Homes Division. This team would have the expertise to examine a broad range of issues that may have contributed to the higher than expected death rate or unusual patterns of death in the home, including whether the deaths were caused intentionally.

D. The Models' Limitations

Although the Ministry models have a number of possible benefits, they also have limitations. Dr. Hillmer emphasized that it would have been "virtually impossible" to detect the Offences that Wettlaufer committed using any of the models. The Offences at Caressant Care (Woodstock) took place over several years, at a rate of one, two, or three per year. The number and timing of the deaths would not have caused the home's standardized mortality ratio, or its overall ranking among homes, to change noticeably from year to year. Although the Ministry models identified that Caressant Care (Woodstock) had a higher than expected death rate during the period in which Wettlaufer worked at the home (with a standardized mortality ratio in the top 10% of

¹¹⁸ Shipman Inquiry, Fifth Report, "Summary," 27.

¹¹⁹ The chief coroner's power to initiate such a process was clarified: *Coroners Act*, RSO 1990, c C. 37, as amended by the *Comprehensive Ontario Police Services Act*, 2019, SO 2019, c 1, Schedule 6, s 9, that came into force on March 26, 2019, which included the following addition:

^{25.1(1)} Without limiting the generality of section 25, the Chief Coroner may exercise the powers in subsection 25(1) in respect of a death that has previously been investigated, or subject to an inquest, by a coroner, which may include causing an investigation into one or more deaths to be conducted only for the purpose set out in clause 15(1)(c).

¹²⁰ Testimony of Dr. Dirk Huyer, Transcript, pp 4223–24.

¹²¹ Affidavit of Dr. Michael Hillmer, para 62; Testimony of Dr. Michael Hillmer, Transcript, p 8474.

homes in Ontario at one time),¹²² several dozen other LTC homes had an even higher standardized mortality ratio. In the years after Wettlaufer left Caressant Care (Woodstock), there was no significant decrease in the home's standardized mortality ratio.¹²³

In the Inquiry into Certain Deaths at the Hospital for Sick Children, Justice Grange underscored how even when organizations have access to mortality data, they may still be unable to detect wrongdoing. In such cases, however, while data considered in the aggregate may look innocuous, a closer look at its individual components could reveal troubling patterns or trends. For example, hospital administrators at SickKids in Toronto were not concerned by the number of children and babies who died at the hospital between June 30, 1980, and March 22, 1981. They did not suspect any wrongdoing because the total number of deaths was not remarkably high. However, when examined at the ward level, the number of deaths on two specific wards revealed a 625% increase over typical numbers. Had the hospital been aware of this significant increase, it might very well have investigated the deaths at an earlier point in time.

Another limitation is the inability of the Ministry models to identify clusters or spikes in deaths that occur within a short period of time or a particular section of an LTC home, or that are associated with a particular caregiver. The models calculate every expected death in an LTC home for a 12-month period. There are insufficient numbers of deaths in homes in a shorter interval – for example, on a monthly or bi-monthly basis – to provide reliable predictions. As Dr. Hillmer explained, "You just need deaths to occur at a certain number for the model to work. And if you picked a month, you would have a whole bunch of homes that had zero deaths and it just would give you a really bad prediction." As for the possibility of analyzing the Ministry data with respect to a particular shift or caregiver (instead of for the entire LTC home), Dr. Hillmer testified:

We don't have that data, and I think even if we did, it would produce an enormously complex model. You could imagine – again, we're talking about a 12-month period, 633 homes, how many data points that would represent, and not having gone through the exercise, I don't know if it

¹²² Affidavit of Dr. Michael Hillmer, para 61.

¹²³ Affidavit of Dr. Michael Hillmer, para 63.

¹²⁴ Ontario, Royal Commission of Inquiry into Certain Deaths at the Hospital for Sick Children and Related Matters, *Report* (Toronto: Ministry of the Attorney General, 1984), 7–9 (Commissioner S.G.M. Grange) (Grange Inquiry).

¹²⁵ Testimony of Dr. Michael Hillmer, Transcript, pp 8444, 8476.

would be valuable. But my sense having done this before is that it would introduce a ton of complexity, and we would have to do it to see if it was valuable, but I would be skeptical that it would be a valuable way to do it ... [A]gain, I would be skeptical that that much extra data would be a useful exercise. 126

Although a shift or caregiver-based analysis is not contemplated by the Ministry models, work could be done, where the models raise concern, to break down the LTC home-level data further. Following Wettlaufer's confession, Ministry inspectors "plotted all shifts that [Wettlaufer] worked and correlated them with the deaths." However, the Ministry inspectors acknowledged that even this review "didn't tell us really anything" in respect of the Offences. Done Ministry witness testified that "We recognized that this could not account for deaths that were not immediate (i.e. where the victims may have died a few days later). Knowing when residents had died could not show when [Wettlaufer] acted maliciously and intended to cause harm." Further, since they had only compiled statistics relating to Wettlaufer's shifts, the Ministry inspectors could not assess whether the number of deaths linked to her shifts was unexpectedly high. In fact, even if the inspectors had compared deaths during Wettlaufer's shifts to deaths during the shifts of all other nurses in the system, it would likely not have provided any meaningful insights.

E. Finalizing a Model

The Ministry models are still at the research stage.¹³¹ Dr. Hillmer testified that, while promising, the models must be subjected to review by scientific and clinical experts, as well as stakeholders from the LTC homes sector.¹³² Those reviews would have to consider, among other things, possible biases built into the models. Small LTC homes present a significant challenge. The small resident populations and, therefore, low number of deaths in smaller homes means less confidence can be had in the models' predicted number of deaths. In addition, fluctuations in the death rate because of the small numbers in the home make it difficult to reliably identify unexpected mortality rates, even where two years of data are analyzed.¹³³

¹²⁶ Testimony of Dr. Michael Hillmer, Transcript, pp 8477–78.

¹²⁷ Affidavit of Rhonda Kukoly, para 91.

¹²⁸ Testimony of Rhonda Kulkoly, Transcript, Aug. 1, 2018, p 6750.

¹²⁹ Affidavit of Rhonda Kukoly, para 91; Testimony of Rhonda Kulkoly, Transcript, p 6750.

¹³⁰ Testimony of Dr. Michael Hillmer, Transcript, pp 8477–78.

¹³¹ Affidavit of Dr. Michael Hillmer, paras 50, 56.

¹³² Affidavit of Dr. Michael Hillmer, para 20; Testimony of Dr. Michael Hillmer, Transcript, pp 8456–57.

¹³³ Affidavit of Dr. Michael Hillmer, para 56; Testimony of Dr. Michael Hillmer, Transcript, p 8451.

The Ministry must move quickly to conduct expert and stakeholder consultations, followed by refinement and implementation of a model. It should then share the information generated by the model with the OCC/OFPS. The OCC/OFPS will then have reliable data on when actual deaths in a home exceed the expected number. That information, used in conjunction with the information from the redesigned IPDR, will better enable the OCC/OFPS to detect suspicious deaths and decide which resident deaths should be the subject of a preliminary consultation and/or death investigation.

VI. A Note of Caution on the Use of Statistics

Statistics can be a valuable tool in detecting suspicious deaths. However, care must be taken to ensure that statistics are not misinterpreted and individuals not wrongly accused of crimes.

In at least one case, the improper use of statistical evidence contributed to a wrongful conviction. Lucia de Berk, a nurse in the Netherlands, was convicted of seven murders and three attempted murders of children receiving care at Juliana Children's Hospital. The case against de Berk was built on the observation that there had been nine incidents on a ward where she worked and that she was present for all of them. The had been all in 342 million chance that the higher number of deaths occurring on de Berk's shift resulted from coincidence. This statistical evidence seemed to have blinded the court to any alternative explanation of the deaths. Toxicology evidence presented at the trial was equivocal, given that the substances found in two of the exhumed bodies could have been present as a result of treatments the children had undergone before they died.

¹³⁴ Nigel Hawkes, "Did statistics damn Lucia de Berk?" (Apr. 10, 2010), *Independent*, online: https://www.independent.co.uk/voices/commentators/nigel-hawkes-did-statistics-damn-lucia-de-berk-1940735.html; "Dutch nurse Lucy de Berk acquitted of patient murders" (Apr. 14, 2010), *BBC News*, online: http://news.bbc.co.uk/2/hi/europe/8620997.stm.

¹³⁵ Ben Goldacre, "Conviction for patients' deaths does not add up" (Apr. 10, 2010), *Guardian*, online: https://www.theguardian.com/commentisfree/2010/apr/10/bad-science-dutch-nurse-case.

¹³⁶ Nigel Hawkes, "Did statistics damn Lucia de Berk?"

¹³⁷ Nigel Hawkes, "Did statistics damn Lucia de Berk?"

In 2008, after new evidence suggested that all the deaths could be explained by natural causes, a judicial inquiry recommended that the case be reopened. At de Berk's 2010 retrial, medical experts testified that, in three key cases, the deaths had been natural, although there had been errors in diagnosis and prescribed medication. Prosecutors also conceded that they had used flawed evidence in building the case, and that their investigation had been shaped by their belief that de Berk was guilty. De Berk was acquitted of all charges on the retrial.

The de Berk case demonstrates three dangers associated with the use of statistics. First, statistics are only as good as the data underlying them. In the de Berk case, the data were gathered by doctors who had already concluded that de Berk was responsible for the deaths. For instance, doctors who knew whether de Berk had been present on a particular shift classified shifts as "with incident" or "without incident." Second, the methods applied to the data must be sound. In the de Berk case, the statistician at the initial trial used erroneous methods to reach his "one in 342 million" figure. 143 Third, those investigating suspicious deaths as a result of data analytics must avoid jumping to conclusions about an individual's guilt, and then conducting the investigation without being open to other possibilities. 144

The need for further investigation must always be borne in mind. Although numbers and data can flag unusual or anomalous patterns, clusters, or spikes in mortality, they cannot provide an explanation for those anomalies. The circumstances underlying the data, and the death itself, must be investigated and analyzed to determine causal relationships.

^{138 &}quot;Dutch nurse Lucy de Berk acquitted of patient murders."

¹³⁹ Ben Goldacre, "Conviction for patients' deaths does not add up."

¹⁴⁰ "Dutch nurse Lucy de Berk acquitted of patient murders."

¹⁴¹ "Dutch nurse Lucy de Berk acquitted of patient murders."

¹⁴² Nigel Hawkes, "Did statistics damn Lucia de Berk?"; Richard Gill, "Serial Killer Nurses: Is There an Epidemic?" presentation at the Isaac Newton Institute, University of Cambridge (Dec. 1, 2016), https://www.turing-gateway.cam.ac.uk/sites/default/files/asset/doc/1612/Gill_Turing_Gateway.pdf, slide 14.

¹⁴³ Peter Grünwald, "Your Honour, This Was Not a Coincidence!" presentation at University College London (Mar. 20, 2007), https://badscience.net/files/evidencehandout.PDF, pp 5, 7.

^{144 &}quot;Dutch nurse Lucy de Berk acquitted of patient murders."

VII. Improving Death Investigations in the Home Care Setting

Above I describe two major strategies for improving the resident death investigation process. In this section, I consider whether either strategy can be used for deaths taking place in the home care setting. This is important because the dangers associated with intentionally caused harm by a healthcare provider are not exclusive to hospitals and LTC homes – Wettlaufer committed the last Offence in a private home, while she was delivering publicly funded nursing services.

The first strategy for improving the resident death investigation process begins with the OCC/OFPS redesigning the IPDR. The redesigned IPDR will have a series of evidence-based questions prompting caregivers to give their clinical observations and assessments of the deceased, and other information that might be relevant to the OCC/OFPS, such as whether there were aspects about the deceased's decline or death that were inconsistent with the expected medical trajectory of death. In order for the OCC/OFPS to receive more information on deaths in the community, I suggest that it create a modified version of the IPDR for use in the home care setting. The modified IPDR would be a tool for those providing home care to help them know when a death warrants the involvement of a coroner.

Although all deaths in LTC homes must be reported to the OCC/OFPS, ¹⁴⁵ there is no such obligation for deaths that occur in private homes. The person who signs the certificate of death for a death in the community need only report the death to the OCC/OFPS if it falls within the criteria in sections 10 or 10.1 of the *Coroners Act*. In general terms, this means that the only deaths in the community that are reported to the OCC/OFPS are those in which the circumstances of death are unnatural (e.g., accident, homicide, suicide, suspicious), those that are the result of medical assistance in dying, and those which fall within legislatively prescribed situations or locations (e.g., deaths while in custody or detention, or in a psychiatric facility).

¹⁴⁵ Coroners Act, s 10(2.1), as amended by the Long-Term Care Homes Act, 2007, SO 2007, c 8, s 201(2).

A modified IPDR would prompt those who provide home care to consider, when a person for whom they were providing care dies, whether there are circumstances surrounding the death that raise questions or cause them concern. The modified IPDR would alert caregivers that in such situations, they should contact the OCC/OFPS. The OCC/OFPS should also provide training on the modified IPDR to the Local Health Integration Network (LHIN)¹⁴⁶ staff, service provider organizations, and community agencies. Through the modified IPDR and training, those providing home care will be better equipped to decide whether concerns about a death warrant contacting the OCC/OFPS. This should lead to the OCC/OFPS getting more information about deaths in the home care setting. With that information, the OCC/OFPS can follow its normal course in determining whether to assign a coroner to do a preliminary investigation and/or conduct a death investigation.

The second strategy for improving the resident death investigation process is based on the Ministry data analytics model discussed above. This strategy cannot be transferred into the home care setting because the requisite data does not exist and cannot be acquired. In LTC homes, residents have round-the-clock care and regular RAI-MDS assessments that generate full data on all aspects of their health. Data of that sort are not collected – and cannot be – for those living in private homes.

¹⁴⁶ On April 18, 2019, *The People's Health Care Act, 2019*, SO 2019, c 5, received royal assent. When the relevant provisions are proclaimed in force, this statute will, among other things, create a new agency known as Ontario Health and allow for the reorganization or dissolution of the 14 Local Health Integration Networks (LHINs). All recommendations in this Report directed to the LHINs should be considered by any successor body with responsibilities relating to the LTC System, including Ontario Health.

RECOMMENDATIONS

Recommendation 86: The Office of the Chief Coroner / Ontario Forensic Pathology Service should increase the number of death investigations of residents in long-term care homes, using information from the redesigned Institutional Patient Death Record. That information should be used when deciding whether, in respect of resident deaths, to initiate a preliminary consultation and/or conduct a death investigation.

Recommendation 87: The Ministry of Health and Long-Term Care (Ministry) has created four preliminary data analytics models that can be used to identify long-term care homes with a higher than expected number of deaths. The Ministry should move, as quickly as possible, to finalize a data analytics model, after consultations with experts and stakeholders. Once the data analytics model is finalized, the Ministry should share information from it with the Office of the Chief Coroner / Ontario Forensic Pathology Service on a regular and ongoing basis.

Recommendation 88: The Office of the Chief Coroner / Ontario Forensic Pathology Service should use data analytics to analyze aggregated data from the redesigned Institutional Patient Death Records to detect patterns and unusual trends in resident deaths in long-term care homes. This information should also be used when deciding whether to initiate a preliminary consultation and/or a death investigation.

Recommendation 89: The Office of the Chief Coroner / Ontario Forensic Pathology Service should use the information from the Ministry of Health and Long-Term Care's data analytics model, once finalized, as well as the redesigned Institutional Patient Death Records (IPDRs) and the data analytics of the redesigned IPDRs when considering whether a multidisciplinary team should be assigned to investigate a resident's death or a home with a pattern of unexpected deaths.

Rationale for Recommendations 86-89

- Very few resident death investigations are conducted. More are needed
 to assist in detecting intentionally caused resident deaths and to
 increase knowledge about geriatric care. The process for deciding which
 resident deaths to investigate must be based on sound scientific and
 medical reasons, with due consideration for using investigative resources
 appropriately.
- The redesigned Institutional Patient Death Record (IPDR) will underpin the informed death investigation process. By providing the Office of the Chief Coroner and the Ontario Forensic Pathology Service (OCC/OFPS) with both objective clinical indicators and assessments, and subjective observations and expectations of nurses, family members, and personal support workers, the redesigned IPDR will assist homes in determining which deaths should be reported to a coroner. If a coroner consultation is initiated, the coroner can use the information in the redesigned IPDR to help decide whether to conduct a death investigation.
- The Ministry of Health and Long-Term Care (Ministry) four preliminary data analytics models referred to in Recommendation 87 have produced a methodologically sound and potentially valuable approach to calculating excessive rates of mortality. To finalize a model, the Ministry must subject the four models to review by scientific and clinical experts and by stakeholders in the long-term care sector. Once a model is finalized, the data must be shared with the OCC/OFPS so that it can be used, in combination with the information in the redesigned IPDR, to determine whether to initiate a coroner consultation and death investigation. When a long-term care home's death rate is higher than expected, it is more likely that a coroner consultation and/or death investigation will be conducted.
- The OCC/OFPS should use aggregated data from the redesigned IPDR to help detect unusual or suspicious trends and patterns in resident deaths.
 This information should also be considered when deciding whether to initiate a death investigation.
- A multidisciplinary investigation, led by a coroner and forensic
 pathologist from the OCC/OFPS, could include public health inspectors,
 epidemiologists, police, long-term care experts, and inspectors from the
 Ministry's Long-Term Care Homes Division. This team would have the
 expertise to examine a broad range of issues that may have contributed
 to the higher than expected death rate, or to patterns and unusual trends
 in deaths in a long-term care home, including whether the deaths were
 caused intentionally.

Recommendation 90: The Office of the Chief Coroner / Ontario Forensic Pathology Service (OCC/OFPS) should modify the Institutional Patient Death Record (IPDR) for use by caregivers when a person receiving publicly funded home care dies. The modified IPDR should assist the caregivers in knowing when to report a death to the OCC/OFPS and how to make that report.

Recommendation 91: The Office of the Chief Coroner / Ontario Forensic Pathology Service should train staff in Local Health Integration Networks (or a successor organization) and service provider organizations on how to use the modified Institutional Patient Death Record.

Rationale for Recommendations 90-91

- Deaths taking place in private homes are not required to be reported to
 the Office of the Chief Coroner and the Ontario Forensic Pathology Service
 (OCC/OFPS) unless the person signing the certificate of death thinks that
 the death falls within the criteria contained in sections 10 and 10.1 of the
 Coroners Act.
- Training on a modified Institutional Patient Death Record (IPDR) for those
 providing home care will enable the caregivers to better understand when
 to report a death to the OCC/OFPS and how to do that.
- Training Local Health Integration Networks (or a successor organization) and service provider organizations on the modified IPDR will increase the likelihood that the OCC/OFPS will be alerted to deaths in private homes that require its involvement.

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I. Introduction

Public inquiries play an important role in Canadian democracy because they investigate tragic events of substantial public interest. They find facts about these events, educate the public, and recommend how to prevent such events from happening again. They also serve the need for public accountability – the public's legitimate "right to know."

While working as a registered nurse, Elizabeth Wettlaufer killed or harmed 13 residents in long-term care (LTC) homes and attempted to kill a home care client in her own home (the Offences). In light of the Offences, the people of Ontario have the right to know the answers to two important questions:

- 1. What failings in our LTC system allowed Wettlaufer to commit those Offences, without detection, while working as a registered nurse?
- 2. What can be done to prevent such tragedies from happening again?

Throughout the Inquiry, members of the public and the Participants have supported its work. They have offered information about their experiences with the LTC system and made suggestions on how to improve it. I am truly grateful for this support. It has helped shape this Report and my recommendations.

In this chapter, I want to acknowledge the many suggestions offered and explain why some did not ultimately become recommendations. There are three primary reasons for this.

First, some suggestions fell outside the Inquiry mandate. My power to make recommendations is circumscribed by that mandate. As I explain in Chapter 2, that means I do not have the right or the power to make any and all recommendations that I think might improve the long-term care system. Rather, I am limited to making recommendations on how to prevent similar tragedies from happening again.

Second, the Commission's investigations and research revealed that some promising suggestions were not workable in practice.

Third, in the case of other suggestions, a weighing of the associated costs (financial and other) and benefits augured against pursuing them.

II. Suggestions Outside the Inquiry Mandate

The Inquiry mandate is to inquire into the events and circumstances surrounding the Offences and to make recommendations on how to prevent similar tragedies from occurring in the future. This mandate is directed at protecting the physical safety of residents of LTC homes and those who receive publicly funded healthcare in their own homes.

The scope of the Inquiry does not *directly* include such things as:

- staffing levels in LTC homes;
- funding for LTC homes;
- labour relations within the LTC system, including the handling of grievances and discipline;
- resident-on-resident violence in LTC homes:
- negligence or incompetence within LTC homes;
- · whether for-profit LTC homes should be phased out;
- determining minimum hours of direct resident care in LTC homes;
- the treatment of nurses with mental health issues and/or addictions who are working in the LTC system; or
- the adequacy of the number of nurses and other caregivers in the LTC system.

There are compelling reasons why the Inquiry had to remain within the scope of its mandate.

First, the Inquiry mandate is the task assigned by the Ontario government through the Order in Council. To ensure that we completed this task on time and in a manner that provided the necessary public accountability, we had to stay focused on that task.

Second, others have responsibility for the issues set out above and are better positioned to address them. Many of the above issues affect parties and institutions that were not Participants in the Inquiry's public hearings or consultations, and some issues extend far beyond the LTC sector.

Third, the serious nature of the Offences, and the magnitude of the harm they caused, dictated that we focus our undivided attention on fulfilling the Inquiry mandate.

Fourth, had I strayed from my mandate, I would have risked making recommendations for which there was an inadequate evidentiary foundation.

III. Suggestions Found to Be Unworkable

There were certain suggestions I chose not to pursue even though they fell within the Inquiry mandate. Why? Because research, evidence led at the public hearings, and consultations with stakeholders in the LTC system showed that the suggestions were unworkable. I discuss three examples below.

1. Profiling Nurses to Detect Healthcare Serial Killers

Many suggested that a "profile" of a healthcare serial killer (HCSK) should be made that would list characteristics or "red flags" thought to signal a possible HCSK. Some went further, suggesting that candidates for employment in LTC homes should be excluded if they showed one or more of those characteristics.

However, research has shown that, despite efforts by experts, no such profile has become apparent.¹ As I explain in Chapter 16, most experts agree that HCSKs are psychopaths but, beyond that general statement, there are no psychological profiles of value associated with HCSKs.² The research shows that convicted healthcare serial killers are all different and have no consistent characteristics. Some have struggled with addictions; others have not. Some have had mental health issues; others have not. Some have stolen medication at their places of employment; others have not. Some performed poorly at work; others have been regarded as excellent caregivers. Professor Crofts Yorker was clear: these matters, on their own or in combination, do not assist in identifying a potential HCSK.³

See, for example, Karl H. Beine, "Homicides of Patients in Hospitals and Nursing Homes: A Comparative Analysis of Case Series" (2003) 26 International Journal of Law and Psychiatry 373–86, 376–77; John Field and Alan Pearson, "Caring to Death: The Murder of Patients by Nurses" (2010) 16(3) International Journal of Nursing Practice 301–9. Although Elizabeth Yardley and David Wilson identify "some common criminological and socio-demographic characteristics in cases of healthcare serial murder," they consider these to be potentially useful in investigating potential HCSKs and do not suggest that individuals with these characteristics should be excluded from employment in the healthcare professions: E. Yardley and D. Wilson, "In search of the 'Angels of Death': Conceptualizing the Contemporary Nurse Healthcare Serial Killer" (2016) 13 Journal of Investigative Psychology and Offender Profiling 39–55, 52–53.

Robert M. Kaplan, Medical Murder: Disturbing Cases of Doctors Who Kill (Sydney, NSW: Allen & Unwin, 2009), 24; Kelly M. Pyrek, Healthcare Crime: Investigating Abuse, Fraud, and Homicide by Caregivers (Boca Raton, Fla: CRC Press, 2011), 161.

³ Testimony of Professor Beatrice Crofts Yorker Schumacher, Transcript, Sept. 12, 2018, p 8023.

2. Testing Blood for Insulin Levels After Death

It was also suggested that, on death, the blood of a resident in an LTC home should be tested for irregularities in insulin levels. It was thought that this testing would detect whether the resident had been injected with excess amounts of insulin. This suggestion is unworkable for three reasons.

First, the Centre of Forensic Sciences does not perform insulin testing, nor is any forensically accredited laboratory in Ontario able to perform insulin testing at this time.⁴

Second, the fact that death can occur days after the insulin was administered makes its detection "virtually impossible." 5

Third, even if such testing could be carried out in Ontario, it is unlikely to provide any meaningful information in the absence of also performing a comprehensive death investigation autopsy. Insulin is naturally present in the body, and changes that occur after death make it difficult to distinguish between naturally produced insulin and synthetic insulin.⁶

Standard Post Mortem Toxicology Testing of All Deceased LTC Home Residents and Home Care Clients

Many suggested that, after a resident in long-term care dies, a bodily sample (such as blood) should be taken and a standard set of laboratory tests be performed on it. Others suggested that samples should be taken from those who died after receiving care within their homes and those samples tested. However, the human and financial resources required, and the minimal likelihood of obtaining any useful information, make this suggestion unworkable.

The collection of bodily samples that must be undertaken in order to conduct post mortem toxicology tests is normally completed by a forensic pathologist as part of an autopsy.⁷ Although long-term care staff might be trained to the appropriate forensic standards to take such samples after a resident dies, it would be a significant and inadvisable departure from their role as caregivers.⁸

⁴ Affidavit of Dr. Michael Pollanen, paras 105–7.

⁵ Affidavit of Dr. Michael Pollanen, para 107; Testimony of Dr. Michael Pollanen, Transcript, July 23, 2018, pp 5049–50.

⁶ Affidavit of Dr. Michael Pollanen, paras 106–7.

⁷ Testimony of Dr. Michael Pollanen, Transcript, July 23, 2018, p 4998.

⁸ Consistent with the testimony of Dr. Michael Pollanen, Transcript, pp 5028–29.

When a resident dies, staff must attend to the deceased and his or her loved ones.

As well, the samples would have to be secured according to forensic standards and placed in appropriate storage facilities, which LTC homes do not have. Such storage would involve a significant financial expenditure.

Nor is it workable to give forensic pathologists the task of routinely performing a standard set of post mortem toxicology tests on all residents who die while in LTC homes. No standard set of toxicology tests is conducted when an individual death is being investigated, whether in the LTC home context or otherwise. Rather, in each individual case, the forensic pathologist must decide whether to order toxicology testing and, if so, for what substances. This decision is made based on the history of the case and the findings of the autopsy. Toxicology tests performed in the absence of a medical and scientific foundation are highly unlikely to produce any meaningful information.

Further, requiring forensic pathologists to perform post mortem toxicology tests on all LTC home residents who die would exponentially increase their workload. For instance, in the fiscal year 2015–16, 21,074 residents in long-term care homes passed away. However, in 2015, only 81 death investigations of residents included autopsies. Has I have explained, toxicology testing is based on the history of the case and the findings of the autopsy. A requirement of toxicology tests on all residents who die while in LTC homes would require that forensic pathologists perform tens of thousands more autopsies annually. The increased workload and associated costs make this unworkable.

Moreover, even if there were sufficient resources (human and financial) to routinely undertake such testing, it would be of little or no value in terms of detection. As I have explained, it would not – and could not – simply be a matter of running a standard set of post mortem toxicology tests for every resident who dies. Rather, each case would require a full death investigation including an autopsy.

In any event, the informed death investigation model which I recommend and discuss in Chapter 18 provides a more practical, evidence-based approach to detection.

⁹ Testimony of Dr. Michael Pollanen, Transcript, pp 5001–2.

¹⁰ Testimony of Dr. Michael Hillmer, Transcript, Sept. 14, 2018, pp 8429–30.

¹¹ Testimony of Dr. Michael Pollanen, Transcript, p 4938; Affidavit of Dr. Michael Pollanen, para 96.

IV. Suggestions in Which Costs Would Outweigh Benefits

The complicated issues this Inquiry faced required a balancing of different – and often competing – interests and concerns. How best to balance the privacy rights of residents and clients in their homes against their safety and security? How best to ensure that nurses' privacy rights are respected while ensuring that those seeking to employ them have adequate information about their ability to practise safely? How best to encourage improvements and changes in a system with finite resources?

After considering questions such as these, I determined that the probable costs of certain suggestions outweighed the likely benefits. Three examples are illustrative.

1. Placing Cameras in Residents' Rooms in LTC Homes and Requiring Random Spot Checks of Home Care

Both these suggestions are intended to deter potential healthcare serial killers by the prospect that they might be caught in the act of harming. Both suggestions raise the same competing considerations: protect the privacy rights of the resident or client in their own homes or allow intrusions against those privacy rights because of safety and security concerns. In weighing these competing considerations, it is important to remember that HCSKs are rare.

I concluded that both suggestions would impose too high a cost to a person's right to privacy within their home. Of course, some residents may choose to place cameras in their rooms, and some home care clients may choose to have a family member or loved one attend when they receive home care visits. But those are personal decisions and not ones dictated by others. In my view, such decisions are best left to the individual. Moreover, as discussed in Chapters 17 and 18, there are less intrusive ways to deter and detect those who might wish to harm.

2. Publicizing Instances Where a Nurse Is or Has Been Under Investigation

The suggestion was made that the College of Nurses of Ontario should make public all instances of a nurse under investigation so that the public would have adequate information about a nurse's ability to practise safely.

There are a number of reasons why the costs of this suggestion outweigh any potential benefits.

First, a policy requiring all investigations to be made public runs the very real risk of discouraging nurses with addictions or mental health challenges from self-reporting and getting the help and support that they need.

Second, the investigation may ultimately show that there is no misconduct, incompetence, or incapacity on the part of the nurse. That finding, however, is unlikely to repair the damage done to the nurse's reputation by revealing the existence of the investigation.

3. Reconsidering Insulin's Status as a Non-Prescription Medication

Another repeated suggestion was to make insulin, now a non-prescription medication in Ontario, available only by prescription. In this way, access to insulin would be restricted to only those who have a medical reason for it. No one without a prescription for insulin, it was thought, could have access to it for purposes of wrongdoing.

I concluded that the costs of making insulin available only by prescription outweigh the benefits of any potential deterrence. Wettlaufer did not obtain the insulin that she used to commit the Offences from community pharmacies. Rather, she took it from her places of employment or from another of her home care clients. She had ready access to insulin in the LTC homes in which she worked. There was no need for a prescription – she just diverted insulin supplied for those in the home who needed it and administered it to others in the commission of the Offences. In the case in which Wettlaufer used insulin to harm a person receiving home care, she stole the insulin from another of her home care clients. In her expert evidence, Professor Crofts Yorker observed that there is no indication that any of the 54 convicted healthcare serial killers who used injectable medications to kill or assault patients used medications of their own.¹²

Requiring a prescription for insulin would pose barriers to access for all those who need it for medical reasons and often need it urgently. This cost is out of proportion to any potential deterrent effect that requiring a prescription might have. In any event, there are more effective methods of deterring healthcare serial killers, as discussed in Chapter 17.

¹² Expert report of Professor Beatrice Crofts Yorker Schumacher, p 12.

V. Conclusion

I wish to conclude this chapter by again expressing my sincere gratitude to the public for its support and participation in the Inquiry's work. Every suggestion you made prompted me and my team to reflect, consult, and research the problems raised. You helped to guide this Report and the recommendations contained in it. I thank you.

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Appendix G - A Just Culture Guide

investigation of a patient safety incident. Only a full

• A just culture guide is not a replacement for an



A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident safely. Action singling out an individual is rarely appropriate requires specific individual support or intervention to work most patient safety issues have deeper causes and require wider action

automatically be examined using this just culture guide, but it can be useful if the investigation of an incident begins to highlights important principles that need to be considered suggest a concern about an individual action. The guide The actions of staff involved in an incident should not pefore formal management action is directed at an ndividual staff member

using the guide helps protect patients by removing the tendency guide can be used by all parties to explain how they will respond incident reporting policies, and as a communication tool to help approach that will be taken if an incident occurs. A just culture An important part of a just culture is being able to explain the response to a member of staff involved in an incident can and should differ according to the circumstances in which an error staff, patients and families understand how the appropriate was made. As well as protecting staff from unfair targeting, to incidents, as a reference point for organisational HR and o treat wider patient safety issues as individual issues.

involved in an incident they must be considered separately to act) through the guide at a time. If multiple actions are investigation can identify the underlying causes that need investigation, but the guide may need to be revisited A just culture guide can be used at any point of an to be acted on to reduce the risk of future incidents.

- The guide can only be used to take one action (or failure should be used in conjunction with organisational policy A just culture guide does not replace HR advice and more information becomes available

END HEBE

Recommendation: Follow organisational quidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff needed to understand how and why patients were not protected from the and referral to police and disciplinary processes. Wider investigation is still

actions of the individual.

Was there any intention to cause harm?

Start here - Q1. deliberate harm test

▼ No go to next question - Q2. health test

2a. Are there indications of substance abuse?

HEBE END

Recommendation: Follow organisational substance abuse at work guidance. Wider

investigation is still needed to understand if substance abuse could have been

recognised and addressed earlier.

HEBE END

which is likely to include occupational health referral. Wider investigation is still needed

to understand if health issues could have been recognised and addressed earlier

Recommendation: Follow organisational guidance for health issues affecting work,

2b. Are there indications of physical ill health?

2c. Are there indications of mental ill health?

if No to all go to next question - Q3. foresight test

Are there agreed protocols/accepted practice in place

3a.

Þ

ЕИД НЕВЕ

Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual

It No to any

if Yes to all go to next guestion - Q4. substitution test

3c. Did the individual knowingly depart from these protocols?

Were the protocols/accepted practice workable that apply to the action/omission in question?

and in routine use?

3b.

- peer group, with comparable experience and qualifications, 4a. Are there indications that other individuals from the same would behave in the same way in similar circumstances?
- Was the individual missed out when relevant training was provided to their peer group? 4b.
- Did more senior members of the team fail to provide supervision that normally should be provided? 4c.

END HEBE

Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. If Yes to any



if No to all go to next question - Q5. mitigating circumstances

5a. Were there any significant mitigating circumstances?



should indicate the wider actions needed to improve safety for future patients. Recommendation: Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation

HEBE END

HEBE END

assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency safety incident investigation should indicate the wider actions needed to improve safety for future patients.

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Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

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